

Annex 7: Local Costs Provided by Japanese Side

Local Costs Provided by Japanese side

1. FY 2005

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)-(B)
Personnel Cost	3,415,494	3,163,511	251,983
Maintenance/Management for Equipment Cost	62,888	67,939	5,131
Consumables Cost	496,500	473,586	22,914
Communication/Transportation Cost	124,960	128,483	3,523
Rental Fee	1,055,336	1,152,377	97,041
Miscellaneous Cost	163,396	188,159	24,763
Sub Total	5,318,494	5,174,055	144,439
Adjustment	▲494	▲494	
Total	5,318,000	5,173,561	144,439
Final Adjustment	5,318,000	5,173,000	145,000

2. FY 2007

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)-(B)
Personnel Cost	5,420,542	4,804,437	616,105
Maintenance/Management for Equipment Cost	89,540	56,304	33,236
Consumables Cost	528,000	510,255	17,745
Communication/Transportation Cost	227,920	169,517	58,403
Rental Fee	1,579,160	1,468,139	111,021
Miscellaneous Cost	44,400	23,100	21,300
Sub Total	7,889,562	7,031,752	857,810
Adjustment	▲562	▲562	
Total	7,889,000	7,031,190	857,810
Final Adjustment	7,889,000	7,031,000	858,000

3. FY 2008

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)-(B)
Personnel Cost	4,230,672	4,369,885	139,213
Maintenance/Management for Equipment Cost	70,070	14,760	55,310
Consumables Cost	460,625	207,453	253,172
Communication/Transportation Cost	440,860	327,645	113,215
Rental Fee	1,466,630	1,333,338	133,292
Miscellaneous Cost	0	0	0
Sub Total	6,668,857	6,253,081	415,776
Adjustment	▲857	▲857	
Total	6,668,000	6,252,224	415,776
Final Adjustment	6,668,000	6,252,000	416,000

4. FY 2009, (From April to August 2009)

Item	Contract Sum (A)	Expenditure (B)	Balance (C)=(A)-(B)
Personnel Cost	5,717,503	1,269,028	4,448,475
Maintenance/Management for Equipment Cost	24,485	7,840	16,645
Consumables Cost	391,875	68,118	323,757
Communication/Transportation Cost	300,960	89,072	211,888
Rental Fee	1,247,730	435,491	812,239
Miscellaneous Cost			
Sub Total	7,682,553	1,869,549	5,813,004
Adjustment	▲553	▲553	

Annex 8: GMP Related Documents

LIST OF GMP DOCUMENTS

Rev.-01

As of 31 August 2009

No.	Name of Documents	Doc. No	Priority	Preparing progress	QA Approval	Remarks
1) Top Ranks Documents (Grade A documents)						
1	Quality manual	QM	1	100%	Approval	
2	GMP control rule	01-RGL-GMP	1	100%	Approval	
3	GMP document control rule	01-RGL-Doc	1	100%	Approval	
2) Standard document (Grade B documents)						
1	Production control	SD-01	1	100%	Approval	
2	Sanitation control	SD-02	1	100%	Approval	
3	Quality control	SD-03	1	100%	Approval	
4	Validation	SD-04	1	100%	Approval	
5	Revision control	SD-05	1	100%	Approval	
6	Release control	SD-06	1	100%	Approval	
7	Education and Training	SD-07	1	100%	Approval	
8	Handling abnormal and deviation	SD-08	1	100%	Approval	
9	Change control	SD-11	1	100%	Approval	
10	Policy for training new staffs	SD-07-01	1	100%	Approval	
11	Validation master plan	-	1	100%	Approval	
12	Policy for self inspection	SD-10	2	100%	Approval	
13	Policy for product recall	SD-13	2	100%	Approval	
14	Policy for market supervision	SD-14	2	100%	Approval	
15	Policy for trend analysis	SD-17	2	100%	Approval	
3) MF (Grade B documents)						
1	MF - Measles	M-MF	3	100%	Approval	
4) Manuals						
1	Material manual for measles vaccine production	M01-MM	2	100%	Approval	
2	Manual for measles equipments	M01-EM	2	50%	---	

Annex 9: SOP Related Documents

LIST OF SOPs

Rev.-01
As of 31 August 2009

No	Document Name	SOP No.	Status				Remarks
			Approved	Non-approved			
				preparing	non preparing	due date	
BULK PRODUCTION DEPARTMENT							
1	Changing to enter grade C	M03-SOP-01-01	X				
2	Changing to enter grade D	M03-SOP-01-02	X				
3	Sanitize grade B,C area	M03-SOP-02-01	X				
4	Sanitation of grade D	M03-SOP-02-02	X				
5	Sanitation of upgraded area	M03-SOP-02-04	X				
6	Procedure to evaluate result of environmental monitoring of clean room	M03-SOP-03-01	X				
7	Procedure to count particle in air	M03-SOP-03-03	X				
8	Procedure to count microorganism in air	M03-SOP-03-04	X				
9	Procedure to count surface microorganism	M03-SOP-03-05	X				
10	Receive SPF egg	M03-SOP-04-01	X				
11	Keep SPF egg	M03-SOP-04-02	X				
12	Incubate SPF egg	M03-SOP-04-03	X				
13	Check SPF egg	M03-SOP-04-04	X				
14	Sterilize surface of egg shell	M03-SOP-04-05	X				
15	Cut egg shell and collect embryo	M03-SOP-04-06	X				
16	Prepare medium for trypsination	M03-SOP-04-07	X				
17	Trypsin chicken embryo cell	M03-SOP-04-08	X				
18	Dispense and centrifuge cell suspension	M03-SOP-04-09	X				
19	Collect cell after centrifugal	M03-SOP-04-10	X				
20	Sample to count cell	M03-SOP-04-11	X				
21	Procedure to count cell	M03-SOP-04-12	X				
22	Dispense suspension and culture cell	M03-SOP-04-13	X				
23	Procedure to prepare virus suspension for injection	M03-SOP-05-01	X				
24	Procedure to inject Measles virus	M03-SOP-05-02	X				
25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
28	Prepare washing Hank and M-199 for the second changing	M03-SOP-05-06	X				
29	Procedure of washing Hank's and the second medium changing	M03-SOP-05-07	X				
30	Evaluate CGI-CPE and harvest vaccine	M03-SOP-05-08	X				
31	Procedure of virus suspension pooling	M03-SOP-06-01	X				
32	Procedure of filtration of bulk suspension	M03-SOP-06-02	X				
33	Procedure of dispensing Vaccine of bulk into tank 10L	M03-SOP-06-03	X				
34	Bulk quick thaw	M03-SOP-06-04	X				
35	Procedure to keep virus seed, bulk and virus sample	M03-SOP-07-01	X				
36	Procedure to thaw vaccine	M03-SOP-07-02	X				
37	Prepare implement for trypsination	M03-SOP-08-01	X				
38	Prepare implement for Measles virus injection	M03-SOP-08-02	X				
39	Prepare implement for the first changing	M03-SOP-08-03	X				
40	Prepare implement for the second changing	M03-SOP-08-04	X				
41	Prepare implement for pooling-filtration	M03-SOP-08-05	X				
42	Prepare clothes	M03-SOP-08-06	X				
43	Raw Material Storage	M03-SOP-08-08		X			
44	Dispense NaHCO ₃	M03-SOP-08-09	X				
45	Prepare medium for bulk production	M03-SOP-08-10	X				
46	Prepare Iode alcohol	M03-SOP-08-11	X				
47	Procedure to inactivate craft serum	M03-SOP-08-12	X				
48	Procedure to check integrity of membrane	M03-SOP-08-13	X				
49	Wash and rinse production implement	M03-SOP-08-14	X				
50	Handle virus infected implement	M03-SOP-10-01	X				
51	Handle with new glass roux	M03-SOP-10-02	X				
52	Procedure to handle with new nibber stopper	M03-SOP-10-03	X				
53	Transport material and implement	M03-SOP-10-05	X				
54	Procedure to operate electronic balance CW1PJ-150IG-L	M03-SOP-11-05	X				
55	Procedure to operate electronic balance LE2202S & TE2101	M03-SOP-11-06	X				
56	Procedure to use Clean bench	M03-SOP-11-07	X				
57	Procedure to use Safety cabinet NSC-HA-1800	M03-SOP-11-08	X				
58	Procedure to use and sterilize UFW - 4 used point	M03-SOP-11-10	X				
59	Procedure of SIP of UFW-4 used point system	M03-SOP-11-15	X				
60	Procedure to use thermal stabilizer TR - 4	M03-SOP-11-17	X				
61	Procedure to use attemperation tank TRW - 170	M03-SOP-11-18	X				
62	Procedures to use dispenser	M03-SOP-11-20	X				
63	Procedure to use magnetic stirrer DP-1M	M03-SOP-11-21	X				

25	Procedure to add M-199 after injection	M03-SOP-05-03	X			
26	Prepare medium for the first medium changing	M03-SOP-05-04	X			
27	Procedure to replace the first medium changing	M03-SOP-05-05	X			
64	Procedure to use CWE-130 washer	M03-SOP-11-24	X			
65	Procedure to use Integri test EXACTA	M03-SOP-11-25	X			
66	Procedure to use magnetic stirrer HPS-500R	M03-SOP-11-26	X			
67	Procedure to use clothes dryer	M03-SOP-11-27	X			
68	Procedure to use centrifugal HL-7	M03-SOP-11-29	X			
69	Procedure to use PPS-05 incubator	M03-SOP-11-32	X			
70	Procedure to use egg keeping cabinet MIR-153	M03-SOP-11-33	X			
71	SOP of installing and collecting sensor and BI in PQ Autoclave	M03-SOP-12-01	X			
72	SOP of installing and collecting sensor and BI in PQ of Dry Oven	M03-SOP-12-02	X			
73	SOP of installing and collecting sensor in PQ of Incubation and cold	M03-SOP-12-03	X			
74	SOP of installing and collecting BI in fumigation PQ	M03-SOP-12-04	X			
75	SOP of installing and collecting sensor in PQ of egg incubator	M03-SOP-12-05	X			
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FINAL PRODUCTION DEPARTMENT						
1	Procedure to enter and exit D grade area	M04-SOP-01-02	X			
2	Procedure to enter and exit grade A, B area	M04-SOP-01-03	X			
3	Wash and antiseptic hand	M04-SOP-01-04	X			
4	Sanitize grade A,B area	M04-SOP-02-01	X			
5	Sanitize grade D area	M04-SOP-02-02	X			
6	Sanitize upgraded area	M04-SOP-02-03	X			
7	Sanitize passroom, passbox and changing room	M04-SOP-02-04	X			
8	Procedure to count bacteria living in air	M04-SOP-03-01	X			
9	Procedure to count particle in air	M04-SOP-03-02	X			
10	Evaluate environmental monitoring result	M04-SOP-03-03		X		
11	Follow temperature of cold store	M04-SOP-03-04	X			
12	Procedure to count surface bacteria	M04-SOP-03-05	X			
13	Vial washing and sterilization	M04-SOP-04-01	X			
14	Prepare Final Measles bulk	M04-SOP-05-01	X			
15	Measles vaccine filling	M04-SOP-05-02	X			
16	Vaccine freeze drying	M04-SOP-05-03	X			
17	WFI filling	M04-SOP-05-04	X			
18	Capping	M04-SOP-06-01	X			
19	Check freeze dried vaccine by eyes	M04-SOP-06-02	X			
20	Check WFI by eyes	M04-SOP-06-03	X			
21	Labeling	M04-SOP-06-04	X			
22	Package	M04-SOP-06-05	X			
23	Sterilize production implement by autoclave	M04-SOP-06-06	X			
24	Nhập nguyên vật liệu đóng ống	M04-SOP-07-01	X			
25	Receive and keep material for filling	M04-SOP-07-04	X			
26	Receive thawed bulk	M04-SOP-07-05	X			
27	Order and receive medium	M04-SOP-07-06	X			
28	Keep vaccine before and after package	M04-SOP-07-07	X			
29	Keep WFI before and after package	M04-SOP-07-08	X			
30	Release vaccine and WFI	M04-SOP-07-09	X			
31	Sample raw material	M04-SOP-07-10	X			
32	Wash implement for final bulk preparation	M04-SOP-08-02	X			
33	Pack implement for vaccine preparation to sterilize	M04-SOP-08-03	X			
34	Prepare implement for Measles vaccine preparation	M04-SOP-08-04	X			
35	Wash implement for Measles vaccine filling	M04-SOP-08-05	X			
36	Pack implement for filling vaccine to be sterilized	M04-SOP-08-06	X			
37	Prepare Measles vaccine filling implement	M04-SOP-08-07	X			
38	Wash and close Tank 70 liters	M04-SOP-08-08	X			
39	Prepare aluminum cap for capping	M04-SOP-08-09	X			
40	Wash WFI filling implement	M04-SOP-08-10	X			
41	Prepare sterilized clothes	M04-SOP-08-11	X			
42	Prepare implement for WFI filling	M04-SOP-08-12	X			
43	Prepare filling implement of WFI for sterilization	M04-SOP-08-13	X			
44	Prepare capping implement	M04-SOP-08-14	X			
45	Prepare to sterilize rubber stopper for filling	M04-SOP-08-15	X			
46	Prepare sterilized clothes of grade D area	M04-SOP-08-16	X			
47	Handle implement and clothes after filling of Measles vaccine	M04-SOP-08-18	X			
48	Prepare, operate and handle vial washing machine	M04-SOP-09-01(1)	X			
49	Sanitize vial washing machine	M04-SOP-09-01(2)	X			
50	Assemble, maintain and replace components of vial washing and	M04-SOP-09-01(3)	X			
51	Calibrate vial washing and sterilization machine	M04-SOP-09-01(4)	X			
52	Prepare, operate and handle filling machine	M04-SOP-09-02(1)	X			
53	Sanitize filling machine	M04-SOP-09-02(2)	X			

25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
54	Assemble, maintain and replace components of filling machine	M04-SOP-09-02(3)	X				
55	Prepare, operate and handle tray loading machine	M04-SOP-09-03(1)	X				
56	Sanitize tray loading machine	M04-SOP-09-03(2)	X				
57	Assemble, maintain and replace components of tray loading machine	M04-SOP-09-03(3)	X				
58	Prepare, operate and handle capping machine	M04-SOP-09-04(1)	X				
59	Sanitize capping machine	M04-SOP-09-04(2)	X				
60	Assemble, maintain and replace components of capping machine	M04-SOP-09-04(3)	X				
61	Prepare, operate and handle labeler machine	M04-SOP-09-05(1)	X				
62	Sanitize labeler machine	M04-SOP-09-05(2)	X				
63	Assemble, maintain and replace components of labeling machine	M04-SOP-09-05(3)	X				
64	Sanitize freeze drying machine	M04-SOP-09-06(2)	X				
65	CIP of freeze drying machine	M04-SOP-09-06(3)	X				
66	SIP of freeze drying machine	M04-SOP-09-06(4)	X				
67	Assemble, maintain and replace components of freeze drying machine	M04-SOP-09-06(5)	X				
68	Calibrate freeze drying	M04-SOP-09-06(6)	X				
69	Check leakage of freeze drying machine	M04-SOP-09-06(7)	X				
70	Operate freeze drying machine	M04-SOP-09-07(2)	X				
71	Use clean bench	M04-SOP-09-17	X				
72	Procedure of using and sterilizing WFI-2 supplying point	M04-SOP-09-20	X				
73	Procedure to use and sterilize WFI-3 supply point	M04-SOP-09-21	X				
74	Procedure to use and sterilize UF-2 supply point	M04-SOP-09-22	X				
75	Procedure to use and sterilize UF-5 supply point	M04-SOP-09-23	X				
76	Use electronic scale	M04-SOP-09-29	X				
77	Set up and collect sensor in sterilizing rubber stopper	M04-SOP-10-01	X				
78	Set up and collect BI in sterilizing rubber stopper	M04-SOP-10-02	X				
79	Set up and collect sensor in sterilizing aluminum cap and implement	M04-SOP-10-03	X				
80	Set up and collect BI in sterilizing aluminum cap and implement	M04-SOP-10-04	X				
81	Set up and collect sensor in sterilizing clothes and sanitation implement	M04-SOP-10-05	X				
82	Set up and collect BI in sterilizing clothes and sanitation implement	M04-SOP-10-06	X				
83	Set up and collect sensor in sterilizing freeze drying frame	M04-SOP-10-07	X				
84	Set up and collect BI in sterilizing freeze drying machine and cap	M04-SOP-10-08	X				
85	Set up and collect BI in fumigating formalin	M04-SOP-10-09	X				
86	Set up and collect sensor in vial sterilization	M04-SOP-10-10	X				
87	Set up and disassemble Endotoxin vial in vial sterilization	M04-SOP-10-11	X				
88	Measure temperature and humidity of clean room	M04-SOP-10-12	X				
89	Handle falling and broken vial during production	M04-SOP-10-13	X				
90	Medium filling	M04-SOP-11-01	X				
91	Operate freeze drying machine in medium filling	M04-SOP-11-02	X				
92	Operate freeze drying machine in medium filling	M04-SOP-12-01	X				
93	Check volume of solution for filling	M04-SOP-12-05	X				
94	Adjust filling volume	M04-SOP-12-06	X				
95	Sample by cleaning freeze drying chamber	M04-SOP-12-07	X				
96	Sample vial during washing	M04-SOP-12-08	X				
97	Sample rubber stopper after sterilization and drying	M04-SOP-12-09	X				
98	Sampling in final production	M04-SOP-12-10	X				
			97				

MEDIUM PRODUCTION DEPARTMENT

1	Changing to enter grade C area	M05-SOP-01-01	X				
2	Changing to enter grade D area	M05-SOP-01-02	X				
3	Sanitation of non-graded area	M05-SOP-02-01	X				
4	Sanitation of grade D area	M05-SOP-02-02	X				
5	Sanitation of grade C area	M05-SOP-02-03	X				
6	Procedure to count bacteria living in air	M05-SOP-03-01	X				
7	Procedure to count particle in air	M05-SOP-03-02	X				
8	Procedure to count bacteria in the surface	M05-SOP-03-03	X				
9	Procedure to monitor environment in clean room	M05-SOP-03-06	X				
10	Use pH meter	M05-SOP-04-01	X				
11	Operate electronic balance CW1P1-300-IG-L	M05-SOP-04-02	X				
12	Operate electronic balance CP 16001S	M05-SOP-04-03	X				
13	Operate electronic balance LE2202S	M05-SOP-04-04	X				
14	Operate electronic balance FBG64EDE-S	M05-SOP-04-05	X				
15	Use surface thermometer	M05-SOP-04-06		X			
16	Operate thermal addition stirrer	M05-SOP-04-08	X				
17	Operate stand stirrer	M05-SOP-04-09	X				

25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
18	Use clean bench E	M05-SOP-04-13	X				
19	Use clean bench C	M05-SOP-04-14	X				
20	Operate Air sampler	M05-SOP-04-17	X				
21	Operate medium dispenser	M05-SOP-04-18	X				
22	Operate Pall integrity testing machine	M05-SOP-04-22	X				
23	Use fridge SANYO MPR-1410R	M05-SOP-04-23	X				
24	Operate particle counter	M05-SOP-04-24	X				
25	Wash implement used for medium and solution production	M05-SOP-05-01	X				
26	Prepare packing implement for medium and solution production	M05-SOP-05-02	X				
27	Wash and prepare implement for water sampling	M05-SOP-05-10	X				
28	Prepare and pack equipment for preparation of TGC and SCD	M05-SOP-05-11	X				
29	Tight filtration system	M05-SOP-06-01	X				
30	Open filtration system	M05-SOP-06-02	X				
31	Procedure to distribute chemicals	M05-SOP-06-03		X			
32	Prepare phenol 0.1% solution	M05-SOP-06-04	X				
33	Sterilized alcohol filtration	M05-SOP-06-05	X				
34	Prepare medium to wash polypepton	M05-SOP-06-06	X				
35	Glucose 25%preparation	M05-SOP-06-07	X				
36	Prepare MEM 5x	M05-SOP-06-08	X				
37	Prepare F12	M05-SOP-06-09	X				
38	Procedure of standard manipulation for production of SCD for MFT	M05-SOP-06-10		X			
39	Procedure of standard manipulation for production of bulk	M05-SOP-06-11		X			
40	Procedure of standard manipulation for production of medium for QC Dept.	M05-SOP-06-12		X			
41	Procedure of standard manipulation of production for vaccine dilution	M05-SOP-06-13		X			
42	Receive input chemical	M05-SOP-07-01	X				
43	Keep input chemical	M05-SOP-07-02	X				
44	Control chemical usage	M05-SOP-07-03	X				
45	Procedure to keep medium	M05-SOP-07-04		X			
46	Abrogate unsatisfied medium	M05-SOP-08-03	X				
47	Number lot and write the label	M05-SOP-08-04	X				
48	Procedure to use and sterilize WFI 4 used point	M05-SOP-09-01	X				
49	Procedure to sample water at points of WFI system	M05-SOP-10-01	X				
50	Procedure to sample water at points of UFW system	M05-SOP-10-02	X				
51	Procedure to sample PS	M05-SOP-10-03	X				
52	Sample water after rinsing implement	M05-SOP-10-04	X				
53	Sample by cleaning implement	M05-SOP-10-05	X				
54	Set up and collect BI of dry oven A-1 (sterilize implement)	M05-SOP-11-05	X				
55	Set up and collect thermal sensor of dry oven A-1 (sterilize implement)	M05-SOP-11-06	X				
56	Set up and collect BI during formalin fumigation	M05-SOP-11-07	X				
57	Set up and collect BI(sterilize implement – Loading pattern 4)	M05-SOP-11-08	X				
58	Set up and collect thermal sensor (sterilize implement – Loading pattern 4)	M05-SOP-11-09	X				
			51				
QC DEPARTMENT							
(BIOLOGICAL)							
1	Procedure to enter and exit control area	M02-SOP-01-01	X				
2	Procedure to enter and exit of material	M02-SOP-01-02	X				
3	Procedure to enter and exit of material after sterilization	M02-SOP-01-03	X				
4	Procedure to enter and exit of wasted material and dirty implement	M02-SOP-01-04	X				
5	Procedure to sanitize upgraded area	M02-SOP-02-01	X				
6	Sanitize grade C area	M02-SOP-02-02	X				
7	Sanitize grade B area	M02-SOP-02-03	X				
8	Procedure to count speck of dust in air	M02-SOP-03-01	X				
9	Procedure to count bacteria living in air	M02-SOP-03-02	X				
10	Procedure to count surface bacteria	M02-SOP-03-03	X				
11	Evaluate result of environmental monitoring	M02-SOP-03-06	X				
12	Check water microorganism	M02-SOP-04-01	X				
13	Procedure to receive and keep SPF egg	M02-SOP-04-02	X				
14	Check sensitivity of agar	M02-SOP-04-03		X			

25	Procedure to add M-199 after injection	M03-SOP-05-03	X			
26	Prepare medium for the first medium changing	M03-SOP-05-04	X			
27	Procedure to replace the first medium changing	M03-SOP-05-05	X			
15	Check sensitivity of medium for Myco test	M02-SOP-04-04	X			
16	Check sensitivity of Thioglycolate- Soybean casein	M02-SOP-04-07	X			
17	Procedure to received final sample	M02-SOP-05-01	X			
18	Procedure to receive bulk sample	M02-SOP-05-02	X			
19	Procedure to dispense and keep final bulk	M02-SOP-05-03	X			
20	Check control cell	M02-SOP-05-04	X			
21	Test on finding virus causing red blood cell absorption	M02-SOP-05-05	X			
22	Test of foreign agent on CEC	M02-SOP-05-06	X			
23	Mycoplasma test	M02-SOP-05-07	X			
24	Sterilization test	M02-SOP-05-08	X			
25	Test of foreign agent on FL	M02-SOP-05-09	X			
26	Test of foreign agent on vero	M02-SOP-05-10	X			
27	Potency test	M02-SOP-05-11	X			
28	Identification test	M02-SOP-05-12	X			
29	Thermal stability test	M02-SOP-05-13	X			
30	Test on finding out foreign agent on CKC	M02-SOP-05-14	X			
31	Test on finding out inhibition factor of Retrovirus, which causes white blood cell on domestic fowls	M02-SOP-05-15		X		
32	Procedure to confirm remaining alive virus after inactivation	M02-SOP-05-16	X			
33	Testing procedure to confirm to remove cell	M02-SOP-05-17	X			
34	Find out foreign agent in Atlantic	M02-SOP-07-01	X			
35	Find out foreign agent in yolk sac	M02-SOP-07-02	X			
36	Common safety test on guinea- pig	M02-SOP-07-03	X			
37	Common safety test on mouse	M02-SOP-07-04	X			
38	Procedure to receive sample, follow to use sample, keep sample and dismiss sample	M02-SOP-08-01		X		
39	Control material of normal store	M02-SOP-08-06		X		
40	Procedure to passage FL cell	M02-SOP-09-01	X			
41	Procedure to passage vero cell	M02-SOP-09-02	X			
42	Procedure of counting and passing chicken embryo cell	M02-SOP-09-03	X			
43	Procedure of passing primary chicken egg	M02-SOP-09-04	X			
44	Procedure of counting and passing chicken kidney cell	M02-SOP-09-05	X			
45	Procedure of GM growing medium preparation	M02-SOP-10-01	X			
46	Medium preparation procedure to maintain MM	M02-SOP-10-02	X			
47	Sterilized steam of medium used for verification	M02-SOP-10-03	X			
48	Procedure to produce SCD agar	M02-SOP-10-04	X			
49	Procedure to produce M Air T catset agar	M02-SOP-10-05	X			
50	Procedure to proliferative virus seed	M02-SOP-11-01		X		
51	Procedure to proliferative Mycoplasma	M02-SOP-11-02	X			
52	Procedure to produce Measles antigen	M02-SOP-11-03	X			
53	Procedure to check potency of Measles antigen	M02-SOP-11-04		X		
54	Procedure to refine antigen	M02-SOP-11-05		X		
55	Procedure to produce Measles antibody	M02-SOP-11-06		X		
56	Procedure to check potency of Measles antibody	M02-SOP-11-07	X			
57	Procedure to produce RSV1,2 seed	M02-SOP-11-08		X		
58	Procedure to produce RAV1,2 seed	M02-SOP-11-09		X		
59	Procedure to titremete of RSV1,2 seed	M02-SOP-11-10		X		
60	Procedure to titremete RAV1,2 seed	M02-SOP-11-11		X		
61	Set up and collect thermal sensor (Autoclave B)	M02-SOP-14-01	X			
62	Set up and collect BI for all autoclave	M02-SOP-14-02		X		
63	Set up and collect thermal sensor for incubator A,B,C,D	M02-SOP-14-03	X			
64	Procedure in receiving and culturing BI for all autoclave	M02-SOP-14-04		X		
65	Set up and collect thermal sensor for vacuum drying oven,	M02-SOP-14-05	X			
66	Set up and collect BI for Formalin fumigation	M02-SOP-14-06	X			
67	Procedure to measure CO2 concentration (CO2 incubator)	M02-SOP-14-08	X			
68	Set up and collect thermal sensor for egg incubator	M02-SOP-14-10	X			
69	Set up and collect BI for fumigation and Dry Oven	M02-SOP-14-11		X		
70	Set up thermal sensor for Autoclave D, E	M02-SOP-14-12	X			
71	Determination of Remaining Formaline concentration	M02-SOP-14-13		X		
72	Receive and culture agar for environmental monitoring	M02-SOP-14-14		X		
73	Read the result and evaluate MFT	M02-SOP-14-15	X			
74	Set up and collect sensor for DryOven	M02-SOP-14-16		X		
75	Set up and collect BI for DryOven	M02-SOP-14-17		X		

25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
76	Evaluate MFT for Bulk production	M02-SOP-14-20		X			
77	Handle dirty implement	M02-SOP-15-01	X				
78	Wash implement	M02-SOP-15-02	X				
79	Procedure in preparing implement for drying	M02-SOP-15-03		X			
80	Procedure in preparing implement for autoclave	M02-SOP-15-04	X				
81	Procedure to wash implement and tube for TOC test	M02-SOP-15-05	X				
82	Procedure to take WFI used in QC	M02-SOP-15-06	X				
83	Procedure to check growing of LH	M02-SOP-16-01	X				
84	Procedure to incubate SPF egg	M02-SOP-16-02	X				
85	Procedure to follow CO ₂ usage	M02-SOP-16-03	X				
86	Procedure of gas usage	M02-SOP-16-04	X				
			65	21			

(CHEMICAL)

1	Test on checking status for freeze dried vaccine	M02-SOP-06-01	X				
2	Test on moisture content of freeze dried vaccine	M02-SOP-06-02	X				
3	PH measure test	M02-SOP-06-03	X				
4	Test on counting unthawed particle of freeze dried vaccine and WFI	M02-SOP-06-04	X				
5	Test on weight deviation for freeze dried vaccine	M02-SOP-06-05	X				
6	Test on endosmosis for freeze dried vaccine	M02-SOP-06-06	X				
7	Test on acid and alkali for WFI	M02-SOP-06-07	X				
8	Chloride test for WFI	M02-SOP-06-08	X				
9	Sulfate test for WFI	M02-SOP-06-09	X				
10	Nitrogen test from Nitrate for WFI	M02-SOP-06-10	X				
11	Nitrogen test from Nitrite for WFI	M02-SOP-06-11	X				
12	Ammonium test for WFI	M02-SOP-06-12	X				
13	Heavy metal test for WFI	M02-SOP-06-13	X				
14	KMnO ₄ test for WFI	M02-SOP-06-14	X				
15	Remaining scale after evaporation for WFI	M02-SOP-06-15	X				
16	Test on checking WFI volume	M02-SOP-06-16	X				
17	Foreign insoluble matter test	M02-SOP-06-17	X				
18	Endotoxin test	M02-SOP-06-18	X				
19	Test of supervising condition of clean water	M02-SOP-06-20	X				
20	Test of checking acid and alkali for clean water	M02-SOP-06-21	X				
21	Chloride test for clean water	M02-SOP-06-22	X				
22	Sulfate test for clean water	M02-SOP-06-23	X				
23	Nitrogen test from Nitrate for clean water	M02-SOP-06-24	X				
24	Nitrogen test from Nitrite for clean water	M02-SOP-06-25	X				
25	Ammonium test for clean water	M02-SOP-06-26	X				
26	Test of heavy metal for clean water	M02-SOP-06-27	X				
27	KMnO ₄ test for clean water	M02-SOP-06-28	X				
28	Residual test after evaporation for clean water	M02-SOP-06-29	X				
29	TOC test for clean water	M02-SOP-06-30	X				
30	Endotoxin test for clean water	M02-SOP-06-31	X				
31	Check acid and alkali of 10ml vial	M02-SOP-06-33	X				
32	Nitrogen test from Nitrite of 10ml vial	M02-SOP-06-34	X				
33	Check rubber stopper perceptibly	M02-SOP-06-35	X				
34	Check foaming of rubber stopper	M02-SOP-06-36	X				
35	KMnO ₄ test of rubber stopper	M02-SOP-06-38	X				
36	Chloride test for rubber stopper	M02-SOP-06-39	X				
37	Nitrogen test from Nitrite of rubber stopper	M02-SOP-06-40	X				
38	Conductivity test	M02-SOP-06-41	X				
39	Moisture content test after evaporating for rubber stopper	M02-SOP-06-42	X				
40	Checking for transparent and color of vaccine	M02-SOP-06-43	X				
41	Test on checking appearance of aluminum cap	M02-SOP-06-44	X				
42	Test on checking appearance of rubber stopper	M02-SOP-06-45	X				
43	Test on checking appearance of vaccine vial	M02-SOP-06-46	X				
44	BSA test	M02-SOP-06-47	X				
45	Moistures content for rubber stopper	M02-SOP-06-48	X				
46	Endotoxin for checking sterilization effect	M02-SOP-06-49	X				
47	Leak test	M02-SOP-06-50	X				
48	Test on measuring alcohol concentration	M02-SOP-06-51	X				
49	Autoclave B	M02-SOP-13-01	X				
50	CO ₂ incubator	M02-SOP-13-04	X				
51	Rotator for microtiter plate	M02-SOP-13-05	X				
52	Procedure to operate pH measuring device (PP-15)	M02-SOP-13-06	X				
53	Safety cabinet A (1 face)	M02-SOP-13-08	X				
54	Use Clean bench	M02-SOP-13-09	X				
55	Use Incubator A	M02-SOP-13-11	X				

25	Procedure to add M-199 after injection	M03-SOP-05-03	X			
26	Prepare medium for the first medium changing	M03-SOP-05-04	X			
27	Procedure to replace the first medium changing	M03-SOP-05-05	X			
56	Use Incubator B	M02-SOP-13-12	X			
57	Use Incubator C	M02-SOP-13-13	X			
58	Use Incubator D	M02-SOP-13-14	X			
59	Centrifuge B	M02-SOP-13-15	X			
60	Operate Endotoxin machine (Well reader), computer and printer of Endotoxin test	M02-SOP-13-16[2]	X			
61	Autoclave D	M02-SOP-13-17	X			
62	Use Autoclave E	M02-SOP-13-18	X			
63	Operate Vacuum drying Oven	M02-SOP-13-20	X			
64	Dryer A	M02-SOP-13-21	X			
65	Dryer B	M02-SOP-13-22		X		
66	Microscope	M02-SOP-13-27	X			
67	Water bath B	M02-SOP-13-29	X			
68	Water bath C	M02-SOP-13-30		X		
69	Compressor	M02-SOP-13-32	X			
70	Vacuum pump	M02-SOP-13-33		X		
71	Osmometer	M02-SOP-13-34		X		
72	Use nitrogen cylinder to keep cell	M02-SOP-13-36	X			
73	Test tube mixer	M02-SOP-13-37	X			
74	Procedure to operate electric scale (LE2202S và LE244S)	M02-SOP-13-42	X			
75	Draft chamber (DF-11AK)	M02-SOP-13-43	X			
76	Operate Pipet washing machine	M02-SOP-13-44	X			
77	Egg incubator B (PPS-03)	M02-SOP-13-45	X			
78	Hot plate	M02-SOP-13-46	X			
79	Operate particle counter in water (K1-04)	M02-SOP-13-49	X			
80	Procedure to operate TOC measuring device (Phoenix 8000)	M02-SOP-13-50	X			
81	Conductivity meter	M02-SOP-13-51	X			
82	Constant temp.device immersion A	M02-SOP-13-53	X			
83	Operate ELISA reader and printer+C174:C198	M02-SOP-13-63	X			
84	Operate ELISA washing machine	M02-SOP-13-65	X			
85	Centrifuge (Rotofix 32)	M02-SOP-13-67	X			
86	Operate Helios spectrum	M02-SOP-13-86	X			
			82	4		

Engineering department

1	Operate water production system	M06-SOP-WSO-01	X			
2	Operate filtration system	M06-SOP-WSO-02	X			
3	Operate active coal and softening system	M06-SOP-WSO-04	X			
4	Operate deionization system	M06-SOP-WSO-07	X			
5	Operate ultra filtered water generation system	M06-SOP-WSO-08	X			
6	Operate ultra filtered water distribution system	M06-SOP-WSO-09	X			
7	Operate WFI generation system	M06-SOP-WSO-11	X			
8	Operate WFI distribution system	M06-SOP-WSO-12	X			
9	Operate and maintain CT 1	M06-SOP-WSO-14	X			
10	Operate and maintain CT 2	M06-SOP-WSO-15	X			
11	Operate PS generation system	M06-SOP-WSO-16	X			
12	Calibrate water generation system	M06-SOP-CAL-38	X			
13	Calibrate HVAC system pressure displaying set	M06-SOP-CAL-60	X			
14	Calibrate cold room and incubation room by temperature	M06-SOP-CAL-63	X			
15	Calibrate temperature and humidity of HVAC system	M06-SOP-CAL-66	X			
16	Operate and maintain temperature calibration equipment AMETEK ITC-320A	M06-SOP-CALEQ-02	X			
17	Operate and maintain pressure calibration equipment CPC320	M06-SOP-CALEQ-03	X			
18	Operate and maintain thermometer and hygrometer TR72U	M06-SOP-CALEQ-05	X			
19	Operate and maintain low temperature water bath EYELA PSL - 1800	M06-SOP-CALEQ-06	X			
20	Operate and maintain Hybrid Recorder	M06-SOP-CALEQ-07	X			
21	Use and maintain AMETEK ITC-155A	M06-SOP-CALEQ-08	X			
22	Operate and maintain AMETEK DTI1000-A equipment	M06-SOP-CALEQ-10		X		
23	Use pressure calibration machine KAL-84	M06-SOP-CALEQ-11	X			
24	Use particle counter KC-01E	M06-SOP-CALEQ-12	X			
25	Instruct to use particle creation machine TSI-TOPAS	M06-SOP-CALEQ-13	X			
26	Use and maintain DTA-4B LITE particle creation machine	M06-SOP-CALEQ-14		X		
27	Use Kanomax machine	M06-SOP-CALEQ-15	X			
28	Use and keep compressor HYTACHI 02-LT-7T	M06-SOP-CALEQ-16		X		

25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
29	Operate HVAC system	M06-SOP-HVACO-01	X				
30	Validate and maintain Clean Bench and Laminar Flow periodically	M06-SOP-VAL-61	X				
31	Validate and maintain sterilization tunnel	M06-SOP-VAL-62	X				
32	Validate and maintain Hepa Filter	M06-SOP-VAL-64	X				
33	Operate city water supply system	M06-SOP-PSO-02		X			
34	Operate and maintain boiler	M06-SOP-BOILER-01	X				
35	Operate and maintain central chiller	M06-SOP-PSO-03		X			
36	Operate and maintain central compressor	M06-SOP-COMP-01	X				
37	Operate and maintain wasted water treatment system	M06-SOP-WWO-01	X				
38	Operate and maintain central generator	M06-SOP-GENE-03	X				
39	Operate and maintain central controlling system	M06-SOP-CNT-01		X			
40	Operate and maintain AHU system	M06-SOP-PSO-04		X			
41	Operation and maintenance for multifunction calibrator	M06-SOP-CALEQ-18		X			
			33	8			

SOP of Department

1	The first changing	M-SOP-01-01	X				
2	Procedure to check suitability of changing	M-SOP-01-02	X				
3	Procedure to sterilize by Formaline fumigation	M-SOP-02-01	X				
4	Sử dụng cồn trong phòng sạch cấp các cấp độ	M-SOP-02-02	X				
5	Procedure to measure remaining Formaline concentration	M-SOP-02-03	X				
6	Procedure to manage, deliver and use chemical	M-SOP-02-04	X				
7	Procedure to control insects	M-SOP-02-05	X				
8	Procedure to control waste	M-SOP-02-06	X				
9	Procedure to follow temperature, humidity and pressure deviation	M-SOP-03-01	X				
10	Calibrate thermal sensor	M-SOP-04-01	X				
11	Wash and pack sterilized clothes	M-SOP-10-01	X				
12	Procedure to handle during power-off	M-SOP-10-03	X				
13	Procedure to answer testing result	M-SOP-14-01	X				
14	Quy trình giao nhận môi trường	M-SOP-14-02	X				
15	Use autoclave	M-SOP-15-01	X				
16	Use dry oven	M-SOP-15-02	X				
17	Use integrity testing machine of Millipore	M-SOP-15-03	X				
18	Procedure to use sampler in air Airport MD8	M-SOP-15-05	X				
19	Procedure to use particle counter A2400	M-SOP-15-06	X				
20	Procedure to use Formalin fumigator FOT2000	M-SOP-15-07	X				
21	Procedure to use neutralizer	M-SOP-15-08	X				
22	Procedure to use incubation and cold room	M-SOP-15-11	X				
23	Use ice maker	M-SOP-15-12	X				
24	Procedure to use deep freezer	M-SOP-15-13	X				
25	Use Measuring device of remaining Formaline concentration	M-SOP-15-14	X				
26	Use automatic alcohol sprayer	M-SOP-15-15	X				
27	Procedure to use and sterilize WF16 used point	M-SOP-15-16	X				
28	Procedure to use and sterilize UFW3 used point	M-SOP-15-17	X				
29	Procedure to use microscope IX 51	M-SOP-15-18	X				
30	Use bag sealer	M-SOP-15-19	X				
31	Procedure to use Recorder AL3000	M-SOP-15-21	X				
			31				

Animal lab

1	Process to entrance and exit animal building applied for staff	M09-SOP - 01-01	x				
2	Control entrance and exit of animal and material	M09-SOP - 01-04	x				
3	Control entrance and exit of wasted animal and material	M09-SOP - 01-05		x			
4	Sanitise area for raising rabbit and guinea pig	M09-SOP - 02 - 02		x			
5	Sanitise area for raising mouse	M09-SOP - 02 - 03		x			
6	Sanitize normal area	M09-SOP - 02 - 04		x			
7	Process to prepare antiseptic solution	M09-SOP - 02 - 05		x			
8	Process to spray insecticide for animal lab.	M09-SOP - 02 - 06	x				
9	Monitor temperature, humidity, pressure difference	M09-SOP - 03 - 01	x				
10	Process to order animal for test	M09-SOP - 04 - 01	x				
11	Process to order material for raising animal for test	M09-SOP - 04 - 02	x				
12	Process to receive animal for test (3 kinds)	M09-SOP - 04 - 03	x				
13	Process to raise guinea pig separately	M09-SOP - 04 - 04	x				
14	Procedure to raise mouse separately	M09-SOP - 04 - 05	x				
15	Procedure to raise rabbit separately	M09-SOP - 04 - 06	x				
16	Process to receive material for raising animal for test	M09-SOP - 04 - 07	x				
17	Process to incubate rice seed	M09-SOP - 04 - 08		x			
18	General system of store in animal building	M09-SOP - 05 - 01		x			

25	Procedure to add M-199 after injection	M03-SOP-05-03	X				
26	Prepare medium for the first medium changing	M03-SOP-05-04	X				
27	Procedure to replace the first medium changing	M03-SOP-05-05	X				
19	Control, monitor entrance and exit of material in store	M09-SOP - 05 - 02		x			
20	Control aseptic	M09-SOP - 05 - 03	x				
21	Process to keep, arrange material in store	M09-SOP - 05 - 04		x			
22	Operate and maintain Autoclave	M09-SOP - 06 - 01		x			
23	Use and maintain electronic balance	M09-SOP - 06 - 02		x			
24	Use and maintain balance	M09-SOP - 06 - 03	x				
25	Use wind bolt	M09-SOP - 06 - 04	x				
26	Use and maintain drinking water filtration system for animal for test	M09-SOP - 06 - 05		x			
27	Use and maintain shelf and cage system	M09-SOP - 06 - 06		x			
28	Use and maintain clean clothes washing machine	M09-SOP - 06 - 07		x			
29	Process to wash clean clothes in grade D area	M09-SOP - 08 - 01	x				
30	Process to prepare, dry-clean clean clothes in grade D area	M09-SOP - 08 - 02	x				
31	Process to sterilize clean boot in grade D area	M09-SOP - 08 - 03	x				
32	Process to wash clothes in non- grade area	M09-SOP - 08 - 04		x			
33	Process to handle dirty cage	M09-SOP - 08 - 05	x				
34	Process to wash, prepare to dry-clean cage	M09-SOP - 08 - 06		x			
35	Handle drinking water bottle and eating spout to prepare for sterilization	M09-SOP - 08 - 07		x			
36	Procedure to raise and look after for guinea pig for test	M09-SOP - 09 - 01	x				
37	Procedure to raise and look after for mouse for test	M09-SOP - 09 - 02	x				
38	Process to raise and look after rabbit for measles antibody production	M09-SOP - 09 - 03		x			
39	Procedure to abrogate animal after test	M09-SOP - 09 - 04	x				
			21	18			

QA

1	Detergent and antiseptic	M01-SOP-02-05	x				
2	Contract calibration for Equipment	01-SOP-04-03	x				
3	Material control	01-SOP-05-01	x				
4	Handle with unsuitable products	01-SOP-06-02	x				
5	Training of new staff	01-SOP-07-01	x				
6	Regulation on coding system	01-SOP-09-01	x				
7	How to write SOP	01-SOP-09-02	x				
8	How to write Batch processing record	01-SOP-09-03	x				
9	How to write SPEC for raw material, intermediate product and packing material	01-SOP-09-04	x				
10	How to write validation Protocol	01-SOP-09-05	x				
11	How to write SPEC for biological materials	01-SOP-09-06	x				
12	How to write SPEC for equipment, implement, spare part of equipment	01-SOP-09-07	x				
13	Control of working seed virus	01-SOP-10-03	x				
14	Handle complain of product	01-SOP-11-01	x				
15	Review Batch processing records.	01-SOP-13-01	x				
16	Use documents, production and quality control record	01-SOP-13-02	x				
17	Distribute and collect of documents, records of production and quality control	01-SOP-13-03	x				
18	Replacement, repair and maintenance of equipment	01-SOP-15-01	x				

Annex 10: Validation Related Documents

Summary Results Table of PQ performance

Updated: 17th December, 2007

Department	Machine Name & PQ Items	PQ Content	Summary of PQ condition	Number of times	Acceptance Criteria	R e s u l t s	Judgement
QC	CO2 Incubator A	Temperature distribution	Temp: 37.0	1 time	37±0.2	Min:36.10 Max:37.10	Pass
			CO2: 5%		5±1 %	Min:4.4% Max:5.6%	
			Temp: 37.0	1 time	37±0.2	Min:36.10 Max:38.00	Pass
	CO2 Incubator B	CO2: 5%	Temp: 37.0	1 time	5±1 %	Min:4.5% Max:5.5%	Pass
			Temp: 37.0	1 time	5±1 %	Min:36.10 Max:36.90	Pass
			CO2: 5%	1 time	5±1 %	Min:4.5% Max:5.5%	Pass
	CO2 Incubator C	Temp & Humi. distribution	Temp: 37.0	1 time	37±0.2	Min:36.80 Max:37.40	Pass
			CO2: 5%	1 time	5±1 %	Min:4.5% Max:5.5%	Pass
			Humid: 92%	1 time	60±10%	Min:63% Max:67%	Pass
	Lab Autoclave E for Chemical lab	Temperature distribution	Loading Pattern 1 (See parameters)	3 times	12±0.2	Min:11.970 Max:12.20	Pass
			Temp: 121.0, Time: 1hour			Min:11.940 Max:12.60	Pass
						Min:12.60 Max:12.80	Pass
	Lab Autoclaves D for Biological lab	Effect of sterilization	Loading Pattern 1 (See parameters)	3 times	BI (-)	BI(15/-): Temp.&time: 0121.0, 4min. FO: Min:1.1 Max:2.3	Pass
			Temp: 121.0, Time: 20m		Temp.&Time: 0121.0, 4min. FO: Min:0.3 Max:2.9	BI(15/-): Temp.&time: 0121.0, 4min. FO: Min:0.3 Max:2.9	Pass
						BI(15/-): Temp.&time: 0121.0, 4min. FO: Min:0.3 Max:2.9	Pass
Dry Oven	Effect of sterilization	Loading Pattern 1 (See parameters)	3 times	BI (-)	BI(15/-): Temp.&time: 0190.0, 28min.	Pass	
		Temp: 140.0, Time: 70m		Temp.&Time: 0190.0, 28min.	BI(15/-): Temp.&time: 0190.0, 28min.	Pass	
					BI(15/-): Temp.&time: 0190.0, 28min.	Pass	
Formalin Fumigation	Effect of sterilization	Grade: A,B,C	1 time	Formalin residual of 3rd line: 0.01um	Formalin residual: Not detect	Pass	
Environmental Monitoring	Confirmation of environmental condition	Grade: A,B,C (at static)	3 times	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	1st: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK 2nd: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK 3rd: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK	Pass	
Gowning Validation	Confirmation of qualified person	4 persons	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Washing of Equipments	Effect of washing	By manual	3 times	Rinse solution: 0.50ppb (TOC) Swab: same as control (TOC)	RinseQ Location: 0.0.0.0 SwabQ Location: same as control (Both data: 0.00ppb) RinseQ Location: 0.0.0.0 SwabQ Location: same as control (Both data: 0.00ppb) RinseQ Location: 0.0.0.0 SwabQ Location: same as control (Both data: 0.00ppb)	Pass	
Autoclave (Tray of F,D)	Effect of sterilization	Loading Pattern 1	3 times	BI (-)	BI(121/-): Temp. OK, FO: 46.67	Pass	
					BI(121/-): Temp. OK, FO: 46.67	Pass	
					BI(121/-): Temp. OK, FO: 46.67	Pass	
Washing of Freezer Dryer	Effect of washing	CIP	3 times	Swab: same as control (TOC) ≤ 100ppb	Samples (16 Locations): Mini 150, Max 250, Contact (16 locations): Mini 110, Max 330 Samples (16 Locations): Mini 150, Max 170, Contact (16 locations): Mini 110, Max 330	Pass	
Quality of rubber stopper received	Confirmation of supplier's certification		1 time	≤ 6000/particle/ml	Rubber stopper for VFI: Particle count: ok, Endotoxin: ok	Pass	
Moisture content of rubber stopper after drying by Autoclave	Qualification of drying Time	By manual	3 times	Rubber Stopper for VFI: 0.0.0.0 5% Stopper for Freeze Dry: 0.0.0.0 5%	For VFI: 0.18~0.25%, For Freeze Dry: 0.20~0.24% For VFI: 0.20~0.31%, For Freeze Dry: 0.18~0.28% For VFI: 0.13~0.20%, For Freeze Dry: 0.18~0.22%	Pass	
Tunnel Sterilizer	Effect of de-endotoxin	(See Parameters) 11st zone temp.: 120.0 Belt Speed: 137mm/min	3 times	Endotoxin: 0.3 log reduction Max Temp: 63.00C	Endotoxin/Location: 0.5 Log reduction, Max temp: 63.00°C, 319.4 °C	Pass	
Measuring of Temp & Humi.	Confirmation of environmental condition	Grade: A,B,D	5 days	Temp: 22±4.0 Humid: 50±5.0%	Disinfection & Vial washing Run: 1 day 0 Humidity: Out of Criteria => Solution: attach the handle deviation report with PQ report All of another data : within Criteria	Pass	
Formalin Fumigation	Effect of sterilization	Grade: A,B	3 times	BI(15/-) log reduction, Formalin residual in 3rd line: C0.1ppm	1st: BI (1818/-): OK, Formaline residual: non detect 2nd: BI (1818/-): OK, Formaline residual: non detect 3rd: Formaline residual: non detect	Pass	
Pre-environmental Monitoring	Confirmation of environmental condition	Grade: A,B,D (at static)	1 time	Microorganism/Airborn organism, settling plate, Contact plate	Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK	Pass	
Environmental Monitoring	Confirmation of environmental condition	Grade: A,B,D (at dynamic)	3 times	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	1st: OK 2nd: OK 3rd: OK	Pass	
Gowning Validation	Confirmation of qualified person	6 persons	3 times	Microorganism/Contact Plate	1st: one person is out of criteria => solution => always implement again and result OK, others OK 2nd: OK 3rd: OK	Pass	
Validation Bringing substance into room	Qualification of SOP	(Root) NC—D, D—B, B—A	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Storage of sterilized substance	Decision of storage period in Sterile room	Storage Location Grade B	1 time	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Confirmation of all process for VFI manufacturing	Confirmation of all process for VFI manufacturing	Same as normal production	1 time	Process control items Lot uniformity	All results: within criteria	Pass	
MFT PV	Confirmation of all process for VFI manufacturing	State as normal production	3 time	Process control items Lot uniformity	All results: within criteria	Pass	
Washing of Equipments	Effect of washing	State as normal production	3 times	No contamination for all lots	All results: within criteria	Pass	
Dry Oven	Effect of sterilization	By manual	3 times	Rinse solution: 0.50ppb Swab: same as control	RinseQ Location: 0.0.0.0 5%, SwabQ Location: Same as control (All data: 0.00ppb) RinseQ Location: 0.0.0.0 5%, SwabQ Location: Same as control (All data: 0.00ppb) RinseQ Location: 0.0.0.0 5%, SwabQ Location: Same as control (All data: 0.00ppb)	Pass	
		Loading Pattern 1 (See parameters)	3 times	BI (-)	BI(15/-): Temp.&time: 2319.3 °C, 30m	Pass	
		Temp: 240.0, Time: 20min.	3 times	Temp.&Time: 2319.3 °C, 30m	BI(15/-): Temp.&time: 2319.3 °C, 30m	Pass	
Measuring of Temp. & Humi.	Confirmation of environmental condition	Grade: B,C,D	24 days	Temp: 22±4.0 Humid: 50±5.0%	1 Room: 1 day 0 Temperature: Out of Criteria => Solution: attach the handle deviation report with PQ report All of another data : within Criteria	Pass	
Formalin Fumigation	Effect of sterilization	Grade: B,C	3 times	BI(15/-) log reduction, Formaline residual in 3rd line: C0.1ppm	BI (1515/-): female residue: 0.01ppm, 0.15ppm, 0.07ppm BI (1515/-): female residue: none detect BI (1515/-): Female residue: non detect	Pass	
Pre-environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at static)	1 time	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK	Pass	
Environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at dynamic)	3 times	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	B grade: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK C grade: Contact plate: 1 point out => inspection => implement 3 lines again, Others OK C grade: reimplementation: OK	Pass	
Gowning Validation	Confirmation of qualified person	5 persons	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Validation Bringing substance into room	Qualification of SOP	NC—D, D—C, C—B	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Quality of Virus diluted solution	Confirmation of filtration process	Same as normal production	3 times	pH Sterilized test	within criteria	Pass	
Autoclave (Cell solution)	Effect of sterilization	Loading Pattern 1,4	3 times	BI (-) Temp.&Time: 0121.0, 0.30min. Dev: Temp: 24.0, FO: 0.12	P.1: (BI: 1515/-): Temp.&time: OK, FO: 4.3, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 47.25 P.1: (BI: 1515/-): Temp.&time: OK, FO: 3.8, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 48.14 P.1: (BI: 1515/-): Temp.&time: OK, FO: 4.5, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 48.52 P.2: (BI: 1515/-): Temp.&time: OK, FO: 4.5, P.3: (BI: 1414/-): Temp.&Time: OK, FO: 33.13 P.2: (BI: 1515/-): Temp.&time: OK, FO: 3.9, P.3: (BI: 1414/-): Temp.&Time: OK, FO: 37.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3	Pass	
Dry Oven (Cell Culture & Virus)	Effect of sterilization	Loading Pattern 1,2,3	3 times	BI (-) Temp.&Time: 0190.0, 0.30min. Dev: Temp: 24.0, FO: 0.12	P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3 P.1: (BI: 1070/-): Temp.&Time: OK, FO: 3.9, P.2: (BI: 1414/-): Temp.&Time: OK, FO: 39.3	Pass	
Incubator Room 1	Temperature distribution	Temp: 37.50	1 time	Temp: 37.5±0.0	Min: 36.50, Max: 38.00	Pass	
Incubator Room 2	Temperature distribution	Temp: 32.0	1 time	Temp: 32±0.0	Min: 31.10, Max: 32.50	Pass	
Cold Room	Temperature distribution	Temp: 5.0	1 time	Temp: 3.40	Min: 4.00, Max: 8.00	Pass	
Revolving Type egg incubator	Temperature distribution	Temp: 37.60, Humid: 60%	1 time	Temp: 37.6±0.0, Humid: 50-70%	Without egg inside: Temp. (Max: 38.6 °C, Min: 36.7 °C) Humid: (Max: 63%; Min: 52%) With egg inside: Temp. (Max: 38.10C, Min: 36.80C) Humid: (Max: 64%; Min: 61%) one time: out of specification due to Autoclave door open when measuring temp. and humidity => already implement again. Other result: OK	Pass	
Measuring of Temp. & Humi.	Confirmation of environmental condition	Grade: B,C,D	3 times	BI(15/-) log reduction, Residual formalin in 3rd line: C0.1ppm	1st: Formaline residue: ok, BI: OK 2nd: Formaline residue: ok, BI: OK 3rd: Formaline residue: ok, BI: OK	Pass	
Formalin Fumigation	Effect of sterilization	Grade: B,C	3 times	BI(15/-) log reduction, Residual formalin in 3rd line: C0.1ppm	1st: Formaline residue: ok, BI: OK 2nd: Formaline residue: ok, BI: OK 3rd: Formaline residue: ok, BI: OK	Pass	
Pre-environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at static)	1 time	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	1st: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK 2nd: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK 3rd: Airborn: OK, Settling plate: OK, Contact plate: OK, Particle count: OK	Pass	
Environmental Monitoring	Confirmation of environmental condition	Grade: B,C,D (at dynamic)	3 times	Microorganism/Airborn organism, settling plate, Contact plate Microsparticle: 0.5um > 5um	1st: OK 2nd: OK 3rd: OK	Pass	
Gowning Validation	Confirmation of qualified person	9 persons	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Validation Bringing substance into room	Qualification of SOP	NC—D, D—C, C—B	3 times	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	
Storage of sterilized substance	Decision of storage period in Sterile room	Storage Location Grade B	1 time	Microorganism/Contact Plate	1st: OK 2nd: OK 3rd: OK	Pass	

Summary Results Table (PQ of Bulk dept. and MFT of Final dept.)						
Updated: 17th December 2007						
Department	Machine Name & Items	Content	Summary of condition	Number of times	Acceptance Criteria	Evaluation
					Results	Judgement
PQ in Bulk Department, August 2007						
Bulk	Mesuring of Temp. & Humi.	Confirmation of environmental condition	Grade: B, C, D	3 times	Temp.: $22 \pm 4^{\circ}\text{C}$ Humi.: $50 \pm 15\%$	one time: out of specification due to Autoclave door open when measuring temp. and humidity. => already implemented again. other result: OK
	Formalin Fumigation	Effect of sterilization	Grade: B, C	3 times	BI: ≥ 3 log reduction, Residual formalin in 3rd time: $\leq 0.1\text{ppm}$	1st: formaline residue: ok; BI: OK 2nd: formaline residue: ok; BI: OK 3rd: formaline residue: OK
	Pre-environmental Monitoring	Confirmation of environmental condition	Grade: B, C, D (at static)	1 time	Microorganism: Airborn organism, settling plate, Contact plate Microparticle: $\leq 5\mu\text{m}$, $> 5\mu\text{m}$	Contact plate: OK Particla counter: OK Air sampler: OK
	Environmental Monitoring	Confirmation of environmental condition	Grade: B, C, D (at dynamic)	3 times	Microorganism: Airborn organism, settling plate, Contact plate Microparticle: $\leq 5\mu\text{m}$, $> 5\mu\text{m}$	1st: Microparticle: OK; Airborn: OK Setting plate: OK Contact plate: OK 2nd: Microparticle: OK; Airborn: OK Setting plate: OK; Contact plate: OK 3rd: Microparticle: OK; Airborn: OK Setting plate: OK; Contact plate: OK
	Gowning Validation	Confirmation of qualified person	9 people	3 times	Microorganism (Contact Plate)	1st: OK 2nd: ok 3rd: OK
	Validation Bringing substance into room	Qualification of SOP	(Row) NC → D, D → C, C → B	3 times	Microorganism (Contact Plate)	1st: OK 2nd: OK 3rd: OK
	Storage of sterilized substance	Decision of storage period in Sterile room	Storage Location: Grade B	1 time	Microorganism (Contact Plate)	OK
MFT result						
Final	MFT	Confirmation of contamination in vaccine filling process.	Storage products in 31°C in 1 week for bacterial development. Storage products in 23°C in 1 week for fungi development	3 times	No Microbacteria, fungi is found in inspection (keep 2 weeks) Environment monitoring: within criteria	1st: environment monitoring: ok; Inspection: No bacteria and fungi was found in inspection after 2 weeks. 2nd: Environment monitoring: OK; Inspection: No bacteria and fungi was found in inspection after 2 weeks. 3rd: Environment monitoring: OK; Inspection: No bacteria and fungi was found in inspection after 2 weeks.

Summary result table of Calibration for HVAC - 2007

Updated: 22/01/2008

No.	Name of Equipment	Place	Method	Criteria	Date	Pass/ Fail	Frequency
1	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2	Final dept.	Temperature (Thermohygro recorder- TRU- 72U)	$\pm 0.81^{\circ}\text{C}$	2007/5/6	Pass	2
2	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-2				2007/5/6	Pass	
3	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1				2007/5/6	Pass	
4	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-1				2007/5/6	Pass	
5	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4				14/5/2007	Pass	
6	TED-P-101-2 SENSOR AND RP1 REORDER - COLD RM-4				14/5/2007	Pass	
7	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3				14/5/2007	Pass	
8	TED-P-101-2 SENSOR AND RP-1 RECORDER- COLD RM-3				14/5/2007	Pass	
9	THE-P-102 SENSOR AND TI-P-102 INDICATOR- FILLING RM				2007/12/5	Pass	
10	THE-P-103 SENSOR AND TI-P-103 INDICATOR- CLEAN RM5				2007/12/5	Pass	
11	THE-P-101 SENSOR AND TI-P-101 INDICATOR- CAPING RM1				2007/12/5	Pass	
12	THE-P-104 SENSOR AND TI-P-104 INDICATOR- VIAL WASHING RM1				2007/12/5	Pass	
13	THE-P-104 SENSOR AND HI-P-104 INDICATOR- VIAL WASHING RM1				2007/12/5	Pass	
14	THE-P-105 SENSOR AND TI-P-105 WASHINH RM3				2007/12/5	Pass	
15	THE-P-102 SENSOR AND HI-P-102 INDICATOR- FILLING RM		Humidity (Thermohygro recorder- TRU- 72U)	$\pm 5.0\%$	2008/12/5	Pass	2
16	THE-P-103 SENSOR AND HI-P-103 INDICATOR- CLEAN RM5				2007/12/5	Pass	
17	THE-P-101 SENSOR AND HI-P-101 INDICATOR- CAPING RM1				2007/12/5	Pass	
18	THE-P-105 SENSOR AND HI-P-105 WASHINH RM3				2007/12/5	Pass	
19	PdIA-P-101 CAPPING RM - CORRIDOR 7		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure $\pm 2.0\text{Pa}$	23/5/2007	Pass	1
20	PdIA-P-102 FILLING RM-CAPPING RM				23/5/2007	Pass	
21	PdIA-P-103 CLEAN RM5-CORRIDOR7				23/5/2007	Pass	
22	PdIA-P-104 IN9-2 - CORRIDOR7				23/5/2007	Pass	
23	PdIA-P-105 FILLING RM - VIAL WASHING RM				23/5/2007	Pass	
24	PdIA-P-106 ANTE RM6 - CORRIDOR7				23/5/2007	Pass	
25	PdIA-P-107 VIAL WASHING RM - CORRIDOR7				23/5/2007	Pass	
26	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2	Bulk and medium depts.	Temperature (Thermohygro recorder- TRU- 72U)	$\pm 0.81^{\circ}\text{C}$	15/5/2007	Pass	2
27	TED-P-103-2 SENSOR AND RP-2 RECORDER - COLD RM-2				15/5/2007	Pass	
28	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1				15/5/2007	Pass	
29	TED-P-104-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-1				15/5/2007	Pass	
30	TED-P-104-2 SENSOR AND TIC-P104-1 INDICATOR - INCUBATION RM-1				15/5/2007	Pass	
31	TED-P-103-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-2				15/5/2007	Pass	
32	TED-P-103-1 SENSOR AND RP-2-1 INDICATOR - INCUBATION RM-2				15/5/2007	Pass	
33	TED-P-103-3 SENSOR AND TIC P103-1 INDICATOR - INCUBATION RM-2				15/5/2007	Pass	
34	THE-P-201 SENSOR AND TI-P-201 THAWING RM				14/5/2007	Pass	
35	THE-P-202 SENSOR AND TI-P-202 CLEAN RM3				14/5/2007	Pass	
36	THE-P-203 SENSOR AND TI-P-203 CLEAN RM4				14/5/2007	Pass	
37	THE-P-206 SENSOR AND TI-P-206 DISINFECTION RM1				15/5/2007	Pass	
38	THE-P-204 SENSOR AND TI-P-204 DISINFECTION RM2				15/5/2007	Pass	
39	THE-P-205 SENSOR AND TI-P-205 WASHING RM1				2007/11/5	Pass	
40	THE-P-207 SENSOR AND TI-P-207 MEDIA PREPARATION RM1.				2007/11/5	Pass	
41	THE-P-209 SENSOR AND TI-P-209 CLEAN RM1.				2007/11/5	Pass	
42	THE-P-210 SENSOR AND TI-P-210 CLEAN RM2.				2007/11/5	Pass	
43	THE-P-208 SENSOR AND TI-P-208 CUTTING RM				2007/11/5	Pass	
44	THE-P-211 SENSOR AND TI-P-211 STERILEFILTRATION RM2				2007/11/5	Pass	
45	THE-P-212 SENSOR AND TI-P-212 OBSERVATION RM2				2007/11/5	Pass	
46	THE-P-201 SENSOR AND HI-P-201 THAWING RM		Humidity (Thermohygro recorder- TRU- 72U)	$\pm 5.0\%$	14/5/2007	Pass	2
47	THE-P-202 SENSOR AND HI-P-202 CLEAN RM3				14/5/2007	Pass	
48	THE-P-203 SENSOR AND HI-P-203 CLEAN RM4				14/5/2007	Pass	
49	THE-P-206 SENSOR AND HI-P-206 DISINFECTION RM1				15/5/2007	Pass	
50	THE-P-204 SENSOR AND HI-P-204 DISINFECTION RM2				15/5/2007	Pass	
51	THE-P-205 SENSOR AND HI-P-205 WASHING RM1				2007/11/5	Pass	
52	THE-P-207 SENSOR AND HI-P-207 MEDIA PREPARATION RM1				2007/11/5	Pass	
53	THE-P-209 SENSOR AND HI-P-209 MEDIA PREPARATION RM1				2007/11/5	Pass	
54	THE-P-210 SENSOR AND HI-P-210 CLEAN RM2				2007/11/5	Pass	
55	THE-P-208 SENSOR AND HI-P-208 CUTTING RM				2007/11/5	Pass	
56	THE-P-211 SENSOR AND HI-P-211 STERILEFILTRATION RM2				2007/11/5	Pass	
57	THE-P-212 SENSOR AND HI-P-212 OBSERVATION RM2				2007/11/5	Pass	

No.	Name of Equipment	Place	Method	Criteria	Date	Pass/ Fail	Frequency
58	PdIA-P-201 THAWING RM - CORRIDOR5	Bulk and medium depts.	Pressure (Difference pressure gauge KAL84 HALSTRUP)	$\pm 2.0\text{Pa}$	22/5/2007	Pass	1
59	PdIA-P-202 CLEAN RM3 - CORRIDOR5				22/5/2007	Pass	
60	PdIA-P-203 CLEAN RM4 - CORRIDOR5				22/5/2007	Pass	
61	PdIA-P-204 ANTE RM4 - CORRIDOR5				22/5/2007	Pass	
62	PdIA-P-205 DISINFECTION RM2 - CORRIDOR5				22/5/2007	Pass	
63	PdIA-P-206 WASHING RM1 - CORRIDOR5				22/5/2007	Pass	
64	PdIA-P-207 DISINFECTION RM1 - CORRIDOR5				22/5/2007	Pass	
65	PdIA-P-208 MEDIA PREPERATION RM - CORRIDOR5				22/5/2007	Pass	
66	PdIA-P-209 CLEAN RM1 - CORRIDOR6				22/5/2007	Pass	
67	PdIA-P-210 CLEAN RM2 - CORRIDOR6				22/5/2007	Pass	
68	PdIA-P-211 CUTTING RM - CORRIDOR6				22/5/2007	Pass	
69	PdIA-P-212 STRELLEFILTRATION RM - CORRIDOR6				22/5/2007	Pass	
70	PdIA-P-213 ANTE RM1 - CORRIDOR6				22/5/2007	Pass	
71	PdIA-P-214 CENTRIFUGATION & OBSERVATION RM1 - CORRIDOR6				22/5/2007	Pass	
72	PdIG-P-203 PR11 - DISINFECTION RM2	QC	Temperature (Thermohygro recorder- TRU-72U)	$\pm 0.81^\circ\text{C}$	22/5/2007	Pass	2
73	PdIG-P-204 PR7 - ANTE RM4				22/5/2007	Pass	
74	PdIG-P-205 PR6 - CORRIDOR3				22/5/2007	Pass	
75	THE-P-215 SENSOR AND TI-P-215 CLEAN RM6				14/5/2007	Pass	
76	THE-P-216 SENSOR AND TI-P-216 CLEAN RM7		Humidity (Thermohygro recorder- TRU-72U)	$\pm 5.0\%$	14/5/2007	Pass	2
77	THE-P-213 SENSOR AND TI-P-213 CLEAN RM8				14/5/2007	Pass	
78	THE-P-214 SENSOR AND TI-P-214 PREPERATION RM				14/5/2007	Pass	
79	THE-P-215 SENSOR AND HI-P-215 CLEAN RM6				14/5/2007	Pass	
80	THE-P-216 SENSOR AND HI-P-216 CLEAN RM7		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure $\pm 2.0\text{Pa}$	14/5/2007	Pass	1
81	THE-P-213 SENSOR AND HI-P-213 CLEAN RM8				14/5/2007	Pass	
82	THE-P-214 SENSOR AND HI-P-214 PREPERATION RM				14/5/2007	Pass	
83	PdIA-P-215 PREPARATION RM - CORRIDOR10				23/5/2007	Pass	
84	PdIA-P-216 CLEAN RM8 - CORRIDOR10		Temperature (Thermohygro recorder- TRU-72U)	Temperature $\pm 0.81^\circ\text{C}$	23/5/2007	Pass	2
85	PdIA-P-217 IN12 - CHANGING RM12				23/5/2007	Pass	
86	PdIA-P-218 CLEAN RM6 - CORRIDOR10				23/5/2007	Pass	
87	PdIA-P-219 CLEAN RM7 - CORRIDOR10				23/5/2007	Pass	
88	PdIG-P-201 OUT 11-2 - PERFORMANCE TEST RM	Animal lab	Humidity (Thermohygro recorder- TRU-72U)	Humidity $\pm 5.0\%$	23/5/2007	Pass	1
89	PdIG-P-202 IN11-2 - CHANGING RM11				23/5/2007	Pass	
90	Rabbit Test		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure $\pm 2.0\text{Pa}$	23/5/2007	Pass	
91	Guinea Pig Test				23/5/2007	Pass	
92	Quarantine Rm1		Temperature (Thermohygro recorder- TRU-72U)	Temperature $\pm 0.81^\circ\text{C}$	23/5/2007	Pass	2
93	Mice Test Rm 1				23/5/2007	Pass	
94	Mice Test Rm 2				23/5/2007	Pass	
95	Quarantine Rm 2				23/5/2007	Pass	
96	Rabbit Test		Humidity (Thermohygro recorder- TRU-72U)	Humidity $\pm 5.0\%$	23/5/2007	Pass	2
97	Guinea Pig Test				23/5/2007	Pass	
98	Quarantine Rm1				23/5/2007	Pass	
99	Mice Test Rm 1				23/5/2007	Pass	
100	Mice Test Rm 2		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different Pressure $\pm 2.0\text{Pa}$	23/5/2007	Pass	1
101	Quarantine Rm 2				23/5/2007	Pass	
102	PdIA_A-101 DIRTY CORRIDOR1 - CORRIDOR1A				23/5/2007	Pass	
103	PdIA_A-102 ANTE RM - CORRIDOR1A				23/5/2007	Pass	
104	PdIA_A-103 DIRTY CORRIDOR2 - CORRIDOR1A				23/5/2007	Pass	

Summary result table of Maintenance validation for HVAC - 2007

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
1	Ante room 6	101-01	Final Dept.	Leak test & Ventilation frequency measureme nt	• Leak test: No clear leakage must be found at any of the measurement locations	23/05/2007	Pass
2		101-02				23/05/2007	Pass
3		101-03				23/05/2007	Pass
4	Clean room 5	101-04				23/05/2007	Pass
5		101-05				23/05/2007	Pass
6		101-06				23/05/2007	Pass
7	Filling room	101-07				23/05/2007	Pass
8		101-08				23/05/2007	Pass
9		101-09				23/05/2007	Pass
10		101-10				23/05/2007	Pass
11		101-11				23/05/2007	Pass
12		101-12				23/05/2007	Pass
13		101-13				23/05/2007	Pass
14		101-14				23/05/2007	Pass
15		101-15				23/05/2007	Pass
16	Al 9-1	101-16			• Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	23/05/2007	Pass
17	Al 9-2	101-17				23/05/2007	Pass
18	In 9-2	101-18				23/05/2007	Pass
19	Al	101-19				23/05/2007	Pass
20	Capping room	102-01				24/05/2007	Pass
21		102-02				24/05/2007	Pass
22		102-03				24/05/2007	Pass
23	Pr 14	102-04				24/05/2007	Pass
24	Washing rm 3	102-05				24/05/2007	Pass
25		102-06				24/05/2007	Pass
26		102-07				24/05/2007	Pass
27		102-08				24/05/2007	Pass
28		102-09				24/05/2007	Pass
29		102-10				24/05/2007	Pass
30	Vial&Sterili rm	102-12				24/05/2007	Pass
31		102-13				24/05/2007	Pass
32		102-14				24/05/2007	Pass
33		102-15				24/05/2007	Pass
34	In Out 10	102-16				24/05/2007	Pass
35	Pr 16	102-17				24/05/2007	Pass
36	Disinfection rm 3	102-18				24/05/2007	Pass
37	Pr 15	102-19				24/05/2007	Pass
38	Corridor 4	201-01	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations	16/05/2007	Pass
39		201-02				16/05/2007	Pass
40		201-03				16/05/2007	Pass
41	Pr 8	201-04				16/05/2007	Pass
42	Freezing rm	201-05				16/05/2007	Pass
43	Thawing	201-06				16/05/2007	Pass
44	Refrigerator rm 2	201-07			• Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	16/05/2007	Pass
45		201-08				16/05/2007	Pass
46	Storage 4	201-09				16/05/2007	Pass
47	In 5	201-10				16/05/2007	Pass
48	Refrigerator rm 2	201-11				16/05/2007	Pass
49	Corridor 3	202-01				17/05/2007	Pass
50		202-02				17/05/2007	Pass
51		202-03				17/05/2007	Pass
52	Clean rm 4	202-04				17/05/2007	Pass
53		202-05				17/05/2007	Pass
54		202-06				17/05/2007	Pass
55		202-07				17/05/2007	Pass
56	Clean rm 3	202-08				17/05/2007	Pass
57		202-09				17/05/2007	Pass
58		202-10				17/05/2007	Pass

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
59	Ante rm 4	202-11	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	17/05/2007	Pass
60		202-12				17/05/2007	Pass
61	Disinfection rm 2	202-13				17/05/2007	Pass
62		202-14				17/05/2007	Pass
63	Storage 3	202-15				17/05/2007	Pass
64	Pr 6	202-16				17/05/2007	Pass
65	Al 6	202-17				17/05/2007	Pass
66	In 6	202-18				17/05/2007	Pass
67	Ante rm 3	202-19				17/05/2007	Pass
68		202-20				17/05/2007	Pass
69	Pr 7	202-21				17/05/2007	Pass
70	Pr 11	202-22				17/05/2007	Pass
71	Corridor 2	203-01				18/05/2007	Pass
72		203-02				18/05/2007	Pass
73		203-03				18/05/2007	Pass
74		203-04				18/05/2007	Pass
75	Centri&Observa	203-05				18/05/2007	Pass
76		203-06				18/05/2007	Pass
77	Storage 2	203-07				18/05/2007	Pass
78	Refrigerator rm 1	203-08				18/05/2007	Pass
79		203-09				18/05/2007	Pass
80		203-10				18/05/2007	Pass
81	Pr 5	203-11				18/05/2007	Pass
82	In 4-2	203-12				18/05/2007	Pass
83	Centri&Observa	203-13				18/05/2007	Pass
84	Clean rm 1	204-01				18/05/2007	Pass
85		204-02				18/05/2007	Pass
86		204-03				18/05/2007	Pass
87		204-04				18/05/2007	Pass
88	Clean rm 2	204-05	Bulk dept.	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	18/05/2007	Pass
89		204-06				18/05/2007	Pass
90		204-07				18/05/2007	Pass
91		204-08				18/05/2007	Pass
92	Ante rm 1	204-09				19/05/2007	Pass
93		204-10				19/05/2007	Pass
94		204-11				19/05/2007	Pass
95		204-12				19/05/2007	Pass
96	Corridor 1	204-13				19/05/2007	Pass
97		204-14				19/05/2007	Pass
98	Storage 1	204-15				19/05/2007	Pass
99	Sterile Filtration	204-16				19/05/2007	Pass
100		204-17				19/05/2007	Pass
101	Cutting rm	204-18				19/05/2007	Pass
102		204-19				19/05/2007	Pass
103	Al 4	204-20				19/05/2007	Pass
104	In 4-1	204-21				19/05/2007	Pass
105	Pr 13	204-22				19/05/2007	Pass
106	Ante rm 2	204-23				19/05/2007	Pass
107	Pr 14	204-24				19/05/2007	Pass
108	Pr 3	204-25				19/05/2007	Pass
109	Pr2	204-26				19/05/2007	Pass
110	Disinfection rm 1	261-01				25/05/2007	Pass
111	In 3-1	261-02				25/05/2007	Pass
112	Media Preparation	262-01				25/05/2007	Pass
113		262-02				25/05/2007	Pass
114	Pr 12	262-03				25/05/2007	Pass
115	In 3-2	262-04				25/05/2007	Pass
116	Check weight	262-05				25/05/2007	Pass
117	Storage 6	212-01				22/05/2007	Pass
118	Storage 5	212-02				22/05/2007	Pass
119	Laundry rm	212-03				22/05/2007	Pass
120		212-04				22/05/2007	Pass

TT	Name of Equip	Code	Place	Method	Criteria	Date	Pass/ Fail
121	Washing rm 1	212-05	Bulk dept.	Leak test & Ventilation frequency measurement		22/05/2007	Pass
122		212-06				22/05/2007	Pass
123		212-07				22/05/2007	Pass
124		212-08				22/05/2007	Pass
125		212-09				22/05/2007	Pass
126	In Out 7	212-10				22/05/2007	Pass
127		212-11				22/05/2007	Pass
128		212-12				22/05/2007	Pass
129		212-13				22/05/2007	Pass
130		212-14				22/05/2007	Pass
131	Washing rm 2	212-15				22/05/2007	Pass
132		212-16				22/05/2007	Pass
133		212-17				22/05/2007	Pass
134	Pr 9	212-18				22/05/2007	Pass
135	Storage 7	212-19				22/05/2007	Pass
136	Pr 1	212-20				22/05/2007	Pass
137	Pr 10	212-21				22/05/2007	Pass
138	Observation Area	208-01	QC	Leak test & Ventilation frequency measurement	• Leak test: No clear leakage must be found at any of the measurement locations • Ventilation frequency measurement: The overall ventilation frequency for a room must be equal to or in excess of 20 times/hour	21/05/2007	Pass
139		208-02				21/05/2007	Pass
140	Refrigerator rm 3	208-03				21/05/2007	Pass
141		208-04				21/05/2007	Pass
142	Clean rm 7	208-05				21/05/2007	Pass
143		208-06				21/05/2007	Pass
144	Incubation rm 2	208-07				21/05/2007	Pass
145	Clean rm 6	208-08				21/05/2007	Pass
146		208-09				21/05/2007	Pass
147	Pr 19	208-10				21/05/2007	Pass
148	Al 11-1	208-11				21/05/2007	Pass
149	In 11-1	208-12				21/05/2007	Pass
150	Clean rm 8	209-01				21/05/2007	Pass
151		209-02				21/05/2007	Pass
152		209-03				21/05/2007	Pass
153	Preparation rm	209-04				21/05/2007	Pass
154		209-05				21/05/2007	Pass
155	Al 12-2	209-06				21/05/2007	Pass
156	Al 12-1	209-07				21/05/2007	Pass
157	In 12	209-08				21/05/2007	Pass
158	Preformance test	211-01				22/05/2007	Pass
159		211-02				22/05/2007	Pass
160	AL 11-2	211-03				22/05/2007	Pass
161	In 11-2	211-04				22/05/2007	Pass
162	Dirty corridor 1	101-01	Nhà d ộng vật			30/05/2007	Pass
163	Quarantine rm 1	101-02				30/05/2007	Pass
164	Material out 1	101-03				30/05/2007	Pass
165	Inocubation rm 1	101-04				30/05/2007	Pass
166	Rabbits test rm	101-05				30/05/2007	Pass
167	Inocubation rm 2	101-06				30/05/2007	Pass
168	Guinea Pigs test rm	101-07				30/05/2007	Pass
169	Clean Corridor 1	101-08				30/05/2007	Pass
170	Ante rm	101-09				30/05/2007	Pass
171	Ante rm	102-01				30/05/2007	Pass
172	Clean orridor 2	102-02				30/05/2007	Pass
173	AutoPsy rm 2	102-03				30/05/2007	Pass
174	Quarantine rm 2	102-04				30/05/2007	Pass
175	Mice Test rm 1	102-05				30/05/2007	Pass
176	Inocubation rm3	102-06				30/05/2007	Pass
177	Mice Test rm 2	102-07				30/05/2007	Pass
178	Inoculation rm 4	102-08				30/05/2007	Pass
179	Dirty corridor 2	102-09				30/05/2007	Pass

Summary Result Table of Calibration for Process Water Supply System 2007

Tân suất chuẩn định hệ thống nước: hàng năm

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
1	SW Heat Exchanger Outlet Temp.	TIRCA-1101	Deionized Water System (1F)	Temperature (Ametek ITC-320A)	Temperature 70°C ± 0.7°C 80°C ± 0.8°C 90°C ± 0.8°C	08/06/07	Pass
2	Soft Water Tank Drain Temp.	TRS-1181		Temperature (Ametek ITC-320A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	08/06/07	Pass
3	Row Temp.	TRS-1201		Temperature (Ametek ITC-320A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	08/06/07	Pass
4	UFW Heater Outlet Temp.	TIRCA-3102	UFW Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	08/06/07	Pass
5	UFW Heater Inlet Temp.	TRS-3101		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
6	UFW Feed Tank Return Temp.	TRS-3103		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
7	UFW Tank Temp.	TRS-4101	UFW Generation (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
8	UFW Return Temp.	TRS-4102		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
9	VF-4102 SIP	TRS-4181		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
10	P-4101 SIP	TRS-4182		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
11	UFW Return SIP Temp.	TRS-4183		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
12	P-4102 Temp.	TRS-4184		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
13	UFW-① SIP Temp.	TRSU-181	Freeze Drying Room (Use Point) (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
14	UFW-② SIP Temp.-1	TRSU-281	Washing Room 3 (Use Point) (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
15	UFW-② SIP Temp.-2	TRSU-282		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
16	UFW-③ SIP Temp.-1	TRSU-381	Washing Room 2 (Use Point) (2F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
17	UFW-③ SIP Temp.-2	TRSU-382		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
18	UFW-④ SIP Temp.	TRSU-481	Disinfection Room 2 (2F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
19	UFW-⑤ SIP Temp.	TRSU-581	Disinfection Room 3 (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	08/06/07	Pass
20	Condenser Outlet Temp.	TIRCA-6101	WFI Generation (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	08/06/07	Pass
21	WFI Cooler Outlet Temp.	TRA-6102		Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.6°C 120°C ± 0.6°C 130°C ± 0.9°C	08/06/07	Pass
22	WFI Heater Outlet Temp.	TIRCA-7103	WFI Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	08/06/07	Pass

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
23	WFI Tank Temp.	TRS-7101	WFI Distribution System (1F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
24	WFI Return Temp.	TRS-7102		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
25	WFI Generation Outlet SIP Temp.	TRS-7181		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
26	P-7101 SIP Temp.	TRS-7182		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
27	WFI Return SIP Temp.	TRS-7183		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
28	HE -7101 Outlet SIP Temp.	TRS-7184		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
29	VF-7101 SIP Temp.	TRS-7185		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
30	WFI-① SIP Temp	TRS-W181	Vial Washing & Sterilization Rm (1F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
31	LC-WFI2 SIP Temp.-1	TRS-W281	Washing Room 3 (1F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
32	LC-WFI2 SIP Temp.-2	TRS-W282		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
33	LC-WFI3 SIP Temp.-1	TRS-W381		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
34	LC-WFI3 SIP Temp.-2	TRS-W382		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
35	LC-WFI2 SIP Temp.-3	TRS-284	Filling Room (1F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
36	LC-WFI4 SIP Temp.-1	TRS-W481	Media Preparation Room (2F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
37	LC-WFI4 SIP Temp.-2	TRS-W482		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
38	WFI-⑤ SIP Temp	TRS-W581	Laundry Room (2F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
39	LC-WFI6 SIP Temp.-1	TRS-W681	Washing Room 1 (2F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
40	LC-WFI6 SIP Temp.-2	TRS-W682		Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
41	UFW&WFI SIP Temp.	TRS-5101	PS Unit (1F)	Temperature (Ametek ITC-320A)	Temperature $110^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $120^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$ $130^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$	08/06/07	Pass
42	UFW Return Pressure	PICA-4101	UFW Generation	Pressure (Ametek CPC200C)	Pressure $0.00\text{MPa} \pm 0.01\text{MPa}$ $0.25\text{MPa} +$	08/06/07	Pass
43	Pure Steam Pressure	PICA-5101	PS Unit	Pressure (Ametek CPC200C)	Pressure $0.00\text{MPa} \pm 0.01\text{MPa}$ $0.25\text{MPa} +$	08/06/07	Pass
44	Pure Steam Pressure	PICA-6101	WFI Generation	Pressure Cal equip.	Pressure $0.00\text{MPa} \pm 0.01\text{MPa}$ $0.25\text{MPa} +$	08/06/07	Pass
45	WFI Return Pressure	PICA-7101	WFI Distribution System	Pressure (Ametek CPC200C)	Pressure $0.00\text{MPa} \pm 0.01\text{MPa}$ $0.25\text{MPa} +$	08/06/07	Pass

POLYVAC

Summary Result Table of Maintenance Validation for Equipment 2007

Tần suất bảo dưỡng thiết bị: hàng năm

No	Name of Equipment	Code No	Place	Method	Criteria	Date	Pass/ Fail
1	Vial Sterilizing Machine	BE-03691	Final	Temperature & Air Velocity	• Check of air velocity in the tunnel. The result of each zone is: 80% is average $\pm 20\%$ 100% is average $\pm 30\%$ • Implement at Infeed zone. Number of 0.3 μm particles are less than 0.01% compared with upper stream. • Implement at cooling zone. Number of 0.3 μm particles are less than 0.01% compared with upper stream. • Room classification in depyrogenation tunnel. Must be satisfying class 5(DIN EN ISO 14644-1) 0.5 μm = 100, no 5.0 μm • Measuring vial temperature contain size: $\varnothing 24.0 \pm 0.2\text{mm} \times 45 \pm 0.5\text{mm}$ vial. Temperature of the container more than 300°C at a moment. Temperature of exit is less than 25°C (measure 1 time)	29 May 2007	Pass
2	Clean Bench B	G264920501	QC			09 June 2007	Pass
3	Clean Bench B	G264930501	QC			09 June 2007	Pass
4	Clean Bench B	G264930502	QC			09 June 2007	Pass
5	Clean Bench A	G264940501	QC			09 June 2007	Pass
6	Clean Bench C	G264910501	Bulk			09 June 2007	Pass
7	Clean Bench D	G264890501	Bulk			09 June 2007	Pass
8	Clean Bench E	G264880502	Bulk			09 June 2007	Pass
9	Clean Bench D	G264890502	Bulk			09 June 2007	Pass
10	Clean Bench D	G264890503	Bulk			09 June 2007	Pass
11	Clean Bench B	G264930503	Bulk			09 June 2007	Pass
12	Clean Bench E	G264870501	Bulk			09 June 2007	Pass
13	Clean Bench F	G264960501	Bulk			09 June 2007	Pass
14	Clean Bench E	G264880501	Medium			09 June 2007	Pass
15	Clean Bench A	G264900501	Medium			09 June 2007	Pass
16	Clean Bench C	G264950501	Final			09 June 2007	Pass
17	Clean Bench E	G264970501	Final			09 June 2007	Pass
18	Laminar Flow Unit	G242550501	Final			09 June 2007	Pass
19	Laminar Flow Unit	G242560501	Final			09 June 2007	Pass
20	Laminar Flow Unit	G242570501	Final			09 June 2007	Pass
21	Laminar Flow Unit	G242580501	Medium			09 June 2007	Pass
22	Laminar Flow Unit	G242590501	Bulk			09 June 2007	Pass
23	Laminar Flow Unit B	5114-01277-CB100	QC - Chemical	Filter Leakage & Air Velocity, Air Volume	• Air velocity and Air Volume The average air velocity shall be within $\pm 20\%$ of specification (0.3m/sec). The air volume shall be within $\pm 20\%$ of specification. • Filter Leakage The downstream concentration must not exceed 0.03% of the upstream concentration, continuously.	09 June 2007	Pass

Summary Result Table of Calibration for Equipment -2007

No.	Dept.	Name of Equip.	Items		Frequency	CAL point	Calibrator	Date	Pass/ Fail
			sensor name	code					
1	QC	Autoclave B	chamber temp. sensor	TE1-1	1	111, 121, 131(°C)	AMETEK ITC-320A	16/01/2007	Pass
			chamber temp. sensor CH 1-	TE1-2		111, 121, 131(°C)			
			Jacket temp. sensor	TE2	3	111, 121, 131(°C)			
			chamber temp. sensor	TE3-1	1	111, 121, 131(°C)			
			chamber temp. sensor CH.2	TE3-2		111, 121, 131(°C)			
			Filter drain temp. sensor	TE4-1	1	111, 121, 131(°C)			
			Filter drain temp. sensor CH3-	TE4-2		111, 121, 131(°C)			
			chamber temp. sensor	TE5-1	1	111, 121, 131(°C)			
			chamber temp. sensor CH4 -	TE5-2		111, 121, 131(°C)			
			chamber temp. sensor CH5 -	TE 6	1	111, 121, 131(°C)			
			chamber temp. sensor CH6 -	TE 7	1	111, 121, 131(°C)			
			chamber pressure sensor	PE - 1-1	1	0,100,200,300,-90(kPa)	AMETEK CPC200C	17/01/2007	
			chamber pressure sensor CH 12 - Recorder	PE - 1-2		0,100,200,300,-90(kPa)			
			chamber pressure sensor	PI1	2	0.4,0.3,0.2,0.1,-0.08(Mpa)			
chamber pressure sensor	PI2	2	0.4,0.3,0.2,0.1,-0.08(Mpa)						
Jacket pressure sensor	PI3	3	0.4,0.3,0.2,0.1,-0.08(Mpa)						
2	QC	Incubator A	No.1 Temp. Sensor	TE1-1	3	40,30,20(°C)	AMETEK ITC-155A	19/01/2007	Pass
			No.2 Temp. Sensor	TE2-1	3	40,30,20(°C)			
			No.3 Temp. Sensor	TE3-1	3	50,40,30(°C)			
3	QC	Incubator B	Temp. sensor	TE1	3	40,30,20(°C)	AMETEK ITC-155A	18/01/2007	Pass
4	QC	Incubator C	No.1 Temp. Sensor	TE1-1	3	60,40,30,25(°C)	AMETEK ITC-155A	17/01/2007	Pass
			No.2 Temp. Sensor	TE2-1	3	60,40,30,25(°C)			
			No.3 Temp. Sensor	TE3-1	3	70,60,50(°C)			
5	QC	Incubator D	Temp. sensor	TE1	3	40,30,25(°C)	AMETEK ITC-155A	16/01/2007	Pass
			Temp. sensor	TE2	3	40,30,25(°C)			
			Temp. sensor	TE3	3	40,30,25(°C)			
6	QC	Recorder of Incubator A	CH.1 Temp. Sensor - Recorder	TE1-1	1	40,30,20(°C)	AMETEK ITC-155A	18/01/2007	Pass
			CH.2 Temp. Sensor - Recorder	TE2-1	1	40,30,20(°C)			
			CH.3 Temp. Sensor - Recorder	TE3-1	1	50,40,30(°C)			
7	QC	Recorder of Incubator B, C	CH.1 Temp. Sensor - Recorder	TE1	1	40,30,20(°C)	AMETEK ITC-155A	19/01/2007	Pass
			CH.4 Temp. Sensor - Recorder	TE2	1	40,30,20(°C)			
			CH.5 Temp. Sensor - Recorder	TE3	1	50,40,30(°C)			
8	QC	Vacuum dry oven	CH.6 Temp. Sensor - Recorder	TE4	1	50,40,30(°C)	AMETEK ITC-155A	24/01/2007	Pass
			Temp. sensor	TE1	1	100,75,50(°C)			
9	QC	CO ₂ Incubator A	Temperature- Recorder	TE1	1	30,40,50(°C)	AMETEK ITC-155A	08/06/07	Pass
			Temperature	TE2	3	30,40,50(°C)			
			CO ₂	COE1	1	3,5,7(%)	FYRITE BACHARAC H GAS ANALIZER		
10	QC	CO ₂ Incubator B	Temperature - Recorder	TE1	1	30,40,50(°C)	AMETEK ITC-155A	08/06/07	Pass
			Temperature	TE2	3	30,40,50(°C)			
			CO ₂	COE1	1	3,5,7(%)	FYRITE BACHARAC H GAS ANALIZER		
11	QC	CO ₂ Incubator C	Temperature - Recorder	TE1	1	30,40,50(°C)	AMETEK ITC-155A	08/06/07	Pass
			Temperature	TE2	3	30,40,50(°C)			
			CO ₂	COE1	1	3,5,7(%)	FYRITE BACHARAC H GAS ANALIZER		
12	QC	Egg Incubator	Temperature- Recorder	TE1	1	30,40,50(°C)	AMETEK ITC-155A	08/06/07	Pass
			Temperature	TE2	3	30,40,50(°C)			
13	QC	Lab. Autoclave for Chemical	Temperature - Recorder	TE1	1	110,120,130(°C)	AMETEK ITC-320A	08/06/07	Pass
			Temperature	TE2	2	110,120,130(°C)			
			Pressure- Recorder	PG1	1	0.1, 0.12, 0.14(Mpa)	AMETEK CPC200C		
14	QC	Lab. Autoclave for Bio.	Temperature - Recorder	TE1	1	110,120,130(°C)	AMETEK ITC-320A	08/06/07	Pass
			Temperature	TE2	2	110,120,130(°C)			
			Pressure- Recorder	PG1	1	0.1, 0.12, 0.14(Mpa)	AMETEK CPC200C		
15	QC	Dry Oven	Temperature - Recorder	TE1-1	1	100,125,250(°C)	AMETEK ITC-320A	08/06/07	Pass
			Temperature	TE1-2		100,125,250(°C)			
			Temperature - Recorder	TE2-1	1	100,125,250(°C)			
			Temperature	TE2-2		100,125,250(°C)			
			Temperature - Recorder	TE3-1	1	100,125,250(°C)			
			Temperature	TE3-2		100,125,250(°C)			
			Pressure- Recorder	PE1-1	1	0,150,300(Pa)	AMETEK CPC 200C		
			Pressure	PE1-2		0,150,300(Pa)			
			Pressure-Recorder	PE2-1	1	0,150,300(Pa)	AMETEK CPC 200C		
			Pressure	PE2-2		0,150,300(Pa)			
			Pressure	PE2-3		0,150,300(Pa)			

No.	Dept.	Name of Equip.	Items		Frequency	CAL point	Calibrator	Date	Pass/ Fail						
			sensor name	code											
16	QC	Freezer : -30°C Q'ty: 4	Temperature - Recorder	TE1-1	1	-30(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass						
			Temperature	TE1-2	3	-30(oC)									
			Temperature - Recorder	TE2-1	1	-30(oC)									
			Temperature	TE2-2	3	-30(oC)									
			Temperature - Recorder	TE3-1	1	-30(oC)									
			Temperature	TE3-2	3	-30(oC)									
			Temperature - Recorder	TE4-1	1	-30(oC)									
17	QC	Freezer : -70°C Q'ty: 4	Temperature	TE4-2	3	-30(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass						
			Temperature - Recorder	TE1-1	1	-70(oC)									
			Temperature	TE1-2	3	-70(oC)									
			Temperature - Recorder	TE2-1	1	-70(oC)									
			Temperature	TE2-2	3	-70(oC)									
			Temperature - Recorder	TE3-1	1	-70(oC)									
			Temperature	TE3-2	3	-70(oC)									
18	QC	Refrigerator : 5°C Q'ty: 2	Temperature - Recorder	TE4-1	1	-70(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass						
			Temperature	TE4-2	3	-70(oC)									
			Temperature - Recorder	TE1-1	1	5(oC)									
			Temperature	TE1-2	3	5(oC)									
19	BP	Autoclave A-2	Temperature - Recorder	TE2-1	1	5(oC)	AMETEK ITC-320A	25/01/2007	Pass						
			Temperature	TE2-2	3	5(oC)									
			chamber temp. sensor	TE1-1	1	111, 121, 131(°C)									
			chamber temp. sensor CH 1-	TE1-2	3	111, 121, 131(oC)									
			Jacket temp. sensor	TE2	3	111, 121, 131(oC)									
			chamber temp. sensor	TE3-1	1	111, 121, 131(oC)									
			chamber temp. sensor CH2-	TE3-2	1	111, 121, 131(oC)									
			Filter drain temp. sensor	TE4-1	1	111, 121, 131(oC)									
			Filter drain temp. sensor CH3-	TE4-2	1	111, 121, 131(oC)									
			chamber temp. sensor	TE5-1	1	111, 121, 131(oC)									
			chamber temp. sensor CH4 -	TE5-2	1	111, 121, 131(oC)									
			chamber temp. sensor CH5 -	TE 6	1	111, 121, 131(oC)									
			chamber temp. sensor CH6 -	TE 7	1	111, 121, 131(oC)									
			chamber pressure sensor	PE - 1-1	1	0,100,200,300,-90(kPa)									
			chamber pressure sensor CH 12 - Recorder	PE - 1-2	1	0,100,200,300,-90(kPa)									
			20	Medium	Autoclave A-3	chamber pressure sensor				PI 1	2	0.4,0.3,0.2,0.1,-0.08(Mpa)	AMETEK CPC200C	24/01/2007	
chamber pressure sensor	PI 2	2				0.4,0.3,0.2,0.1,-0.08(Mpa)									
Jacket pressure sensor	PI 3	3				0.4,0.3,0.2,0.1,-0.08(Mpa)									
chamber temp. sensor	TE1-1	1				111, 121, 131(°C)									
chamber temp. sensor CH 1-	TE1-2	3				111, 121, 131(oC)									
Jacket temp. sensor	TE2	3				111, 121, 131(oC)									
chamber temp. sensor	TE3-1	1				111, 121, 131(oC)									
chamber temp. sensor CH2-	TE3-2	1				111, 121, 131(oC)									
Filter drain temp. sensor	TE4-1	1				111, 121, 131(oC)									
Filter drain temp. sensor CH3-	TE4-2	1				111, 121, 131(oC)									
chamber temp. sensor	TE5-1	1				111, 121, 131(oC)									
chamber temp. sensor CH4 -	TE5-2	1				111, 121, 131(oC)									
chamber temp. sensor CH5 -	TE 6	1				111, 121, 131(oC)									
chamber temp. sensor CH6 -	TE 7	1				111, 121, 131(oC)									
chamber pressure sensor	PE - 1-1	1				0,100,200,300,-90(kPa)									
21	BP	Egg Incubator				chamber pressure sensor CH 12 - Recorder	PE - 1-2	1	0,100,200,300,-90(kPa)	AMETEK CPC200C	31/01/2007	Pass			
			chamber pressure sensor	PI 1	2	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			chamber pressure sensor	PI 2	2	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			Jacket pressure sensor	PI 3	3	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			Temperature - Recorder	TE1	1	30,40,50(oC)									
			Temperature	TE2	3	30,40,50(oC)									
			Humidity- Recorder	HE1	1	70(%)									
			Temperature	TE1	3	10,15,20 (oC)									
			Temperature - Recorder	TE2	1	10,15,20 (oC)									
			Temperature - Recorder	TE1-1	1	100,125,250(oC)									
			Temperature	TE1-2	1	100,125,250(oC)									
			Temperature - Recorder	TE2-1	1	100,125,250(oC)									
			Temperature	TE2-2	1	100,125,250(oC)									
			Temperature - Recorder	TE3-1	1	100,125,250(oC)									
			Temperature	TE3-2	1	100,125,250(oC)									
			22	BP	Incubator for egg stock	Pressure- Recorder	PE1-1	1	0,150,300(Pa)				AMETEK ITC-320A	08/06/07	Pass
Pressure	PE1-2	1				0,150,300(Pa)									
Pressure-Recorder	PE2-1	1				0,150,300(Pa)									
Pressure	PE2-2	1				0,150,300(Pa)									
Pressure	PE2-3	1				0,150,300(Pa)									
Temperature - Recorder	TE1-1	1				-30(oC)									
Temperature	TE1-2	3				-30(oC)									
Temperature - Recorder	TE2-1	1				-30(oC)									
Temperature	TE2-2	3				-30(oC)									
Temperature - Recorder	TE3-1	1				-30(oC)									
Temperature	TE3-2	3				-30(oC)									
Temperature - Recorder	TE4-1	1				-30(oC)									
Temperature	TE4-2	3				-30(oC)									
23	BP	Dry Oven				Temperature - Recorder	TE1-1	1	-30(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass			
						Temperature	TE1-2	3	-30(oC)						
						Temperature - Recorder	TE2-1	1	-30(oC)						
			Temperature	TE2-2	3	-30(oC)									
			Temperature - Recorder	TE3-1	1	-30(oC)									
			Temperature	TE3-2	3	-30(oC)									
			Temperature - Recorder	TE4-1	1	-30(oC)									
			Temperature	TE4-2	3	-30(oC)									
			Temperature - Recorder	TE1-1	1	-30(oC)									
			Temperature	TE1-2	3	-30(oC)									
			Temperature - Recorder	TE2-1	1	-30(oC)									
			Temperature	TE2-2	3	-30(oC)									
			Temperature - Recorder	TE3-1	1	-30(oC)									
			Temperature	TE3-2	3	-30(oC)									
			Temperature - Recorder	TE4-1	1	-30(oC)									
			Temperature	TE4-2	3	-30(oC)									

No.	Dept.	Name of Equip.	Items		Frequency	CAL point	Calibrator	Date	Pass/ Fail						
			sensor name	code											
25	BP	Freezer:-70°C Qty: 4	Temperature - Recorder	TE1-1	1	-70(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass						
			Temperature	TE1-2	3	-70(oC)									
			Temperature - Recorder	TE2-1	1	-70(oC)									
			Temperature	TE2-2	3	-70(oC)									
			Temperature - Recorder	TE3-1	1	-70(oC)									
			Temperature	TE3-2	3	-70(oC)									
			Temperature - Recorder	TE4-1	1	-70(oC)									
26	BP	Freezer:-70°C Qty: 4	Temperature	TE4-2	3	-70(oC)	HYBRID RECORDER & SENSOR T 1	08/06/07	Pass						
			Temperature - Recorder	TE1-1	1	-70(oC)									
			Temperature	TE1-2	3	-70(oC)									
			Temperature - Recorder	TE2-1	1	-70(oC)									
			Temperature	TE2-2	3	-70(oC)									
			Temperature - Recorder	TE3-1	1	-70(oC)									
			Temperature	TE3-2	3	-70(oC)									
30	Medium	Dry Oven	Temperature - Recorder	TE4-1	1	-70(oC)	AMETEK ITC-320A	08/06/07	Pass						
			Temperature	TE4-2	3	-70(oC)									
			Temperature- Recorder	TE1-1	1	100,125,250(oC)									
			Temperature	TE1-2	1	100,125,250(oC)									
			Temperature- Recorder	TE2-1	1	100,125,250(oC)									
			Temperature	TE2-2	1	100,125,250(oC)									
			Temperature- Recorder	TE3-1	1	100,125,250(oC)									
			Temperature	TE3-2	1	100,125,250(oC)									
			Pressure- Recorder	PE1-1	1	0,150,300(Pa)									
			Pressure	PE1-2	1	0,150,300(Pa)									
31	FP	Vial washing machine	Pressure-Recorder	PE2-1	1	0,150,300(Pa)	AMETEK CPC 200C	19/01/2007	Pass						
			Pressure	PE2-2	1	0,150,300(Pa)									
			Pressure	PE2-3	1	0,150,300(Pa)									
			Temp. sensor	B210	1	40,60,100(oC)									
			Pressure sensor	PIA 110	1	950,500,0(kPa)									
32	FP	Vial Sterilizing machine	WFI pressure sensor	PIA 120	1	950,500,0(kPa)	AMETEK CPC200C	02/01/07	Pass						
			Entrance shower pressure sensor	PIA 121	1	250,125,0(kPa)									
			Pressure sensor	PIA 130	1	950,500,0(kPa)									
			Temp. sensor	TE 211	1	250,300,350(oC)									
33	FP	Autoclave A-1	Temp. sensor	TE 213	1	250,300,350(oC)	AMETEK ITC-650A	31/01/2007	Pass						
			chamber temp. sensor	TE1-1	1	111, 121, 131(°C)									
			chamber temp. sensor CH 1-	TE1-2	1	111, 121, 131(oC)									
			Jacket temp. sensor	TE2	3	111, 121, 131(oC)									
			chamber temp. sensor	TE3-1	1	111, 121, 131(oC)									
			chamber temp. sensor CH.2-	TE3-2	1	111, 121, 131(oC)									
			Filter drain temp. sensor	TE4-1	1	111, 121, 131(oC)									
			Filter drain temp. sensor CH3-	TE4-2	1	111, 121, 131(oC)									
			chamber temp. sensor	TE5-1	1	111, 121, 131(oC)									
			chamber temp. sensor CH4 -	TE5-2	1	111, 121, 131(oC)									
			chamber temp. sensor CH5 -	TE 6	1	111, 121, 131(oC)									
			chamber temp. sensor CH6 -	TE 7	1	111, 121, 131(oC)									
			chamber pressure sensor	PE - 1-1	1	0,100,200,300,-90(kPa)									
			chamber pressure sensor CH 12- Recorder	PE - 1-2	1	0,100,200,300,-90(kPa)									
			chamber pressure sensor	PI 1	2	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			chamber pressure sensor	PI 2	2	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			Jacket pressure sensor	PI 3	3	0.4,0.3,0.2,0.1,-0.08(Mpa)									
			33	FP	Freeze dryer	Self temp sensor N1-Recorder				TE101	1	120,20,0(oC)	AMETEK ITC-155A	23/01/2007	Pass
						Self temp sensor N2 -Recorder				TE102	1	120,20,0(oC)			
						Self temp sensor N3-Recorder				TE103	1	120,20,0(oC)			
						Self temp sensor N4-Recorder				TE104	1	120,20,0(oC)			
						Self temp sensor N5-Recorder				TE105	1	120,20,0(oC)			
						Self temp sensor N6-Recorder				TE106	1	120,20,0(oC)			
Self temp sensor N7-Recorder	TE107	1				120,20,0(oC)									
Self temp sensor N8-Recorder	TE108	1				120,20,0(oC)									
Self temp sensor N9-Recorder	TE109	1				120,20,0(oC)									
Self temp sensor N10-Recorder	TE110	1				120,20,0(oC)									
Self temp sensor N11-Recorder	TE111	1				120,20,0(oC)									
Self temp sensor N12-Recorder	TE112	1				120,20,0(oC)									
Self temp sensor N13-Recorder	TE113	1				120,20,0(oC)									
Temp. sensor-Recorder	TE201	1				30,20,0(oC)									
Temp. sensor-Recorder	TE201A	1				30,20,0(oC)									
Temp. sensor-Recorder	TE202	1				30,20,0(oC)									
Temp. sensor-Recorder	TE203	1				30,20,0(oC)									
Temp. sensor-Recorder	TE204	1				30,20,0(oC)									
Temp. sensor-Recorder	TE205	1				30,20,0(oC)									
Temp. sensor-Recorder	TE212	1				130,120,110(oC)									
Temp. sensor-Recorder	TE212A	1				130,120,110(oC)									
Temp. sensor-Recorder	TE213	1				130,120,110(oC)									
Temp. sensor-Recorder	TE213A	1				130,120,110(oC)									
Temp. sensor-Recorder	TE214	1	130,120,110(oC)												
Temp. sensor-Recorder	TE214A	1	130,120,110(oC)												
			Pressure sensor	PT101	2	21,30,57(□Bar)	MT220	20/01/2007							
			Pressure sensor	PT105	2	21,30,57(□Bar)									
			Pressure sensor	PT203	2	21,30,57(□Bar)									
			Pressure sensor	PT301	2	21,30,57(□Bar)									

POLYVAC**Result of Annalytical method transfer validation of QC 2007**

No.	Name of Method	Protocol No.	Result
1	Mycoplasma test for Measle vaccine	M02-TV-02	Pass
2	Potency test for Measles vaccine by PFU method	M02-TV-06	Pass
3	Identity test for final product	M02-TV-07	Pass
4	Sterility test for final product	M02-TV-08	Pass
5	Test for stability of final product	M02-TV-09	Pass
6	General safety test on animals	M02-TV-10	Pass
7	Potency test for Measles Bulk by PFU method	M02-TV-14	Pass
8	Potency test for Measles Final Bulk by PFU method	M02-TV-15	Pass
9	Mycoplasma test for measles Bulk	M02-TV-16	Pass
10	Sterility test for measles Bulk	M02-TV-19	Pass
11	Sterility test for measles final bulk	M02-TV-21	Pass
12	Innocation test into chicken allantoic memberance	M02-TV-25	Pass
13	Test for none disolved foreign body in vaccine	M02-TV-26	Pass
14	pH test for measles vaccine	M02-TV-27	Pass
15	Osmosis test for vaccine	M02-TV-28	Pass
16	Innocation test into chicken Yolk sac	M02-TV-29	Pass
17	Particle counter test for vaccine	M02-TV-31	Pass
18	Residual moisture content test for measles vaccine	M02-TV-32	Pass
19	Test for weight deviation for vaccine	M02-TV-33	Pass
20	BSA test	M02-TV-35	Pass

POLYVAC

Summary of validation and revalidation for equipment in 2008

Dept.	PQ validation	Content	Summary of condition for implementation (PQ)	Times of implementation	Accepted criteria	Evaluation
Bulk	Autoclave A2 (Cell area)	Sterilization effect	Loading pattern 1, implement for Trypsination, Loading Pattern 4	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
	Autoclave A3 (virus area)	Sterilization effect	Loading pattern 2,3	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
	Dry oven (Loading 1,2,3)	Sterilization effect	Loading pattern 1,2,3	1	BI:(-). temperature and time: $\geq 190^{\circ}\text{C}, \geq 30\text{minutes}$. $F_0 \geq 12$	Pass
Final Product	Autoclave A-1 (loading pattern 01,02)	Sterilization effect	Loading 1,2	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
		Sterilization effect				Pass
	Revalidation of rubber sterilization by autoclave	Sterilization effect	Sterilize rubber according to condition and sampling (stated in Protocol)	1	Remaining water (of rubber stopper for freeze dried vaccine) $\leq 0.30\%$ Remaining water (of rubber stopper used for WFI) $\leq 0.50\%$	Pass
	Revalidation of vial washing machine	Sterilization effect	Vials used Measles Vaccine production which are washed and tested by implement as during OQ.	1	Quantity of dirty particle after washing: Size is more than $10\mu\text{m}$: $< 6000\text{particle/lvial}$ Size is more than $25\mu\text{m}$: $< 600\text{hat/lvial}$	Pass
	Validation of autoclave A1 (loading pattern 05,06)	Sterilization effect	loading pattern 5,6	3	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
QC	Revalidation of dry oven (Dry oven)	Sterilization effect	As regulation in SOP	1	BI (-), temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
	Revalidation of autoclave D (Autoclave D)	Sterilization effect	Loading Pattern 1	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
	Revalidation of autoclave B (Autoclave B)	Sterilization effect	As regulation in SOP	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
Medium	Autoclave A2 (sterilize implement - Loading Pattern 4)	Sterilization effect	Loading Pattern 4	3	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass

Summary of validation and revalidation of implementation procedure in 2008

Dept.	PQ validation	Implementation content	Summary of implementation content (PQ)	Times of implementation	Accepted criteria	Evaluation
Bulk	Revalidation of sterilization of room by formaline fumigation	Sterilization effect	Grade:B,C	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass
	Revalidation of transportation of material and implement	Validate procedure in SOP	(Rout) NC→D, D→C, C→B	1	Microorganism (Contact Plate)	Pass
	Revalidation of change	Confirm changing activities of trained staffs	06 people	1	Microorganism (Contact Plate)	Pass
	Operate in-whole process of Measles bulk	Confirm who process before starting Measles vaccine production.	100-140 eggs, 130-160 roux	3	Meet criteria stated in SOP	Pass
	Inactivation of Measles vaccine by NaClO	Effect of virus of NaClO	Javen 12% with 100-200 times of dilution, temperature $< 30^{\circ}\text{C}$, 1h, 2h, 3h, 4h	3	Remaining virus after checking ≤ 0.20 log /0,5 ml	Pass
	Validation of egg sterilization	Sterilization effect	Benzalkonium 0,1% Iod alcohol 3% alcohol 70% (2 times)	3	Benzalkonium 0,1% : quantity of forming unit/leg < 15 Iod alcohol 3% : Quantity of forming unit/leg < 10 Alcohol 70% (2 times) : number of forming unit/leg ≤ 1	Pass
	Validate stability of Measles vaccine during thawing of bulk	Confirm thawing to be done strictly before production	01 tank 08 litre of measles bulk with two times of thawing	3	After thawing, titration is not different and is not different with titration with titration before thawing ≤ 0.31 g PFU/0,5ml	Pass
	Validate washing procedure and dry production implement	Effect of cleaning washing implement by hand	Validate implements which are subjects of procedure: - Trypsinization procedure - Inoculation procedure - Hank's washing procedure and replace medium the second time - Pooling and filtration procedure Washing method: According to SOP	3	There is no dirty on the surface of implement Implement is dried completely	Pass
	Confirm stability of temperature in Roux cultured in incubation room 1 (incubation room 2) during power-off	Confirm whether it effects to temperature in Roux for culture in incubator or not?	Incubator 1: Culture 140 Roux (containing 190ml WFI) at 32°C Incubation room 2: Culture 170 Roux (containing 190ml WFI) at 32°C	3	Temperature in roux is in $32^{\circ}\text{C} \pm 1$	Pass

Summary of validation and revalidation of implementation procedure in 2008

Dept.	PQ validation	Implementation content	Summary of implementation content (PQ)	Times of implementation	Accepted criteria	Evaluation
Final product	Revalidate sterilization of room by formaline fumigation	Sterilization effect	1500ppm; 12 hours	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass
	Revalidate transportation of material and implement	Validate procedure in SOP	(Route) NC $\rightarrow$ D, D $\rightarrow$ B, B $\rightarrow$ A	1	Contact Plate	Pass
	Revalidation of changing	Confirm changing of trained staffs	06 persons	1	Contact Plate	Pass
	Revalidate vial sterilization of sterilization cellar	Sterilization effect	Biological challenge Endotoxin 600EU/lq	1	Temperature $\geq 300^{\circ}\text{C}$ Sterilization effect ≥ 3 log	Pass
	Revalidate rubber stopper sterilization by autoclave	Drying effect	Sterilize rubber stopper according to condition and sampling (state in Protocol)	1	Remaining water (of rubber stopper for freeze dried vaccine) $\leq 0.30\%$ Remaining water (of rubber stopper used for WFI) $\leq 0.50\%$	Pass
	Revalidate procedure of washing implement in Measles vaccine	Sterilization effect	As regulated in SOP	1	TOC concentration ≤ 500 ppb	Pass
	Revalidate CIP at freeze drying chamber	Sterilization effect			Result of TOC concentration of clothe sample after CIP and there is no odd in control sample	Pass
QC	Revalidate changing procedure	Confirm changing of trained staffs	03 persons	1	Contact Plate	Pass
	Effect of Formalin fumigation of QC area	Sterilization effect	Grade B, C area	1	BI: Decrease ≥ 3 log Remaining Formaline concentration ≤ 0.1 ppm	Pass
Medium	Revalidate the second time of changing to enter grade C	Give out revalidation for changing of staffs in grade C area	Grade C area	1	Contact Plate	Pass
	Revalidate transportation procedure of implement	Verify transportation procedure of sterilized implement into production area	(Route) NC $\rightarrow$ D, D $\rightarrow$ C, C $\rightarrow$ B	1	Contact Plate	Pass
	Revalidate washing procedure of implement for medium production	Confirm effect of washing procedure	As regulated in SOP	1	TOC concentration ≤ 500 ppb	Pass
	Revalidate procedure of Formalin fumigation of medium production area	Sterilization effect	1500ppm; 10-12 hours	1	BI: Decrease ≥ 3 log Remaining Formaline concentration ≤ 0.1 ppm	Pass

Result of calibration of HVAC system in 2008

Updated on: 04/09/2008

No.	Name of equipment	Dept.	Validation method of equipment	Criteria	Date of implementation	Pass/not pass	CAL frequency (year)	Expired date
1	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2	Final Production	Temperature (Thermohygro recorder-TRU-72U)	Different temperature $\pm 0.81^{\circ}\text{C}$	14/03/2008	Pass	1	14/03/2009
2	TED-P-101-3 SENSOR AND RP-1-4 RECORDER - FREEZER RM-2				14/03/2008			14/03/2009
3	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1				14/03/2008			14/03/2009
4	TED-P-101-2 SENSOR AND RP-1 RECORDER - FREEZER RM-1				14/03/2008			14/03/2009
5	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4				14/03/2008			14/03/2009
6	TED-P-101-2 SENSOR AND RP1 RECORDER - COLD RM-4				14/03/2008			14/03/2009
7	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3				14/03/2008			14/03/2009
8	TED-P-101-2 SENSOR AND RP-1 RECORDER - COLD RM-3				14/03/2008			14/03/2009
9	PdIA-P-191 CAPPING RM - CORRIDOR 7		Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different pressure $\pm 2.0\text{Pa}$	18/03/2008	Pass	1	18/03/2009
10	PdIA-P-102 FILLING RM-CAPPING RM				18/03/2008			18/03/2009
11	PdIA-P-103 CLEAN RM5-CORRIDOR7				18/03/2008			18/03/2009
12	PdIA-P-104 IN9-2 - CORRIDOR7				18/03/2008			18/03/2009
13	PdIA-P-105 FILLING RM - VIAL WASHING RM				18/03/2008			18/03/2009
14	PdIA-P-106 ANTE RM6 - CORRIDOR7				18/03/2008			18/03/2009
15	PdIA-P-107 VIAL WASHING RM - CORRIDOR7				18/03/2008			18/03/2009
16	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2	Bulk and Medium Dept	Temperature (Thermohygro recorder-TRU-72U)	Different temperature $\pm 0.81^{\circ}\text{C}$	14/03/2008	Pass	1	14/03/2009
17	TED-P-103-2 SENSOR AND RP-2 RECORDER - COLD RM-2				14/03/2008			14/03/2009
18	TED-P-103-4 SENSOR AND TIC-P103-2 INDICATOR - COLD RM-2				14/03/2008			14/03/2009
19	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1				17/03/2008			14/03/2009
20	TED-P-104-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-1				17/03/2008			14/03/2009
21	TED-P-104-2 SENSOR AND TIC-P104-1 INDICATOR - INCUBATION RM-1				14/03/2008			14/03/2009
22	TED-P-103-1 SENSOR AND RP-2 RECORDER - INCUBATION RM-2				14/03/2008			14/03/2009
23	TED-P-103-1 SENSOR AND RP-2-1 INDICATOR - INCUBATION RM-2				14/03/2008			14/03/2009
24	TED-P-103-3 SENSOR AND TIC P103-1 INDICATOR - INCUBATION RM-2				14/03/2008			14/03/2009
25	TED-P-105-1 SENSOR AND RP-2-4 INDICATOR - COLD RM-1				17/03/2008			17/03/2009
26	TED-P-105-1 SENSOR AND RP-2-2 RECORDER - COLD RM-1				17/03/2008			17/03/2009
27	TED-P-107-2 SENSOR AND TIC P107-1 INDICATOR - INCUBATION RM-3				17/03/2008			17/03/2009
28	TED-P-107-2 SENSOR AND RP-3 -2000 RECORDER - INCUBATION RM-3				17/03/2008			17/03/2009
29	TED-P-107-2 SENSOR AND RP-3-2-INDICATOR - INCUBATION RM-3				17/03/2008			17/03/2009
30	TED-P-107-1 SENSOR AND RP-3-2-INDICATOR - COLD RM-5				17/03/2008			17/03/2009
31	TED-P-107-1 SENSOR AND RP-3-2 RECORDER - COLD RM-5				17/03/2008			17/03/2009
32	PdIA-P-201 THAWING RM - CORRIDOR5		Pressure	Different pressure $\pm 2.0\text{Pa}$	25/03/2008	Pass	1	25/03/2009
33	PdIA-P-202 CLEAN RM3 - CORRIDOR5				25/03/2008			25/03/2009
34	PdIA-P-203 CLEAN RM4 - CORRIDOR5				25/03/2008			25/03/2009
35	PdIA-P-204 ANTE RM4 - CORRIDOR5				25/03/2008			25/03/2009
36	PdIA-P-205 DISINFECTION RM2 - CORRIDOR5				25/03/2008			25/03/2009
37	PdIA-P-206 WASHING RM1 - CORRIDOR5				25/03/2008			25/03/2009
38	PdIA-P-207 DISINFECTION RM1 - CORRIDOR5				25/03/2008			25/03/2009
39	PdIA-P-208 MEDIA PREPARATION RM - CORRIDOR5				25/03/2008			25/03/2009
40	PdIA-P-209 CLEAN RM1 - CORRIDOR6				25/03/2008			25/03/2009
41	PdIA-P-210 CLEAN RM2 - CORRIDOR6				25/03/2008			25/03/2009
42	PdIA-P-211 CUTTING RM - CORRIDOR6				25/03/2008			25/03/2009
43	PdIA-P-212 STERILIZATION RM - CORRIDOR6				25/03/2008			25/03/2009
44	PdIA-P-213 ANTE RM1 - CORRIDOR6				25/03/2008			25/03/2009
45	PdIA-P-214 PREPARATION RM - CORRIDOR10				18/03/2008			18/03/2009
46	PdIA-P-214 CENTRIFUGATION & OBSERVATION RM1 - CORRIDOR6				22/05/2007			22/05/2008
47	PdIG-P-203 PR11 - DISINFECTION RM2				25/03/2008			25/03/2009
48	PdIG-P-204 PR7 - ANTE RM4				25/03/2008			25/03/2009
49	PdIG-P-205 PR6 - CORRIDOR3				25/03/2008			25/03/2009
50		Medium	Temperature					May-09
51								May-09
52								May-09
53								May-09
54			Humidity					May-09
55								May-09
56			Pressure					May-09
57								May-09
58		QC	Pressure	Different pressure $\pm 2.0\text{Pa}$	18/03/2008	Pass	1	18/03/2009
59	PdIA-P-215 PREPARATION RM - CORRIDOR10				18/03/2008			18/03/2009
60	PdIA-P-216 CLEAN RM8 - CORRIDOR10				18/03/2008			18/03/2009
61	PdIA-P-217 IN12 - CHANGING RM12				18/03/2008			18/03/2009
62	PdIA-P-218 CLEAN RM6 - CORRIDOR10				18/03/2008			18/03/2009
63	PdIA-P-219 CLEAN RM7 - CORRIDOR10				18/03/2008			18/03/2009
64	PdIG-P-201 OUT 11-2 - PERFORMANCE TEST RM				18/03/2008			18/03/2009
65	PdIG-P-202 IN11-2 - CHANGING RM11				18/03/2008			18/03/2009
66	PdIA_A-101 DIRTY CORRIDOR1 - CORRIDOR1A	Animal lab	Pressure	Different pressure $\pm 2.0\text{Pa}$	19/03/2008	Pass	1	19/03/2009
67	PdIA_A-102 ANTE RM - CORRIDOR1A				19/03/2008			19/03/2009
68	PdIA_A-103 DIRTY CORRIDOR2 - CORRIDOR1A				19/03/2008			19/03/2009

Result of validating and maintaining HVAC system in 2008

Updated on: 29/08/2008

Validate and maintain HVAC system periodically: 1 time/ 1 year

Protocol Doc.#: M06-PRO-VAL-64

No.	Name of equipment	Code	Dept.	Method	Criteria	Validate date	Pass/not pass	Expired date
1	Ante room 6	101-01	Final Production	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	28/04/2008	Pass	28/04/2009
2		101-02				28/04/2008	Pass	28/04/2009
3		101-03				28/04/2008	Pass	28/04/2009
4	Clean room 5	101-04				28/04/2008	Pass	28/04/2009
5		101-05				28/04/2008	Pass	28/04/2009
6	Filling room	101-06				28/04/2008	Pass	28/04/2009
7		101-07				28/04/2008	Pass	28/04/2009
8		101-08				28/04/2008	Pass	28/04/2009
9		101-09				28/04/2008	Pass	28/04/2009
10		101-10				28/04/2008	Pass	28/04/2009
11		101-11				28/04/2008	Pass	28/04/2009
12		101-12				28/04/2008	Pass	28/04/2009
13		101-13				28/04/2008	Pass	28/04/2009
14		101-14				28/04/2008	Pass	28/04/2009
15		101-15				28/04/2008	Pass	28/04/2009
16	AI 9-1	101-16				28/04/2008	Pass	28/04/2009
17	AI 9-2	101-17				28/04/2008	Pass	28/04/2009
18	In 9-2	101-18				28/04/2008	Pass	28/04/2009
19	AI	101-19				28/04/2008	Pass	28/04/2009
20	Capping room	102-01				28/04/2008	Pass	28/04/2009
21		102-02				28/04/2008	Pass	28/04/2009
22	In 9-1	102-03				28/04/2008	Pass	28/04/2009
23	Pr 14	102-04				28/04/2008	Pass	28/04/2009
24	Washing rm 3	102-05				28/04/2008	Pass	28/04/2009
25		102-06				28/04/2008	Pass	28/04/2009
26		102-07				28/04/2008	Pass	28/04/2009
27		102-08				28/04/2008	Pass	28/04/2009
28		102-09				28/04/2008	Pass	28/04/2009
29		102-10				28/04/2008	Pass	28/04/2009
30	Vial&Sterili rm	102-11				25/04/2008	Pass	25/04/2009
31		102-12				25/04/2008	Pass	25/04/2009
32		102-13				25/04/2008	Pass	25/04/2009
33		102-14				25/04/2008	Pass	25/04/2009
34		102-15				25/04/2008	Pass	25/04/2009
35	In Out 10	102-16				25/04/2008	Pass	25/04/2009
36	Pr 16	102-17				25/04/2008	Pass	25/04/2009
37	Disinfection rm 3	102-18				25/04/2008	Pass	25/04/2009
38	Pr 15	102-19				25/04/2008	Pass	25/04/2009
39	Corridor 4	201-01	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	16/04/2008	Pass	16/04/2009
40		201-02				16/04/2008	Pass	16/04/2009
41		201-03				16/04/2008	Pass	16/04/2009
42	Pr 8	201-04				16/04/2008	Pass	16/04/2009
43	Freezing rm	201-05				16/04/2008	Pass	16/04/2009
44	Thawing	201-06				16/04/2008	Pass	16/04/2009
45	Refrigerator rm 2	201-07				16/04/2008	Pass	16/04/2009
46		201-08				16/04/2008	Pass	16/04/2009
47	Storage 4	201-09				16/04/2008	Pass	16/04/2009
48	In 5	201-10				16/04/2008	Pass	16/04/2009
49	Refrigerator rm 2	201-11				16/04/2008	Pass	16/04/2009
50	Corridor 3	202-01				16/04/2008	Pass	16/04/2009
51		202-02				16/04/2008	Pass	16/04/2009
52	Clean rm 4	202-03				16/04/2008	Pass	16/04/2009
53		202-04				16/04/2008	Pass	16/04/2009
54		202-05				16/04/2008	Pass	16/04/2009
55		202-06				16/04/2008	Pass	16/04/2009
56	Clean rm 3	202-07				16/04/2008	Pass	16/04/2009
57		202-08				16/04/2008	Pass	16/04/2009
58		202-09				16/04/2008	Pass	16/04/2009
59		202-10				16/04/2008	Pass	16/04/2009

No.	Name of equipment	Code	Dept.	Method	Criteria	Validate date	Pass/not pass	Expired date
60	Ante rm 4	202-11	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	16/04/2008	Pass	16/04/2009
61		202-12				16/04/2008	Pass	16/04/2009
62	Disinfection rm 2	202-13				16/04/2008	Pass	16/04/2009
63		202-14				16/04/2008	Pass	16/04/2009
64	Storage 3	202-15				16/04/2008	Pass	16/04/2009
65	Pr 6	202-16				16/04/2008	Pass	16/04/2009
66	Al 6	202-17				16/04/2008	Pass	16/04/2009
67	In 6	202-18				16/04/2008	Pass	16/04/2009
68	Ante rm 3	202-19				16/04/2008	Pass	16/04/2009
69		202-20				16/04/2008	Pass	16/04/2009
70	Pr 7	202-21				16/04/2008	Pass	16/04/2009
71	Pr 11	202-22				16/04/2008	Pass	16/04/2009
72	Corridor 2	203-01				2008/10/4	Pass	2009/10/4
73		203-02				2008/10/4	Pass	2009/10/4
74		203-03				2008/10/4	Pass	2009/10/4
75		203-04				2008/10/4	Pass	2009/10/4
76	Centri&Observa	203-05				2008/10/4	Pass	2009/10/4
77		203-06				2008/10/4	Pass	2009/10/4
78	Storage 2	203-07				2008/10/4	Pass	2009/10/4
79		203-08				2008/10/4	Pass	2009/10/4
80	Refrigerator rm 1	203-09				2008/10/4	Pass	2009/10/4
81		203-10				2008/10/4	Pass	2009/10/4
82	Pr 5	203-11				2008/10/4	Pass	2009/10/4
83	In 4-2	203-12				2008/10/4	Pass	2009/10/4
84	Centri&Observa	203-13				2008/11/4	Pass	2009/11/4
85	Clean rm 1	204-01				2008/9/4	Pass	2009/9/4
86		204-02				2008/9/4	Pass	2009/9/4
87		204-03				2008/9/4	Pass	2009/9/4
88		204-04				2008/9/4	Pass	2009/9/4
89	Clean rm 2	204-05				2008/9/4	Pass	2009/9/4
90		204-06				2008/9/4	Pass	2009/9/4
91		204-07				2008/9/4	Pass	2009/9/4
92		204-08				2008/9/4	Pass	2009/9/4
93	Ante rm 1	204-09				2008/9/4	Pass	2009/9/4
94		204-10				2008/9/4	Pass	2009/9/4
95		204-11				2008/9/4	Pass	2009/9/4
96		204-12				2008/9/4	Pass	2009/9/4
97	Corridor 1	204-13				2008/9/4	Pass	2009/9/4
98		204-14				2008/9/4	Pass	2009/9/4
99	Storage 1	204-15				2008/9/4	Pass	2009/9/4
100	Sterile Filtration	204-16				2008/10/4	Pass	2009/10/4
101		204-17				2008/10/4	Pass	2009/10/4
102	Cutting rm	204-18				2008/10/4	Pass	2009/10/4
103		204-19				2008/10/4	Pass	2009/10/4
104	Al 4	204-20				2008/10/4	Pass	2009/10/4
105	In 4-1	204-21				2008/10/4	Pass	2009/10/4
106	Pr 13	204-22				2008/10/4	Pass	2009/10/4
107	Ante rm 2	204-23				2008/10/4	Pass	2009/10/4
108	Pr 14	204-24				2008/10/4	Pass	2009/10/4
109	Pr 3	204-25				2008/10/4	Pass	2009/10/4
110	Pr2	204-26				2008/10/4	Pass	2009/10/4
111	Disinfection rm 1	261-01				2008/9/4	Pass	2009/9/4
112	In 3-1	261-02				2008/8/4	Pass	2009/8/4
113	Media Preparation	262-01				2008/8/4	Pass	2009/8/4
114		262-02				2008/9/4	Pass	2009/9/4
115		262-03				2008/8/4	Pass	2009/8/4
116	In 3-2	262-04				2008/8/4	Pass	2009/8/4
117	Check weight	262-05				2008/11/4	Pass	2009/11/4
118	Storage 6	212-01				2008/11/4	Pass	2009/11/4
119	Storage 5	212-02				2008/11/4	Pass	2009/11/4
120	Laundry rm	212-03				2008/11/4	Pass	2009/11/4
121		212-04				2008/11/4	Pass	2009/11/4

No.	Name of equipment	Code	Dept.	Method	Criteria	Validate date	Pass/not pass	Expired date
122	Washing rm 1	212-05	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	2008/11/4	Pass	2009/11/4
123		212-06				2008/11/4	Pass	2009/11/4
124		212-07				2008/11/4	Pass	2009/11/4
125		212-08				2008/11/4	Pass	2009/11/4
126		212-09				2008/11/4	Pass	2009/11/4
127		212-10				2008/11/4	Pass	2009/11/4
128		212-11				2008/11/4	Pass	2009/11/4
129		212-12				2008/11/4	Pass	2009/11/4
130	In Out 7	212-13				2008/11/4	Pass	2009/11/4
131	Washing rm 2	212-14				2008/11/4	Pass	2009/11/4
132		212-15				2008/11/4	Pass	2009/11/4
133		212-16				2008/11/4	Pass	2009/11/4
134		212-17				2008/11/4	Pass	2009/11/4
135	Pr 9	212-18				2008/11/4	Pass	2009/11/4
136	Storage 7	212-19				2008/11/4	Pass	2009/11/4
137	Pr 1	212-20				2008/11/4	Pass	2009/11/4
138	Pr 10	212-21				2008/11/4	Pass	2009/11/4
139	Observation Area	208-01	QC	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	21/04/2008	Pass	21/04/2009
140	Refrigerator rm 3	208-02				21/04/2008	Pass	21/04/2009
141		208-03				21/04/2008	Pass	21/04/2009
142		208-04				21/04/2008	Pass	21/04/2009
143	Clean rm 7	208-05				21/04/2008	Pass	21/04/2009
144		208-06				21/04/2008	Pass	21/04/2009
145	Incubation rm 2	208-07				21/04/2008	Pass	21/04/2009
146	Clean rm 6	208-08				21/04/2008	Pass	21/04/2009
147		208-09				21/04/2008	Pass	21/04/2009
148	Pr 19	208-10				21/04/2008	Pass	21/04/2009
149	Al 11-1	208-11				21/04/2008	Pass	21/04/2009
150	In 11-1	208-12				21/04/2008	Pass	21/04/2009
151	Clean rm 8	209-01				23/04/2008	Pass	23/04/2009
152		209-02				23/04/2008	Pass	23/04/2009
153	Preparation rm	209-03				23/04/2008	Pass	23/04/2009
154		209-04				23/04/2008	Pass	23/04/2009
155		209-05				23/04/2008	Pass	23/04/2009
156	Al 12-2	209-06				23/04/2008	Pass	23/04/2009
157	Al 12-1	209-07				23/04/2008	Pass	23/04/2009
158	In 12	209-08				23/04/2008	Pass	23/04/2009
159	Preformance test	211-01				23/04/2008	Pass	23/04/2009
160		211-02				23/04/2008	Pass	23/04/2009
161	AL 11-2	211-03				23/04/2008	Pass	23/04/2009
162	In 11-2	211-04				23/04/2008	Pass	23/04/2009
163	Dirty corridor 1	101-01	Animal Lab	Check leakage and air changing frequency	• There is no leakage in any checking position • Air exchange frequency ≥ 20 times/1 hour	2008/8/5	Pass	2009/8/5
164	Quarantine rm 1	101-02				2008/8/5	Pass	2009/8/5
165	Material out 1	101-03				2008/8/5	Pass	2009/8/5
166	Inocubation rm 1	101-04				2008/8/5	Pass	2009/8/5
167	Rabbits test rm	101-05				2008/8/5	Pass	2009/8/5
168	Inocubation rm 2	101-06				2008/8/5	Pass	2009/8/5
169	Guinea Pigs test rm	101-07				2008/8/5	Pass	2009/8/5
170	Clean Corridor 1	101-08				2008/8/5	Pass	2009/8/5
171	Ante rm	101-09				2008/8/5	Pass	2009/8/5
172	Ante rm	102-01				2008/8/5	Pass	2009/8/5
173	Clean orridor 2	102-02				2008/8/5	Pass	2009/8/5
174	AutoPsy rm 2	102-03				2008/8/5	Pass	2009/8/5
175	Quarantine rm 2	102-04				2008/8/5	Pass	2009/8/5
176	Mice Test rm 1	102-05				2008/8/5	Pass	2009/8/5
177	Inocubation rm3	102-06				2008/8/5	Pass	2009/8/5
178	Mice Test rm 2	102-07				2008/8/5	Pass	2009/8/5
179	Inoculation rm 4	102-08				2008/8/5	Pass	2009/8/5
180	Dirty corridor 2	102-09				2008/8/5	Pass	2009/8/5

Validation and maintenance in 2008

Updated date: 1/9/2008

Periodical validation and maintenance for equipment: 1 time/ 1 year

Protocol Doc #: M06-PRO-VAL-62

No.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
1	Vial Sterilizing Machine	BE-03691	Final Production	Temperature and wind flow	• Check wind speed in sterilization cellar. Result measured from each area must satisfy: 80% must pass = average velocity is $\pm 20\%$ 100% must pass = average velocity is $\pm 30\%$ • Check HEPA in sterilization cellar: - Infeed zone. Number of particle is 0.3 μm which must be less than 0.01% of total particles for infeed. - Heating zone. Quantity of particle is 0.3 μm which must be less than 0.05% of particles for infeed. - Cooling zone. Number of particle is 0.3 μm which must be less than 0.01% of total particles for infeed. • Check cleanliness in sterilization cellar - Infeed zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute - Heating zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute - Cooling zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute • Check heat distribution in sterilization cellar - Temperature in the chamber must be more than 300°C. - Output temperature must be smaller than 25°C	2008/12/5	Pass	2009/12/5
2	Clean Bench B	G264920501	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ 0.3 μm	23/04/2008	Pass	23/04/2009
3	Clean Bench B	G264930501	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ 0.3 μm	23/04/2008	Pass	23/04/2009
4	Clean Bench B	G264930502	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ 0.3 μm	23/04/2008	Pass	23/04/2009

No.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
5	Clean Bench A	G264940501	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	23/04/2008	Pass	23/04/2009
6	Clean Bench C	G264910501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/4/4	Pass	2009/4/4
7	Clean Bench D	G264890501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
8	Clean Bench E	G264880502	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
9	Clean Bench D	G264890502	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
10	Clean Bench D	G264890503	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
11	Clean Bench B	G264930503	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
12	Clean Bench E	G264870501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/7/4	Pass	2009/7/4
13	Clean Bench F	G264960501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	14/05/2008	Pass	14/05/2009
14	Clean Bench E	G264880501	Medium	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/4/4	Pass	2009/4/4
15	Clean Bench A	G264900501	Medium	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/4/4	Pass	2009/4/4

No.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
16	Clean Bench C	G264950501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	25/04/2008	Pass	25/04/2009
17	Clean Bench E	G264970501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	25/04/2008	Pass	25/04/2009
18	Laminar Flow Unit	G242550501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: - AFU 1: $241\text{m}^3/\text{min} \pm 241\text{m}^3*20\%$ - AFU 1: $133\text{m}^3/\text{min} \pm 133\text{m}^3*20\%$ • Leakage: - Filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	28/04/2008	Pass	28/05/2009
19	Laminar Flow Unit	G242560501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	29/04/2008	Pass	29/05/2009
20	Laminar Flow Unit	G242570501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	29/04/2008	Pass	29/05/2009
21	Laminar Flow Unit	G242580501	Medium	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/4/4	Pass	2009/4/4
22	Laminar Flow Unit	G242590501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$ • Wind velocity and flow - Average wind velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage: filtration output Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/3/4	Pass	2009/3/4
23	Laminar Flow Unit B	5114-01277-CB100	QC - Chemical	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average wind velocity: $\geq 0.35\text{m/sec}$ • Leakage: Filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	23/04/2008	Pass	23/04/2009
24	Biological Safety Cabinet	NSC-IIA-1800	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity - The distance between the below and surface of Hepa Filter 100mm : $0.35\text{m/sec} \pm 0.025\text{m/s}$ -At wind suction in gate : $0.53 \pm 0.025\text{m/s}$ • Leakage: Filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2008/3/7	Pass	2009/3/7

Result of calibrating sensor of water generation system in 2008

Updated date: 05/08/2008

Frequency of calibrating sensor for WFI generation production: 1time 1year

No.	Name of equipment	Code	Position	Calibration machine	Criteria	Calibration date	Pass/not pass	Expired date
1	SW Heat Exchanger Outlet Temp.	TIRCA-1101	Dionization system of water (first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature 70°C ± 0.7°C 80°C ± 0.8°C 90°C ± 0.8°C	24/04/2008	Pass	24/04/2009
2	Soft Water Tank Drain Temp.	TRS-1181		Temperature calibration equipment (Ametek ITC-155A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	24/04/2008	Pass	24/04/2009
3	Row Temp.	TRS-1201		Temperature calibration equipment (Ametek ITC-155A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	24/04/2008	Pass	24/04/2009
4	UFW Heater Outlet Temp.	TIRCA-3102	WFI distribution system (First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	21/04/2008	Pass	21/04/2009
5	UFW Heater Inlet Temp.	TRS-3101		Temperature calibration equipment (Ametek ITC-155A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/04/2008	Pass	21/04/2009
6	UFW Feed Tank Return Temp.	TRS-3103		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/04/2008	Pass	21/04/2009
7	UFW Tank Temp.	TRS-4101	Water generation system UFW(First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4
8	UFW Return Temp.	TRS-4102		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	29/04/2008	Pass	2009/12/4
9	VF-4102 SIP	TRS-4181		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4

No.	Name of equipment	Code	Position	Calibration machine	Criteria	Calibration date	Pass/not pass	Expired date
10	P-4101 SIP	TRS-4182	Water generation system UFW(First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4
11	UFW Return SIP Temp.	TRS-4183		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4
12	P-4102 Temp.	TRS-4184		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4
13	UFW-① SIP Temp.	TRSU-181	Freeze drying (Used point) (First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	23/4/2008	Pass	23/4/2009
14	UFW-② SIP Temp.-1	TRSU-281	Washing room No. 3 (Used point) (First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	23/4/2008	Pass	23/4/2009
15	UFW-② SIP Temp.-2	TRSU-282		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	23/4/2008	Pass	23/4/2009
16	UFW-③ SIP Temp.-1	TRSU-381	Washing room 2 (Used point) (Second floor 2)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
17	UFW-③ SIP Temp.-2	TRSU-382		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
18	UFW-④ SIP Temp.	TRSU-481	Sterilization room 2 (second 2)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	16/4/2008	Pass	16/4/2009
19	UFW-⑤ SIP Temp.	TRSU-581	Sterilization room 3 (First floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	23/4/2008	Pass	23/4/2009

No.	Name of equipment	Code	Position	Calibration machine	Criteria	Calibration date	Pass/not pass	Expired date
20	Condenser Outlet Temp.	TIRCA-6101	Water generation system UFW(first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	19/4/2008	Pass	19/4/2009
21	WFI Cooler Outlet Temp.	TRA-6102		Temperature calibration equipment (Ametek ITC-155A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
22	WFI Heater Outlet Temp.	TIRCA-7103	WFI distribution system (first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	19/4/2009	Pass	19/4/2009
23	WFI Tank Temp.	TRS-7101		Temperature calibration equipment (Ametek ITC-155A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
24	WFI Return Temp.	TRS-7102		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
25	WFI Generation Outlet SIP Temp.	TRS-7181		Temperature calibration equipment (Ametek ITC-155A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
26	P-7101 SIP Temp.	TRS-7182		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
27	WFI Return SIP Temp.	TRS-7183		Temperature calibration equipment (Ametek ITC-155A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009
28	HE-7101 Outlet SIP Temp.	TRS-7184		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/4/2008	Pass	21/4/2009
29	VF-7101 SIP Temp.	TRS-7185		Temperature calibration equipment (Ametek ITC-155A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	19/4/2008	Pass	19/4/2009

No.	Name of equipment	Code	Position	Calibration machine	Criteria	Calibration date	Pass/not pass	Expired date
30	WFI-① SIP Temp	TRS-W181	Vial washing and sterilization room (first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
31	LC-WFI2 SIP Temp.-1	TRS-W281	Washing room 3 first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
32	LC-WFI2 SIP Temp.-2	TRS-W282		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
33	LC-WFI3 SIP Temp.-1	TRS-W381		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
34	LC-WFI3 SIP Temp.-2	TRS-W382	Filtration room (first floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	18/4/2008	Pass	18/4/2009
35	LC-WFI2 SIP Temp.-3	TRS-W284		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	14/4/2008	Pass	14/4/2009
36	LC-WFI4 SIP Temp.-1	TRS-W481		Temperature calibration equipment (Ametek ITC-155A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	14/4/2008	Pass	14/4/2009
37	LC-WFI4 SIP Temp.-2	TRS-W482	Medium preparation room(second floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	16/4/2008	Pass	16/4/2009
38	WFI-⑤ SIP Temp	TRS-W581	Washing room (second floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	14/4/2008	Pass	14/4/2009

No.	Name of equipment	Code	Position	Calibration machine	Criteria	Calibration date	Pass/not pass	Expired date
39	LC-WF16 SIP Temp.-1	TRS-W681	Washing room 1 (second floor)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	14/4/2008	Pass	14/4/2009
40	LC-WF16 SIP Temp.-2	TRS-W682		Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	14/4/2008	Pass	14/4/2009
41	UFW&WF1 SIP Temp.	TRS-5101	PS Unit (1F)	Temperature calibration equipment (Ametek ITC-155A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	2008/12/4	Pass	2009/12/4
42	UFW Return Pressure	PICA-4101	UFW generation system	Pressure calibration equipment (Ametek CPC200C)	Ap suất 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	2008/12/4	Pass	2009/12/4
43	Pure Steam Pressure	PICA-5101	PS Unit	Pressure calibration equipment (Ametek CPC200C)	Ap suất 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	2008/12/4	Pass	2009/12/4
44	Pure Steam Pressure	PICA-6101	UFW generation system	Pressure calibration equipment (Ametek CPC200C)	Ap suất 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	19/4/2008	Pass	19/4/2009
45	WF1 Return Pressure	PICA-7101	WF1 distribution system	Pressure calibration equipment (Ametek CPC200C)	Ap suất 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	19/4/2008	Pass	19/4/2009

Result of calibration for equipment 2008

No.	Equipment	Item	Cat point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
1	QC	Autoclave B						
		Thermal sensor- Temperature channel of chamber	TE1-1	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.1	TE1-2	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	
		Thermal sensor- Temperature channel of jacket	TE2	111, 121, 131(°C)	18/01/2008	Pass	18/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE3-1	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.2	TE3-2	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	
		Thermal sensor- Temperature channel of waste water filter	TE4-1	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Thermal sensor- kênh ghi nhiệt bộ lọc nước thải CH.3	TE4-2	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	
		Thermal sensor- Temperature channel of chamber	TE5-1	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.4	TE5-2	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	
		Thermal sensor- Temperature channel of chamber CH.5	TE 6	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.6	TE 7	111, 121, 131(°C)	18/01/2008	Pass	18/01/2009	1
		Loop to measure pressure of chamber	PE - 1-1	0,100,200,300,-90(kPa)	17/01/2008	Pass	18/01/2009	1
		Loop to record pressure of chamber CH.12	PE - 1-2	0,100,200,300,-90(kPa)	17/01/2008	Pass	18/01/2009	1
2	QC	Incubator A						
		Loop to measure pressure of chamber	PI1	0,4,0,3,0,2,0,1,-0,08(MPa)	17/01/2008	Pass	17/01/2010	2
		Loop to measure pressure of chamber	PI2	0,4,0,3,0,2,0,1,-0,08(MPa)	17/01/2008	Pass	17/01/2010	2
		Loop to measure pressure of chamber	PI3	0,4,0,3,0,2,0,1,-0,08(MPa)	17/01/2008	Pass	17/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE1-1	40,30,20(°C)	2008/10/1	Pass	2011/10/1	3
		Thermal sensor- Temperature channel of chamber	TE2-1	40,30,20(°C)	2008/11/1	Pass	2011/11/1	3
		Thermal sensor- Temperature channel of chamber	TE3-1	50,40,30(°C)	2008/10/1	Pass	2011/10/1	3
		Thermal sensor- Temperature channel of chamber	TE1	40,30,20(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE1-1	40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE2-1	40,30,25(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE3-1	70,60,50,40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE1-1	At 20°C: ≤±0.5(°C) At 30°C: ≤±0.5(°C) At 40°C: ≤±0.6(°C)	2008/11/1	Pass	2009/11/1	1
		Thermal sensor- Temperature channel of chamber	TE2-1	At 20°C: ≤±0.5(°C) At 30°C: ≤±0.5(°C) At 40°C: ≤±0.6(°C)	2008/10/1	Pass	2009/10/1	1
		Thermal sensor- Temperature channel of chamber	TE3-1	At 30°C: ≤±0.5(°C) At 40°C: ≤±0.5(°C) At 50°C: ≤±0.6(°C)	2008/10/1	Pass	2009/10/1	1
3	QC	Incubator B						
		Thermal sensor- Temperature channel of chamber	TE1	40,30,20(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE1-1	40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE2-1	40,30,25(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE3-1	70,60,50,40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
4	QC	Incubator C						
		Thermal sensor- Temperature channel of chamber	TE1	40,30,20(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE1-1	40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE2-1	40,30,25(°C)	15/01/2008	Pass	15/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE3-1	70,60,50,40,30,25(°C)	14/01/2008	Pass	14/01/2011	3
5	QC	(Recorder of Incubator A)						
		Thermal sensor- Temperature channel of chamber	TE1-1	40,30,20(°C)	2008/11/1	Pass	2009/11/1	1
		Thermal sensor- Temperature channel of chamber	TE2-1	40,30,20(°C)	2008/10/1	Pass	2009/10/1	1
		Thermal sensor- Temperature channel of chamber	TE3-1	50,40,30(°C)	2008/10/1	Pass	2009/10/1	1

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
6	QC (Recorder of Incubator B, C)	Sensor nhiet độ - Temperature channel of chamber Incubator B 23oC (CH.5)	TE1	40,30,20(oC)	At 20oC: $\leq \pm 0.5(oC)$ At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$	Pass	2009/3/4	1
		Thermal sensor- Temperature channel of chamber Incubator C 31oC (CH.11)	TE2	40,30,20(oC)	At 20oC: $\leq \pm 0.5(oC)$ At 30oC: $\leq \pm 0.5(oC)$ At $\geq 40oC$: $\leq \pm 0.6(oC)$	Pass		1
		Thermal sensor- Temperature channel of chamber Incubator C 31oC (CH.4)	TE3	50,40,30(oC)	At 20oC: $\leq \pm 0.5(oC)$ At 30oC: $\leq \pm 0.5(oC)$ At $\geq 40oC$: $\leq \pm 0.6(oC)$	Pass		1
		Thermal sensor- Temperature channel of chamber Incubator C 58oC (CH.6)	TE4	50,40,30(oC)	At 20oC: $\leq \pm 0.5(oC)$ At 30oC: $\leq \pm 0.5(oC)$ At $\geq 40oC$: $\leq \pm 0.6(oC)$	Pass		1
		Channel measures temperature of chamber	TE1	50,60,70	$\leq \pm 1(oC)$	Pass		1
7	Vacuum dry oven	Thermal sensor- channel displays and temperature of chamber	TE1	30,40,50(oC)	$\leq \pm 1(oC)$	Pass	8/6/2009	2
8	QC CO ₂ Incubator A M02-15-30/03/03	Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$ At 50oC: $\leq \pm 0.7(oC)$	Pass	2010/3/4	1
		Sensor to measure CO2 concentration	COE1	3.5,7(%)	$\leq \pm 1(%)$	Pass	2009/2/4	1
		Thermal sensor- channel displays temperature of chamber	TE1	30,40,50(oC)	$\leq \pm 1(oC)$	Pass	2009/8/6	2
9	QC CO ₂ Incubator B M02-15-01/03/03	Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$ At 50oC: $\leq \pm 0.7(oC)$	Pass	2009/2/4	1
		Sensor to measure CO2 concentration	COE1	3.5,7(%)	$\leq \pm 1(%)$	Pass	2009/2/4	1
		Thermal sensor- channel displays temperature of chamber	TE1	30,40,50(oC)	$\leq \pm 1(oC)$	Pass	2009/8/6	2
10	QC CO ₂ Incubator C	Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$ At 50oC: $\leq \pm 0.7(oC)$	Pass	2009/2/5	1
		Sensor to measure CO2 concentration	COE1	3.5,7(%)	$\leq \pm 1(%)$	Pass	2009/2/4	1
		Thermal sensor- Temperature channel of chamber	TE1	30,40,50(oC)	$\leq \pm 1(oC)$	Pass	2009/8/6	1
11	QC Egg Incubator	Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$ At 50oC: $\leq \pm 0.7(oC)$	Pass	2009/2/4	1
		Sensor to measure CO2 concentration	COE1	3.5,7(%)	$\leq \pm 1(%)$	Pass	2009/2/4	1
		Thermal sensor- Temperature channel of chamber	TE1	30,40,50(oC)	$\leq \pm 1(oC)$	Pass	13/03/2009	1
12	QC Lab. Autoclave for Chemical	Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: $\leq \pm 0.5(oC)$ At 40oC: $\leq \pm 0.6(oC)$ At 50oC: $\leq \pm 0.7(oC)$	Pass	13/03/2010	2
		Thermal sensor- Temperature channel of chamber	TE1	110,120,130(oC)	$\leq \pm 1(oC)$	Pass	2009/4/3	1
		Thermal sensor- Temperature channel of chamber	TE2	110,120,130(oC)	$\leq \pm 0.8(oC)$	Pass	2010/4/3	2
13	QC Lab. Autoclave for Bio.	Loop to measure pressure of chamber	PG1	0.1, 0.12, 0.14(Mpa)	$\leq \pm 0.01(Mpa)$	Pass	2009/4/3	1
		Thermal sensor- Temperature channel of chamber	TE1	110,120,130(oC)	$\leq \pm 1(oC)$	Pass	2009/4/3	1
		Thermal sensor- Temperature channel of chamber	TE2	110,120,130(oC)	$\leq \pm 0.8(oC)$	Pass	2010/4/3	2
13	QC Lab. Autoclave for Bio.	Loop to measure pressure of chamber	PG1	0.1, 0.12, 0.14(Mpa)	$\leq \pm 0.01(Mpa)$	Pass	2009/4/3	1

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
14	QC	Dry Oven	TE1-1	100,125,250(oC)				1
			TE1-2	100,125,250(oC)				
			TE2-1	100,125,250(oC)	2008/5/3	Pass	2009/5/3	1
			TE2-2	100,125,250(oC)				
			TE3-1	100,125,250(oC)				
			TE3-2	100,125,250(oC)				
			PE1-1	0,150,300(Pa)				
			PE1-2	0,150,300(Pa)				
			PE1-3	0,150,300(Pa)				
			TE1-1	-30(oC)				
			TE1-2	-30(oC)				
			TE2-1	-30(oC)				
15	QC	Deep Freezer : -30℃ Qty: 4	TE2-2	-30(oC)	2008/12/3	Pass	2009/12/3	3
			TE3-1	-30(oC)				
			TE3-2	-30(oC)				
			TE4-1	-30(oC)				
			TE4-2	-30(oC)				
			TE1-1	-70(oC)				
			TE1-2	-70(oC)				
			TE2-1	-70(oC)				
			TE2-2	-70(oC)				
			TE3-1	-70(oC)	2008/12/3	Pass	2009/12/3	3
16	QC	Deep Freezer : -70℃ Qty: 4	TE3-2	-70(oC)				
			TE4-1	-70(oC)	2008/12/3	Pass	2009/12/3	3
			TE4-2	-70(oC)				
			TE1-1	-70(oC)				
			TE1-2	-70(oC)				
			TE2-1	-70(oC)				
			TE2-2	-70(oC)				
			TE3-1	-70(oC)				
			TE3-2	-70(oC)				
			TE4-1	-70(oC)	2008/12/3	Pass	2009/12/3	3
			TE4-2	-70(oC)				
17	QC	Refrigerator : 5℃ Qty: 2	TE1-1	5(oC)	2008/12/3	Pass	2009/12/3	3
			TE1-2	5(oC)				
			TE2-1	5(oC)				
			TE2-2	5(oC)				
			TE1-1	5(oC)				
			TE1-2	5(oC)				

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
19	Medium Autoclave A-3	Thermal sensor- Temperature channel of chamber	TE1-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	22/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.1	TE1-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	22/01/2011	3
		Thermal sensor- Temperature channel of jacket	TE2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE3-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.2	TE3-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of waste water filter	TE4-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of waste water filter CH.3	TE4-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE5-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.4	TE5-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.5	TE 6	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.6	TE 7	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Loop to measure pressure of chamber	PE - 1-1	0,100,200,300,400,-90(kPa)	≤±5(kPa)	Pass	23/01/2009	1
		Loop to record pressure of chamber CH.12	PE - 1-2	0,100,200,300,400,-90(kPa)	≤±5(kPa)	Pass	23/01/2009	1
		Loop to measure pressure of chamber	PI 1	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1
20	Medium Dry Oven	Loop to measure pressure of chamber	PI 2	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1
		Loop to measure pressure of Jacket	PI 3	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE1-1	100,125,250(°C)	At 100: ≤±0.61(°C) At 125: ≤±0.64(°C) At 250: ≤±0.82(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE1-2	100,125,250(°C)	At 100: ≤±0.51(°C) At 125: ≤±0.63(°C) At 250: ≤±0.92(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE2-1	100,125,250(°C)	At 100: ≤±0.51(°C) At 125: ≤±0.63(°C) At 250: ≤±0.92(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE2-2	100,125,250(°C)	At 100: ≤±0.51(°C) At 125: ≤±0.63(°C) At 250: ≤±0.92(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE3-1	100,125,250(°C)	At 100: ≤±0.51(°C) At 125: ≤±0.63(°C) At 250: ≤±0.92(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE3-2	100,125,250(°C)	At 100: ≤±0.51(°C) At 125: ≤±0.63(°C) At 250: ≤±0.92(°C)	Pass	23/01/2009	1
		Pressure sensor - Channel to measure pressure of chamber	PE1-1	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	23/01/2009	1
		Pressure sensor - Channel top record pressure of chamber	PE1-2	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	23/01/2009	1
		Pressure sensor - Channel to record pressure of chamber	PE2-1	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	23/01/2009	1
		Pressure sensor - Channel to measure pressure of chamber	PE2-2	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	23/01/2009	1
		Pressure sensor - Channel to measure pressure of chamber	PE2-3	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE1-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
21	BP Autoclave A-2	Thermal sensor- Temperature channel of chamber CH.1	TE1-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of jacket	TE2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE3-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.2	TE3-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of waste water filter	TE4-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of waste water filter CH.3	TE4-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber	TE5-1	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.4	TE5-2	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.5	TE 6	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.6	TE 7	111, 121, 131(°C)	≤±0.5(°C)	Pass	23/01/2009	1
		Loop to measure pressure of chamber	PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	Pass	23/01/2009	1
		Loop to record pressure of chamber CH.12	PE - 1-2	0,100,200,300,-90(kPa)	≤±5(kPa)	Pass	23/01/2009	1
		Loop to measure pressure of chamber	PI 1	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1
		Loop to measure pressure of chamber	PI 2	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1
		Loop to measure pressure of Jacket	PI 3	0,4,0,3,0,2,0,1,-0,08(Mpa)	≤±0.0065(MPa)	Pass	23/01/2009	1

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
22	BP	Thermal sensor- Temperature channel of chamber	TE1	30,40,50(oC)	≤±1(oC)		13/03/2010	2
		Thermal sensor- Temperature channel of chamber	TE2	30,40,50(oC)	At 30oC: ≤±0.5(oC) At 40oC: ≤±0.6(oC) At 50oC: ≤±0.7(oC)	Pass	13/03/2009	1
		Humidity Sensor - channel to measure humidity	HE1	70(%)	≤±5(%)		13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE1	10,15,20 (oC)	≤±1(oC)		13/03/2009	1
23	BP	Thermal sensor- Temperature channel of chamber	TE2	10,15,20 (oC)	At 10oC: ≤±0.4(oC) At 15oC: ≤±0.5(oC) At 20oC: ≤±0.5(oC)	Pass	20/03/2010	2
		Thermal sensor- Temperature channel of chamber	TE1-1	100,125,250(oC)	At 100: ≤±0.61(oC) At 125: ≤±0.64(oC) At 250: ≤±0.82(oC)			1
		Thermal sensor- Temperature channel of chamber	TE1-2	100,125,250(oC)				
		Thermal sensor- Temperature channel of chamber	TE2-1	100,125,250(oC)	At 100: ≤±0.37(oC) At 125: ≤±0.63(oC) At 250: ≤±0.92(oC)			1
24	BP	Thermal sensor- Temperature channel of chamber	TE2-2	100,125,250(oC)				
		Thermal sensor- Temperature channel of chamber	TE3-1	100,125,250(oC)	At 100: ≤±3.5(oC) At 125: ≤±3.5(oC) At 250: ≤±3.5(oC)			1
		Thermal sensor- Temperature channel of chamber	TE3-2	100,125,250(oC)				
		Pressure Sensor - channel to measure pressure of chamber	PE1-1	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	Pass	2009/5/3	1
		Pressure Sensor - channel to measure pressure of chamber	PE1-2	0,150,300(Pa)				
		Pressure Sensor - Channel to measure pressure of chamber	PE1-1	0,150,300(Pa)				
		Pressure Sensor - Channel to measure pressure of chamber	PE1-2	0,150,300(Pa)				
		Pressure Sensor - Channel to record pressure of chamber	PE1-3	0,150,300(Pa)				
25	BP	Thermal sensor- Temperature channel of chamber	TE1-1	-30(oC)	≤±7(oC)		13/03/2011	3
		Thermal sensor- Recorder	TE1-2	-30(oC)	≤±7(oC)	Pass	13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE2-1	-30(oC)	≤±7(oC)		13/03/2011	3
		Thermal sensor- Recorder	TE2-2	-30(oC)	≤±7(oC)		13/03/2009	1
	Freezer:-30°C	Thermal sensor- Temperature channel of chamber	TE3-1	-30(oC)	≤±7(oC)	Pass	13/03/2011	3
		Thermal sensor- Recorder	TE3-2	-30(oC)	≤±7(oC)		13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE4-1	-30(oC)	≤±7(oC)	Pass	13/03/2011	3
		Thermal sensor- Recorder	TE4-2	-30(oC)	≤±7(oC)		13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE1-1	-70(oC)	≤±7(oC)		13/03/2011	3
		Thermal sensor- Recorder	TE1-2	-70(oC)	≤±7(oC)		13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE2-1	-70(oC)	≤±7(oC)	Pass	13/03/2011	3
		Thermal sensor- Recorder	TE2-2	-70(oC)	≤±7(oC)		13/03/2009	1
26	BP	Thermal sensor- Temperature channel of chamber	TE3-1	-70(oC)	≤±7(oC)	Pass	13/03/2011	3
		Thermal sensor- Recorder	TE3-2	-70(oC)	≤±7(oC)		13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE4-1	-70(oC)	≤±7(oC)	Pass	13/03/2011	3
		Thermal sensor- Recorder	TE4-2	-70(oC)	≤±7(oC)		13/03/2009	1

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
27	BP (Freezer-70°C) Qty: 4 MDF-UT2V	Thermal sensor- Temperature channel of chamber	TE1-1	≤±7(°C)			13/03/2011	3
		Thermal sensor- Recorder	TE1-2	≤±7(°C)			13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE2-1	≤±7(°C)			13/03/2011	3
		Thermal sensor- Recorder	TE2-2	≤±7(°C)	14/03/2008	Pass	13/03/2009	1
		Thermal sensor- Temperature channel of chamber	TE3-1	≤±7(°C)			13/03/2011	3
		Thermal sensor- Recorder	TE3-2	≤±7(°C)			13/03/2009	1
28	FP (Vial washing machine)	Thermal sensor- channel to measure temperature of circulated washing water	B210	≤±2(°C)				1
		Pressure measuring channel	PIA 110	≤±4(kPa)				1
		Pressure measuring channel	PIA 120	≤±30(kPa)	14/04/2008	Pass	14/04/2009	1
		Pressure measuring channel	PIA 121	≤±30(kPa)				1
		Pressure measuring channel	PIA 130	≤±30(kPa)				1
		Channel to measure and record temperature in area 1	TE 211	At 280: ≤±2.0(°C) At 300: ≤±2.2(°C) At 320: ≤±2.4(°C)	2008/8/3	Pass	2009/8/3	1
29	FP (Vial Sterilizing machine)	Channel to measure record temperature of area 2	TE 213	At 280: ≤±2.0(°C) At 300: ≤±2.2(°C) At 320: ≤±2.4(°C)				1
		Thermal sensor- Temperature channel of chamber	TE1-1	≤±0.5(°C)			29/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.1	TE1-2	≤±0.5(°C)				
		Thermal sensor- Temperature channel of jacket	TE2	≤±0.5(°C)			29/01/2011	3
		Thermal sensor- Temperature channel of chamber	TE3-1	≤±0.5(°C)				1
		Thermal sensor- Temperature channel of chamber CH.2	TE3-2	≤±0.5(°C)				
30	FP (Autoclave A-1)	Thermal sensor- Temperature channel of waste water filter	TE4-1	≤±0.5(°C)				1
		Thermal sensor- Temperature channel of waste water filter CH.3	TE4-2	≤±0.5(°C)				
		Thermal sensor- Temperature channel of chamber	TE5-1	≤±0.5(°C)				
		Thermal sensor- Temperature channel of chamber CH.4	TE5-2	≤±0.5(°C)	29/01/2008	Pass	29/01/2009	1
		Thermal sensor- Temperature channel of chamber CH.5	TE 6	≤±0.5(°C)				1
		Thermal sensor- Temperature channel of chamber CH.6	TE 7	≤±0.5(°C)				1
		Loop to measure pressure of chamber	PE - 1-1	≤±5(kPa)				
		Loop to record pressure in CH.12	PE - 1-2	≤±5(kPa)				1
		Loop to measure pressure of chamber	PI 1	≤±0.0065(MPa)			29/01/2010	2
		Loop to measure pressure of chamber	PI 2	≤±0.0065(MPa)			29/01/2011	3

No.	Equipment	Item	Cal point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
30	FP (Freeze dryer)	Thermal sensor- Temperature channel of chamber (product 1 temp)	TE101	≤±1(°C)	29/02/2008	Pass	29/02/2009	1
		Thermal sensor- Temperature channel of chamber (product 2 temp)	TE102	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 3 temp)	TE103	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 4 temp)	TE104	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 5 temp)	TE105	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 6 temp)	TE106	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 7 temp)	TE107	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 8 temp)	TE108	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 9 temp)	TE109	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 10 temp)	TE110	≤±1(°C)				1
		Thermal sensor- Temperature channel of chamber (product 11 temp)	TE111	≤±1(°C)	1			
		Thermal sensor- Temperature channel of chamber (product 12 temp)	TE112	≤±1(°C)	1			
		Thermal sensor- Temperature channel of chamber (product 13 temp)	TE113	≤±1(°C)	1			
		Thermal sensor- Temperature channel(silicool oil inlet temp)	TE201	≤±1(°C)	2008/4/3	Pass	2009/4/3	1
		Thermal sensor- Temperature channel(silicool oil outlet temp)	TE201A	≤±1(°C)				1
	FP (Freeze dryer)	Thermal sensor- Temperature channel(silicool oil outlet)	TE202	≤±1(°C)	2008/3/3	Pass	2009/3/3	1
		Thermal sensor- Temperature channel(condenser coil 1 temp)	TE203	≤±1(°C)				1
		Thermal sensor- Temperature channel(condenser coil 2 temp)	TE204	≤±1(°C)				1
		Thermal sensor- Temperature channel(condenser coil 3 temp)	TE205	≤±1(°C)				1
		Thermal sensor- Temperature channel(chamber drain temp)	TE212	≤±1(°C)				1
		Thermal sensor- Temperature channel(condenser drain temp)	TE212A	≤±1(°C)				1
		Thermal sensor- Temperature channel(condenser drain temp)	TE213	≤±1(°C)				1
		Thermal sensor- Temperature channel(condenser drain temp)	TE213A	≤±1(°C)				1
		Thermal sensor- Temperature channel(filter drain temp)	TE214	≤±1(°C)				1
		Thermal sensor- Temperature channel(filter drain temp)	TE214A	≤±1(°C)				1
		Pressure sensor	PT101	21,30,57(□Bar)	See the table of calibration by outside companies			2
		Pressure sensor	PT105	21,30,57(□Bar)				2
		Pressure sensor	PT203	21,30,57(□Bar)				2
		Pressure sensor	PT301	21,30,57(□Bar)				2

Result of calibration of equipment in 2008 by outside companies

No.	name of equipment	Quantity	Dept.	Agent	Model	Serial	Cal frequency	Cal date in 2008	Receive certificate of equipment
1	Integrity testing machine	3	Final Production	Millipore	XIY4S0001	IT40332	1	15/06/2008	x
			Medium	Millipore	XIY4S0001	IT40001		15/06/2008	x
			Bulk	Millipore	XITXACTP1	W20855		15/06/2008	x
2	Particle counter A2400	3	Final Production	Hach Ultra	A2400 LL	50601041	1	16/05/2008	x
			Bulk	Hach Ultra		50601042		16/05/2008	x
			QC	Hach Ultra		50601043		16/05/2008	x
3	Particle counter (portable) 227B	5	Final Production	Hach Ultra	227B	51200047	1	29/05/2008	x
				Hach Ultra	227B			chua lam bao gio	x
				Hach Ultra	227B				x
				Hach Ultra	227B	51200048		29/05/2008	x
				Hach Ultra	227B	51200049		2009/12/8	x
4	Air Sampler B (M Air T)	1	Medium	Millipore	Cat No.: ATBPUMP01	276	1	15/06/2008	x
5	Air Sampler A	3	Final Production	Sartorius	MD8 Air port 16757		1	27/05/2008	x
			QC	Sartorius	MD8 Air port 16757			27/05/2008	x
			Bulk	Sartorius	MD8 Air port 16757	17601125		27/05/2008	x
6	Integrity test	1	Medium	Palfi	Part No:FFSXC	22289526	1	2008/12/11	x
7	Surface temp. meter	2	Medium	TES-Taiwan	TES-I304		1		x
			Final Production	TES-Taiwan	TES-I304	050500759	1	29/12/2008	x
8	(Sensors to measure conductivity: CIRA-7101, C11201; C11202, C11302, CIRA-4101, CIRA-6101 Sensor do TOC: TOC-7101; Sensor to measure level water of tank: LIA-7101, LIA-4101;)	9 (sensors)	Engineering Dept.	Melter and Yamatake			1	28/04/2008	x
9	Particle counter KC-01E	1	Engineering Dept.	Rion Japan	KC-01E		1	15/02/2008	x
10	Standard Thermometer	1	Engineering Dept.	Sato Japan	Code :0022 *Temp range: -50 to 0 degC		3	Not done yet due to it is still in use.	
11	Standard Thermometer	1	Engineering Dept.	Sato Japan	Code: 0022 *Temp range: 0 to 50 degC		3		
12	Standard Thermometer	1	Engineering Dept.	Sato Japan	Code: No.0022 *Temp range: 50 to 100 degC		3		
13	Standard Thermometer	1	Engineering Dept.	Sato Japan	Code: No.0022 *Temp range: 100 to 150 degC		3		
14	Hybrid Recorder	2	Engineering Dept.	Yokogawa Japan	DR232-12-00-1S/M1/H1	91FC57643	2	29/12/2008	x
			Engineering Dept.			91FC57644		29/12/2008	x
15	Temperature Calibrator	1	Engineering Dept.	JOFR/AMETEK DENMARK/EU	ITC-320 A 115/230V+PE	552656-00181	1	29/12/2008	x
16	Pressure Calibration	1	Engineering Dept.	JOFR/AMETEK DENMARK/EU	CPC200CC/INDG	9185017	1	29/12/2008	x
17	Thermo-Hygro Recorder	30	Engineering Dept.	T&D Japan	TR72U	có 30 thiết bị	2	29/12/2008	x
18	Digital temperature indicator	1	Engineering Dept.	AMETEK	DTI-1000	564803-00193	1	29/12/2008	x
19	Dry block temperature calibrator	1	Engineering Dept.	AMETEK	ITC-155A	560279-00634	1	29/12/2008	x
20	Anemometer	1	Engineering Dept.	KANOMAX	6541/6543	635537	1	29/12/2008	x
21	Micro manometer	1	Engineering Dept.	HALSTRUP KRONE COMPANY	KAL 84	9095.0208KH08073	1	29/12/2008	x
22	Particle counter 237B	1	Engineering Dept.	HACH ULTRA ANALYTICS	237B		1	2008/4/12	x
23	Thermal Sensor of freeze drying machine	3	Final Production	Edward		076012021	2	25/11/2008	x
						66179601		25/11/2008	x
						66468721		25/11/2008	x

7.13 List of Validation Related Documents (2009)

POLYVAC

Summary of validation and revalidation of equipment in 2009

Dept.	PQ validation	Implementation content	Summary of implementation condition(PQ)	Times of implementation	Accepted criteria	Evaluation
Bulk	Revalidate autoclave A2, loading 1,4 (Cell area)	Sterilization effect	Loading pattern 1 implement for Trypsinization, Loading Parttern 4	1	BI:(-). Temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
	Revalidate autoclavet A3, loading 2 (virus area)	Sterilization effect	Loading pattern 2	1	BI:(-). Temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
	Revalidate dry oven A3 (Loading 2,3)	Sterilization effect	Loading pattern 2,3	1	BI:(-). Temperature and time: $\geq 190^{\circ}\text{C}, \geq 30\text{minutes}$. $F_0 \geq 12$	Pass
	Lò sấy ướt A-1 (cầu hình sấy 01,02)	Sterilization effect	Loading 1,2	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
		Sterilization effect				Pass
	Tái thẩm định quy trình sấy nút cao su bằng lò sấy ướt	Sterilization effect	Sấy tiết trùng nút cao su theo điều kiện và lấy mẫu (ghi trong Protocol)	1	Nước tồn dư (của nút cao su dùng cho lọ vắc xin đông khô) $\leq 0,30\%$ Nước tồn dư (của nút cao su dùng cho lọ nước cất pha tiêm) $\leq 0,50\%$	Pass
	Revalidate dry oven A2 (Loading 1)	Sterilization effect	Loading pattern 1	1	BI:(-). temperature and time: $\geq 190^{\circ}\text{C}, \geq 30\text{minutes}$. $F_0 \geq 12$	Pass
	Validate autoclave A3, loading 3	Sterilization effect	Loading parttern 3: Implement for pooling and filtration	3	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
Final Production	Revalida vial washing machine	Sterilization effect	Vial used for Measles vaccine which are washed and tested by equipment as in implementation of OQ	1	Number of dirty particle after washing: Size is more than $10\mu\text{m}$: $<600\text{particles}/\text{l vial}$ Size is more than $25\mu\text{m}$: $<600\text{particle}/\text{l vial}$	Pass
	Validate autoclave A2	Sterilization effect	Loading pattern 08,09	3	BI (-), temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
QC	Revalidate Dry oven	Sterilization effect	As regulated in SOP	1	BI (-), temperature and time: $\geq 190^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
	Validate Autoclave D	Sterilization effect	Loading Parttern 2	3	BI (-), temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
	Validate Autoclave B	Sterilization effect	Loading Parttern 1,2	3	BI (-), temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
	Revalidate Autoclave D	Sterilization effect	Loading Parttern 1	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass
Medium	Revalidate Dry oven	Sterilization effect	Sterilize implement for preparation and filtration of medium	1	BI (-), temperature and time: $\geq 190^{\circ}\text{C}, \geq 20\text{minutes}$; $F_0 \geq 12$	Pass
	Revalidate autoclave A2 (sterilize implement - Loading Parttern 4)	Sterilization effect	Loading Parttern 4	1	BI:(-). temperature and time: $\geq 121^{\circ}\text{C}, \geq 20\text{minutes}$. $F_0 \geq 12$	Pass

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Summary of validation and revalidation of procedure in 2009

Dept.	PQ validation	Implementation content	Summary of implementation condition (PQ)	Time of implementation	Accepted criteria	Evaluation
Bulk	Revalidate sterilization by formaline fumigation	Sterilization effect	1500ppm; 12 hours	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass
	Revalidate procedure of transportation of material and implement	Validate process in SOP	(Route) NC $\rightarrow$ D, D $\rightarrow$ C, C $\rightarrow$ B	1	Grade B: < 5 CFU/Plate Grade C: < 25 CFU/Plate Grade D: < 50 CFU/Plate	Pass
	Revalidate changing procedure	Confirm changing of trained staffs	06 persons	1	Checked position is < 5 CFU/Plate	Pass
	Revalidate sterilization of egg	Sterilization effect	Benzalkonium 0,1% Iod 3% alcohol 70% alcohol (2 times)	1	Benzalkonium 0,1% : Quantity of forming unit/leg < 15 Iod 3% alcohol: Quantity of forming unit/leg < 10 70% alcohol (2 times) : Quantity of forming unit/leg ≤ 1	Pass
	Revalidate MFT of bulk production procedure	Validate sterilization during bulk production	Stimulate real production condition	1	There is no bacterium and fungus in cultural procedure	Pass
Final Production	Revalidate sterilization by formaline fumigation	Sterilization effect	1500ppm; 12Hours	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass
	Revalidate vial sterilization procedure of sterilization cellar	Sterilization effect	Bio challenge Endotoxin 600EU/vial	1	Temperature $\geq 300^{\circ}\text{C}$ Elimination effect ≥ 3 log	Pass
	Revalidate MFT of bulk production procedure	Validate sterilization during filling of WFI and Measles vaccine	Stimulate real production condition and some additional interference	1	There is no bacterium and fungus in cultural procedure	Pass
	PV of 3 lot production with maximum capacity on sufficient and real scale	Guarantee that all equipment and procedure operate according to estimate with good quality of Vaccine	As production condition	3 lần	As criteria in standard procedure	Pass
QC	Revalidate changing procedure	Confirm changing of trained staffs	03 persons	1	Grade B: Palm: < 5 CFU/Plate Head, mask, chest, thigh : < 20 CFU/Plate	Pass
	Formalin fumigation effect of QC area	Sterilization effect	1500ppm; 12Hours	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass
Medium	Revalidate the second changing procedure when enter Grade C area	Give out revalidation for changing of staffs in grade C area	Grade C area	1	Checked position is < 5 CFU/Plate	Pass
	Revalidate transportation of implement	Verify transportation procedure of sterilized implement into production area	(Route) NC $\rightarrow$ D, D $\rightarrow$ C, C $\rightarrow$ B	1	Grade B: < 5 CFU/Plate Grade C: < 25 CFU/Plate Grade D: < 50 CFU/Plate	Pass
	Revalidate washing procedure of medium production implement	Confirm effect of washing procedure	As regulated in SOP	1	TOC concentration ≤ 500 ppb	Pass
	Revalidate formaline fumigation of medium production area	Sterilization effect	1500ppm; 12Hours	1	BI: Decrease ≥ 3 log Remaining formaline concentration ≤ 0.1 ppm	Pass

Result of calibration of HVAC system in 2009

Updated on: 30/08/2009

No.	Name of equipment	Dept.	Validation method for equipment	Criteria	Implementati on date	Pass/not pass	CAL frequency (year)	Expired date
1	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2	Final production	Temperature (Thermohygro recorder- TRU-72U)	Different temperature ± 0.81 °C	11/12/2008	Pass	1	11/12/2009
2	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-2				11/12/2008			11/12/2009
3	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1				11/12/2008			11/12/2009
4	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - FREEZER RM-1				11/12/2008			11/12/2009
5	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4				11/12/2008			11/12/2009
6	TED-P-101-2 SENSOR AND RP-1-4 INDICATOR - COLD RM-4				11/12/2008			11/12/2009
7	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3				11/12/2008			11/12/2009
8	TED-P-101-2 SENSOR AND RP-1-2 INDICATOR - COLD RM-3				11/12/2008			11/12/2009
9	TED-P-102 SENSOR AND TI-P-102 INDICATOR - FILLING RM				2009/12/5			2010/12/5
10	TED-P-103 SENSOR AND TI-P-103 INDICATOR - CLEAN RM5				2009/12/5			2010/12/5
11	TED-P-101 SENSOR AND TI-P-101 INDICATOR - CAPING RM1				2009/12/5			2010/12/5
12	TED-P-104 SENSOR AND TI-P-104 INDICATOR - VIAL WASHING RM1				2009/12/5			2010/12/5
13	TED-P-105 SENSOR AND TI-P-105 WASHINH RM3				2009/12/5			2010/12/5
14	TED-P-101 SENSOR AND HI-P-101 INDICATOR - CAPPING RM				2009/12/5			2011/12/5
15	TED-P-102 SENSOR AND HI-P-102 INDICATOR - FILLING RM				2009/12/5			2011/12/5
16	TED-P-103 SENSOR AND HI-P-103 INDICATOR - CLEAN RM5				2009/12/5			2011/12/5
17	TED-P-104 SENSOR AND HI-P-101 INDICATOR - CAPING RM2				2009/12/5			2011/12/5
18	TED-P-105 SENSOR AND HI-P-105 WASHINH RM3				2009/12/5			2011/12/5
9	PIA-P-101 CAPPING RM - CORRIDOR 7	Bulk and Medium Dept.	Pressure (Difference pressure gauge KAL84 HALSTRUP)	Different pressure ± 2.0Pa	11/12/2008	Pass	1	11/12/2009
10	PIA-P-102 FILLING RM-CAPPING RM				11/12/2008			11/12/2009
11	PIA-P-103 CLEAN RM5-CORRIDOR7				11/12/2008			11/12/2009
12	PIA-P-104 IN9-2 - CORRIDOR7				11/12/2008			11/12/2009
13	PIA-P-105 FILLING RM - VIAL WASHING RM				11/12/2008			11/12/2009
14	PIA-P-106 ANTE RM6 - CORRIDOR7				11/12/2008			11/12/2009
15	PIA-P-107 VIAL WASHING RM - CORRIDOR7				11/12/2008			11/12/2009
16	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2				13/03/2009			13/03/2010
17	TED-P-103-2 SENSOR AND RP-2-2 INDICATOR - COLD RM-2				13/03/2009			13/03/2010
18	TED-P-103-4 SENSOR AND TIC-PI03-2 INDICATOR - COLD RM-2				13/03/2009			13/03/2010
19	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1				13/03/2009			13/03/2010
20	TED-P-104-1 SENSOR AND RP-2-3 INDICATOR - INCUBATION RM-1				13/03/2009			13/03/2010
21	TED-P-104-2 SENSOR AND TIC-PI04-1 INDICATOR - INCUBATION RM-1				13/03/2009			13/03/2010
22	TED-P-103-1 SENSOR AND RP-2-2 INDICATOR - INCUBATION RM-2				13/03/2009			13/03/2010
23	TED-P-103-1 SENSOR AND RP-2-1 INDICATOR - INCUBATION RM-2				13/03/2009			13/03/2010
24	TED-P-103-3 SENSOR AND TIC-PI03-1 INDICATOR - INCUBATION RM-2				13/03/2009			13/03/2010
25	TED-P-105-1 SENSOR AND RP-2-4 INDICATOR - COLD RM-1				13/03/2009			13/03/2010
26	TED-P-105-1 SENSOR AND RP-2-42000 RECORDER - COLD RM-1				13/03/2009			13/03/2010
27	TED-P-107-2 SENSOR AND TIC-PI07-1 INDICATOR - INCUBATION RM-3				19/03/2009			13/03/2010
28	TED-P-107-2 SENSOR AND RP-3 - 12000 RECORDER - INCUBATION RM-3				19/03/2009			13/03/2010
29	TED-P-107-2 SENSOR AND RP-3-2-INDICATOR - INCUBATION RM-3				19/03/2009			13/03/2010
30	TED-P-107-1 SENSOR AND RP-3-2-INDICATOR - COLD RM-5				19/03/2009			13/03/2010
31	TED-P-107-1 SENSOR AND RP-3-12000 RECORDER - COLD RM-5				19/03/2009			13/03/2010

No.	Name of equipment	Dept.	Validation method for equipment	Criteria	Implementati on date	Pass/not pass	CAL frequency (year)	Expired date
42	THE-P-201 SENSOR AND TI-P-201 THAWING RM	Bulk and Medium Dept.	Temperature (Thermohygro recorder- TRU-72U)	Different temperature ± 0.81°C	08/01/2009	Pass	2	08/01/2011
43	THE-P-202 SENSOR AND TI-P-202 CLEAN RM3				08/01/2009			08/01/2011
44	THE-P-203 SENSOR AND TI-P-203 CLEAN RM4				08/01/2009			08/01/2011
45	THE-P-206 SENSOR AND TI-P-206 DISINFECTION RM1				08/01/2009			08/01/2011
46	THE-P-204 SENSOR AND TI-P-204 DISINFECTION RM2				08/01/2009			08/01/2011
47	THE-P-205 SENSOR AND TI-P-205 WASHING RM1		Humidity	Different humidity ± 0.5%	08/01/2009	Pass	2	08/01/2011
48	THE-P-207 SENSOR AND TI-P-207 MEDIA PREPARATION RM1.				08/01/2009			08/01/2011
49	THE-P-209 SENSOR AND TI-P-209 CLEAN RM1.				08/01/2009			08/01/2011
50	THE-P-210 SENSOR AND TI-P-210 CLEAN RM2.				08/01/2009			08/01/2011
51	THE-P-208 SENSOR AND TI-P-208 CUTTING RM				08/01/2009			08/01/2011
52	THE-P-211 SENSOR AND TI-P-211 STERILEFILTRATION RM2		Pressure	Different pressure ± 2.0Pa	08/01/2009	Pass	1	08/01/2011
53	THE-P-212 SENSOR AND TI-P-212 OBSERVATION RM2				08/01/2009			08/01/2011
54	THE-P-201 SENSOR AND HI-P-201 THAWING RM				08/01/2009			08/01/2011
55	THE-P-202 SENSOR AND HI-P-202 CLEAN RM3				08/01/2009			08/01/2011
56	THE-P-203 SENSOR AND HI-P-203 CLEAN RM4				08/01/2009			08/01/2011
57	THE-P-206 SENSOR AND HI-P-206 DISINFECTION RM1				08/01/2009			08/01/2011
58	THE-P-204 SENSOR AND HI-P-204 DISINFECTION RM2				08/01/2009			08/01/2011
59	THE-P-205 SENSOR AND HI-P-205 WASHING RM1		Pressure	Different pressure ± 2.0Pa	08/01/2009	Pass	1	08/01/2011
60	THE-P-207 SENSOR AND HI-P-207 MEDIA PREPARATION RM1				08/01/2009			08/01/2011
61	THE-P-209 SENSOR AND HI-P-209 MEDIA PREPARATION RM1				08/01/2009			08/01/2011
62	THE-P-210 SENSOR AND HI-P-210 CLEAN RM2				08/01/2009			08/01/2011
63	THE-P-208 SENSOR AND HI-P-208 CUTTING RM				08/01/2009			08/01/2011
64	THE-P-211 SENSOR AND HI-P-211 STERILEFILTRATION RM2		Pressure	Different pressure ± 2.0Pa	08/01/2009	Pass	1	08/01/2011
65	THE-P-212 SENSOR AND HI-P-212 OBSERVATION RM2				08/01/2009			08/01/2011
32	PdIA-P-201 THAWING RM - CORRIDORS				09/01/2009	Pass	1	09/01/2010
33	PdIA-P-202 CLEAN RM3 - CORRIDORS				09/01/2009			09/01/2010
34	PdIA-P-203 CLEAN RM4 - CORRIDORS				09/01/2009			09/01/2010
35	PdIA-P-204 ANTE RM4 - CORRIDORS				09/01/2009			09/01/2010
36	PdIA-P-205 DISINFECTION RM2 - CORRIDORS				09/01/2009			09/01/2010
37	PdIA-P-206 WASHING RM1 - CORRIDORS		Pressure	Different pressure ± 2.0Pa	09/01/2009	Pass	1	09/01/2010
38	PdIA-P-207 DISINFECTION RM1 - CORRIDORS				09/01/2009			09/01/2010
39	PdIA-P-208 MEDIA PREPARATION RM - CORRIDORS				09/01/2009			09/01/2010
40	PdIA-P-209 CLEAN RM1 - CORRIDOR6				09/01/2009			09/01/2010
41	PdIA-P-210 CLEAN RM2 - CORRIDOR6				09/01/2009			09/01/2010
42	PdIA-P-211 CUTTING RM - CORRIDOR6		Pressure	Different pressure ± 2.0Pa	09/01/2009	Pass	1	09/01/2010
43	PdIA-P-212 STERILEFILTRATION RM - CORRIDOR6				09/01/2009			09/01/2010
44	PdIA-P-213 ANTE RM1 - CORRIDOR6				09/01/2009			09/01/2010
45	PdIA-P-214 PREPARATION RM - CORRIDOR10				09/01/2009			09/01/2010
46	PdIA-P-214 CENTRIFUGATION & OBSERVATION RM1 - CORRIDOR6				09/01/2009			09/01/2010
47	PdIG-P-203 PR11 - DISINFECTION RM2	Bulk and Medium Dept.	Pressure	Different pressure ± 2.0Pa	20/03/2009	Pass	1	20/03/2009
48	PdIG-P-204 PR7 - ANTE RM4				20/03/2009			20/03/2009
49	PdIG-P-205 PR6 - CORRIDORS				20/03/2009			20/03/2009

No.	Name of equipment	Dept.	Validation method for equipment	Criteria	Implementati on date	Pass/not pass	CAL frequency (year)	Expired date
84	THE-P-215 SENSOR AND TI-P-215 CLEAN RM6	QC	Temperature	Different temperature $\pm 0.81^{\circ}\text{C}$	20/03/2009	Pass	2	20/03/2011
85	THE-P-216 SENSOR AND TI-P-216 CLEAN RM7				20/03/2009			20/03/2011
86	THE-P-213 SENSOR AND TI-P-213 CLEAN RM8		Humidity	Different humidity $\pm 0.5\%$	20/03/2009			20/03/2011
87	THE-P-214 SENSOR AND TI-P-214 PREPERATION RM				20/03/2009			20/03/2011
88	THE-P-215 SENSOR AND HI-P-215 CLEAN RM6				20/03/2009			20/03/2011
89	THE-P-216 SENSOR AND HI-P-216 CLEAN RM7				20/03/2009			20/03/2011
90	THE-P-213 SENSOR AND HI-P-213 CLEAN RM8				20/03/2009			20/03/2011
91	THE-P-214 SENSOR AND HI-P-214 PREPERATION RM				20/03/2009			20/03/2011
59	PdIA-P-215 PREPARATION RM - CORRIDORI0		Pressure	Different pressure $\pm 2.0\text{Pa}$	18/03/2009	Pass	1	18/03/2010
60	PdIA-P-216 CLEAN RM8 - CORRIDORI0				18/03/2009			18/03/2010
61	PdIA-P-217 IN12 - CHANGING RM12				18/03/2009			18/03/2010
62	PdIA-P-218 CLEAN RM6 - CORRIDORI0				18/03/2009			18/03/2010
63	PdIA-P-219 CLEAN RM7 - CORRIDORI0				18/03/2009			18/03/2010
64	PdIG-P-201 OUT 11-2 - PERFORMANCE TEST RM	Animal lab	Pressure	Different pressure $\pm 2.0\text{Pa}$	18/03/2009	Pass	1	18/03/2010
65	PdIG-P-202 IN11-2 - CHANGING RM11				18/03/2009			18/03/2010
66	PdIA_A-101 DIRTY CORRIDORI - CORRIDORIA				19/03/2009			19/03/2010
67	PdIA_A-102 ANTE RM - CORRIDORIA				19/03/2009			19/03/2010
68	PdIA_A-103 DIRTY CORRIDOR2 - CORRIDORIA				19/03/2009			19/03/2010

Result of validation and maintenance of HVAC system in 2009

Updated on: 30/08/2009

Periodical validation and maintenance of HVAC system : 1 time/ 1 year

Protocol Doc.#: M06-PRO-VAL-64

NO.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
1	Ante room 6	101-01	Final producti on	Check leakage and air changing frequency	• There is no leakage in any checking point • Air changing frequency ≥ 20 times/1 hour	28/04/2009	Pass	28/04/2010
2		101-02				28/04/2009	Pass	28/04/2010
3		101-03				28/04/2009	Pass	28/04/2010
4	Clean room 5	101-04				28/04/2009	Pass	28/04/2010
5		101-05				28/04/2009	Pass	28/04/2010
6		101-06				28/04/2009	Pass	28/04/2010
7	Filling room	101-07				28/04/2009	Pass	28/04/2010
8		101-08				28/04/2009	Pass	28/04/2010
9		101-09				28/04/2009	Pass	28/04/2010
10		101-10				28/04/2009	Pass	28/04/2010
11		101-11				28/04/2009	Pass	28/04/2010
12		101-12				28/04/2009	Pass	28/04/2010
13		101-13				28/04/2009	Pass	28/04/2010
14		101-14				28/04/2009	Pass	28/04/2010
15		101-15				28/04/2009	Pass	28/04/2010
16	AI 9-1	101-16				28/04/2009	Pass	28/04/2010
17	AI 9-2	101-17				28/04/2009	Pass	28/04/2010
18	In 9-2	101-18				28/04/2009	Pass	28/04/2010
19	AI	101-19				28/04/2009	Pass	28/04/2010
20	Capping room	102-01				28/04/2009	Pass	28/04/2010
21		102-02				28/04/2009	Pass	28/04/2010
22	In 9-1	102-03				28/04/2009	Pass	28/04/2010
23	Pr 14	102-04				28/04/2009	Pass	28/04/2010
24	Washing rm 3	102-05				28/04/2009	Pass	28/04/2010
25		102-06				28/04/2009	Pass	28/04/2010
26		102-07				28/04/2009	Pass	28/04/2010
27		102-08				28/04/2009	Pass	28/04/2010
28		102-09				28/04/2009	Pass	28/04/2010
29		102-10				28/04/2009	Pass	28/04/2010
30	Vial&Sterili rm	102-11				25/04/2009	Pass	25/04/2010
31		102-12				25/04/2009	Pass	25/04/2010
32		102-13				25/04/2009	Pass	25/04/2010
33		102-14				25/04/2009	Pass	25/04/2010
34		102-15				25/04/2009	Pass	25/04/2010
35	In Out 10	102-16				25/04/2009	Pass	25/04/2010
36	Pr 16	102-17				25/04/2009	Pass	25/04/2010
37	Disinfection rm 3	102-18				25/04/2009	Pass	25/04/2010
38	Pr 15	102-19				25/04/2009	Pass	25/04/2010
39	Corridor 4	201-01	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking point • Air changing frequency ≥ 20 times/1 hour	16/01/2009	Pass	16/01/2010
40		201-02				16/01/2009	Pass	16/01/2010
41		201-03				16/01/2009	Pass	16/01/2010
42	Pr 8	201-04				16/01/2009	Pass	16/01/2010
43	Freezing rm	201-05				16/01/2009	Pass	16/01/2010
44	Thawing	201-06				16/01/2009	Pass	16/01/2010
45	Refrigerator rm 2	201-07				16/01/2009	Pass	16/01/2010
46		201-08				16/01/2009	Pass	16/01/2010
47	Storage 4	201-09				16/01/2009	Pass	16/01/2010
48	In 5	201-10				16/01/2009	Pass	16/01/2010
49	Refrigerator rm 2	201-11				16/01/2009	Pass	16/01/2010
50	Corridor 3	202-01				15/01/2009	Pass	15/01/2010
51		202-02				15/01/2009	Pass	15/01/2010
52	Clean rm 4	202-03				15/01/2009	Pass	15/01/2010
53		202-04				15/01/2009	Pass	15/01/2010
54		202-05				15/01/2009	Pass	15/01/2010
55		202-06				15/01/2009	Pass	15/01/2010
56	Clean rm 3	202-07				15/01/2009	Pass	15/01/2010
57		202-08				15/01/2009	Pass	15/01/2010
58		202-09				15/01/2009	Pass	15/01/2010
59		202-10				15/01/2009	Pass	15/01/2010

NO.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
60	Ante rm 4	202-11	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking point • Air changing frequency ≥ 20 times/1 hour	15/01/2009	Pass	15/01/2010
61		202-12				15/01/2009	Pass	15/01/2010
62	Disinfection rm 2	202-13				15/01/2009	Pass	15/01/2010
63		202-14				15/01/2009	Pass	15/01/2010
64	Storage 3	202-15				15/01/2009	Pass	15/01/2010
65	Pr 6	202-16				15/01/2009	Pass	15/01/2010
66	Al 6	202-17				15/01/2009	Pass	15/01/2010
67	In 6	202-18				15/01/2009	Pass	15/01/2010
68	Ante rm 3	202-19				15/01/2009	Pass	15/01/2010
69		202-20				15/01/2009	Pass	15/01/2010
70	Pr 7	202-21				15/01/2009	Pass	15/01/2010
71	Pr 11	202-22				15/01/2009	Pass	15/01/2010
72	Corridor 2	203-01				15/01/2009	Pass	15/01/2010
73		203-02				15/01/2009	Pass	15/01/2010
74		203-03				15/01/2009	Pass	15/01/2010
75	Centri&Observa	203-04				15/01/2009	Pass	15/01/2010
76		203-05				15/01/2009	Pass	15/01/2010
77	Storage 2	203-06				15/01/2009	Pass	15/01/2010
78		203-07				15/01/2009	Pass	15/01/2010
79	Refrigerator rm 1	203-08				15/01/2009	Pass	15/01/2010
80		203-09				15/01/2009	Pass	15/01/2010
81		203-10				15/01/2009	Pass	15/01/2010
82	Pr 5	203-11				15/01/2009	Pass	15/01/2010
83	In 4-2	203-12				15/01/2009	Pass	15/01/2010
84	Centri&Observa	203-13				15/01/2009	Pass	15/01/2010
85	Clean rm 1	204-01				14/01/2009	Pass	14/01/2010
86		204-02				14/01/2009	Pass	14/01/2010
87		204-03				14/01/2009	Pass	14/01/2010
88		204-04				14/01/2009	Pass	14/01/2010
89	Clean rm 2	204-05				14/01/2009	Pass	14/01/2010
90		204-06				14/01/2009	Pass	14/01/2010
91		204-07				14/01/2009	Pass	14/01/2010
92	Ante rm 1	204-08				14/01/2009	Pass	14/01/2010
93		204-09				14/01/2009	Pass	14/01/2010
94		204-10				14/01/2009	Pass	14/01/2010
95		204-11				14/01/2009	Pass	14/01/2010
96	Corridor 1	204-12				14/01/2009	Pass	14/01/2010
97		204-13				14/01/2009	Pass	14/01/2010
98	Storage 1	204-14				14/01/2009	Pass	14/01/2010
99		204-15				14/01/2009	Pass	14/01/2010
100	Sterile Filtration	204-16				14/01/2009	Pass	14/01/2010
101		204-17				14/01/2009	Pass	14/01/2010
102	Cutting rm	204-18				14/01/2009	Pass	14/01/2010
103		204-19				14/01/2009	Pass	14/01/2010
104	Al 4	204-20				14/01/2009	Pass	14/01/2010
105	In 4-1	204-21				14/01/2009	Pass	14/01/2010
106	Pr 13	204-22				14/01/2009	Pass	14/01/2010
107	Ante rm 2	204-23				14/01/2009	Pass	14/01/2010
108	Pr 14	204-24				14/01/2009	Pass	14/01/2010
109	Pr 3	204-25				14/01/2009	Pass	14/01/2010
110	Pr2	204-26				14/01/2009	Pass	14/01/2010
111	Disinfection rm 1	261-01				14/01/2009	Pass	14/01/2010
112	In 3-1	261-02				14/01/2009	Pass	14/01/2010
113	Media Preparation	262-01				14/01/2009	Pass	14/01/2010
114		262-02				14/01/2009	Pass	14/01/2010
115	Pr 12	262-03				14/01/2009	Pass	14/01/2010
116	In 3-2	262-04				14/01/2009	Pass	14/01/2010
117	Check weight	262-05				14/01/2009	Pass	14/01/2010
118	Storage 6	212-01				13/01/2009	Pass	13/01/2010
119	Storage 5	212-02				13/01/2009	Pass	13/01/2010
120	Laundry rm	212-03				13/01/2009	Pass	13/01/2010
121		212-04				13/01/2009	Pass	13/01/2010

NO.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
122	Washing rm 1	212-05	Bulk Dept.	Check leakage and air changing frequency	• There is no leakage in any checking point • Air changing frequency ≥ 20 times/1 hour	13/01/2009	Pass	13/01/2010
123		212-06				13/01/2009	Pass	13/01/2010
124		212-07				13/01/2009	Pass	13/01/2010
125		212-08				13/01/2009	Pass	13/01/2010
126		212-09				13/01/2009	Pass	13/01/2010
127		212-10				13/01/2009	Pass	13/01/2010
128		212-11				13/01/2009	Pass	13/01/2010
129		212-12				13/01/2009	Pass	13/01/2010
130	In Out 7	212-13				13/01/2009	Pass	13/01/2010
131	Washing rm 2	212-14				13/01/2009	Pass	13/01/2010
132		212-15				13/01/2009	Pass	13/01/2010
133		212-16				13/01/2009	Pass	13/01/2010
134		212-17				13/01/2009	Pass	13/01/2010
135	Pr 9	212-18				13/01/2009	Pass	13/01/2010
136	Storage 7	212-19				13/01/2009	Pass	13/01/2010
137	Pr 1	212-20				13/01/2009	Pass	13/01/2010
138	Pr 10	212-21				13/01/2009	Pass	13/01/2010
139	Observation Area	208-01	QC	Check leakage and air changing frequency	• There is no leakage at any checking point • Air changing frequency ≥ 20 times/1 hour	25/03/2009	Pass	25/03/2010
140		208-02				25/03/2009	Pass	25/03/2010
141	Refrigerator rm 3	208-03				25/03/2009	Pass	25/03/2010
142		208-04				25/03/2009	Pass	25/03/2010
143	Clean rm 7	208-05				25/03/2009	Pass	25/03/2010
144		208-06				25/03/2009	Pass	25/03/2010
145	Incubation rm 2	208-07				25/03/2009	Pass	25/03/2010
146	Clean rm 6	208-08				25/03/2009	Pass	25/03/2010
147		208-09				25/03/2009	Pass	25/03/2010
148	Pr 19	208-10				25/03/2009	Pass	25/03/2010
149	AI 11-1	208-11				25/03/2009	Pass	25/03/2010
150	In 11-1	208-12				25/03/2009	Pass	25/03/2010
151	Clean rm 8	209-01				25/03/2009	Pass	25/03/2010
152		209-02				25/03/2009	Pass	25/03/2010
153		209-03				25/03/2009	Pass	25/03/2010
154	Preparation rm	209-04				25/03/2009	Pass	25/03/2010
155		209-05				25/03/2009	Pass	25/03/2010
156	AI 12-2	209-06				25/03/2009	Pass	25/03/2010
157	AI 12-1	209-07				25/03/2009	Pass	25/03/2010
158	In 12	209-08				25/03/2009	Pass	25/03/2010
159	Performance test	211-01				25/03/2009	Pass	25/03/2010
160		211-02				25/03/2009	Pass	25/03/2010
161	AL 11-2	211-03				25/03/2009	Pass	25/03/2010
162	In 11-2	211-04				25/03/2009	Pass	25/03/2010
163	Dirty corridor 1	101-01	Animal lab	Check leakage and air changing frequency	• There is no leakage at any checking point • Air changing frequency ≥ 20 times/1 hour	17/04/2009	Pass	17/04/2010
164	Quarantine rm 1	101-02				17/04/2009	Pass	17/04/2010
165	Material out 1	101-03				17/04/2009	Pass	17/04/2010
166	Inocubation rm 1	101-04				17/04/2009	Pass	17/04/2010
167	Rabbits test rm	101-05				17/04/2009	Pass	17/04/2010
168	Inocubation rm 2	101-06				17/04/2009	Pass	17/04/2010
169	Guinea Pigs test rm	101-07				17/04/2009	Pass	17/04/2010
170	Clean Corridor 1	101-08				17/04/2009	Pass	17/04/2010
171	Ante rm	101-09				17/04/2009	Pass	17/04/2010
172	Ante rm	102-01				17/04/2009	Pass	17/04/2010
173	Clean corridor 2	102-02				17/04/2009	Pass	17/04/2010
174	AutoPsy rm 2	102-03				17/04/2009	Pass	17/04/2010
175	Quarantine rm 2	102-04				17/04/2009	Pass	17/04/2010
176	Mice Test rm 1	102-05				18/04/2009	Pass	17/04/2010
177	Inocubation rm3	102-06				18/04/2009	Pass	17/04/2010
178	Mice Test rm 2	102-07				18/04/2009	Pass	17/04/2010
179	Inoculation rm 4	102-08				17/04/2009	Pass	17/04/2010
180	Dirty corridor 2	102-09				17/04/2009	Pass	17/04/2010

Validation and maintenance in 2009

Updated date: 30/08/2009

Periodical validation and maintenance for equipment: 1 time/ 1 year
Protocol Doc#: M06-PRO-VAL-62

No.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
1	Máy tiệt trùng lọ (Vial Sterilizing Machine)	BE-03691	Final Production	Temperature and Wind flow	• Check wind speed in sterilization cellar. Result measured from each area must satisfy: 80% must pass = average velocity is $\pm 20\%$ 100% must pass = average velocity is $\pm 30\%$ • Check HEPA in sterilization cellar: - Infeed zone. Number of particle is 0.3 μm which must be less than 0.01% of total particles for infeed. - Heating zone. Quantity of particle is 0.3 μm which must be less than 0.05% of particles for infeed. - Cooling zone. Number of particle is 0.3 μm which must be less than 0.01% of total particles for infeed. • Check cleanliness in sterilization cellar - Infeed zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute - Heating zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute - Cooling zone. Quantity of particle is 0.5 μm which must be less than 100 particles and there is no 5 μm particles during one minute • Check heat distribution in sterilization cellar Temperature in the chamber must be more than 300°C.	2008/12/12	Pass	2009/12/12
2	Clean Bench B	G264920501	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow Average velocity: $0.35\text{m/sec} \pm 0.35*20\%$ Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ 0.3 μm	19/05/2009	Pass	19/05/2010
3	Clean Bench B	G264930501	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow Average velocity: $0.35\text{m/sec} \pm 0.35*20\%$ Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ 0.3 μm	19/05/2009	Pass	19/05/2010
4	Clean Bench B	G264930502	QC	Check leakage, wind velocity and wind flow	• Wind velocity and flow Average velocity: $0.35\text{m/sec} \pm 0.35*20\%$ Wind flow: $23.5\text{m}^3/\text{min} \pm 23.5\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ 0.3 μm	19/05/2009	Pass	19/05/2010

No.	Name of equipment	Code	Dept.	Method	Criteria	Validation date	Pass/not pass	Expired date
16	Clean Bench C	G264950501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.35\text{m/sec} \pm 0.35*20\%$ - Wind flow: $36\text{m}^3/\text{min} \pm 36\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2009/8/5	Pass	2010/8/5
17	Clean Bench E	G264970501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.4\text{m/sec} \pm 0.4*20\%$ - Wind flow: $23\text{m}^3/\text{min} \pm 23\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2009/8/5	Pass	2010/8/5
18	Laminar Flow Unit	G242550501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: - AFU 1: $241\text{m}^3/\text{min} \pm 241\text{m}^3*20\%$ - AFU 1: $133\text{m}^3/\text{min} \pm 133\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2009/7/5	Pass	2010/8/6
19	Laminar Flow Unit	G242560501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: $53\text{m}^3/\text{min} \pm 53\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2009/6/5	Pass	2010/8/7
20	Laminar Flow Unit	G242570501	Final Production	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: $43\text{m}^3/\text{min} \pm 43\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	2009/6/5	Pass	2010/8/8
21	Laminar Flow Unit	G242580501	Medium	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: $30\text{m}^3/\text{min} \pm 30\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	22/01/2009	Pass	22/01/2010
22	Laminar Flow Unit	G242590501	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $0.3\text{m/sec} \pm 0.3*20\%$ - Wind flow: $18\text{m}^3/\text{min} \pm 18\text{m}^3*20\%$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	22/01/2009	Pass	22/01/2010
23	Laminar Flow Unit B	5114-01277-CB100	QC - Chemical	Check leakage, wind velocity and wind flow	• Wind velocity and flow - Average velocity: $\geq 0.35\text{m/sec}$ • Leakage : filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	20/05/2009	Pass	20/05/2010
24	Biological Safety Cabinet	NSC-IIA-1800	Bulk	Check leakage, wind velocity and wind flow	• Wind velocity - The distance between the below and surface of Hepa Filter 100mm : $0.35\text{m/sec} \pm 0.025\text{m/s}$ -At wind suction in gate : $0.53 \pm 0.025\text{m/s}$ • Leakage: Filtration output of Hepa $\geq 99.97\%$ $0.3\text{ }\mu\text{m}$	22/01/2009	Pass	22/01/2010

Result of calibrating sensor of water generation system in 2009

Updated on: 30/08/2009

Frequency of Cal of sensor of WFI generation system: 1time 1year

NO.	Name of equipment	Code of equipment	Position	Calibrator	Criteria	Cal date	Pass/not pass	Expried Date
1	SW Heat Exchanger Outlet Temp.	TIRCA-1101	Deionization system of water (First floor)	Thermal Cal equipment (Ametek ITC-155A)	Temperature 70°C ± 0.7°C 80°C ± 0.8°C 90°C ± 0.8°C	21/01/2009	Pass	21/01/2010
2	Soft Water Tank Drain Temp.	TRS-1181		Thermal Cal equipment (Ametek ITC-155A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	21/01/2009	Pass	21/01/2010
3	Row Temp.	TRS-1201		Thermal Cal equipment (Ametek ITC-155A)	Temperature 70°C ± 0.6°C 80°C ± 0.6°C 90°C ± 0.7°C	21/01/2009	Pass	21/01/2010
4	UFW Heater Outlet Temp.	TIRCA-3102	WFI distribution system (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	21/01/2009	Pass	21/01/2010
5	UFW Heater Inlet Temp.	TRS-3101		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
6	UFW Feed Tank Return Temp.	TRS-3103		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
7	UFW Tank Temp.	TRS-4101	UFW generation system (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
8	UFW Return Temp.	TRS-4102		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
9	VF-4102 SIP	TRS-4181		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
10	P-4101 SIP	TRS-4182		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
11	UFW Return SIP Temp.	TRS-4183		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
12	P-4102 Temp.	TRS-4184		Thermal Cal equipment (Ametek ITC-320A)	Temperature 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010

NO.	Name of equipment	Code of equipment	Position	Calibrator	Criteria	Cal date	Pass/hot pass	Expired Date
13	UFW-① SIP Temp.	TRSU-181	Freeze drying room (Used point) (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
14	UFW-② SIP Temp.-1	TRSU-281	Washing room 3 (Used point) (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
15	UFW-② SIP Temp.-2	TRSU-282		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
16	UFW-③ SIP Temp.-1	TRSU-381	Washing room 2 (Used point) (second floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
17	UFW-③ SIP Temp.-2	TRSU-382		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
18	UFW-④ SIP Temp.	TRSU-481	Sterilization room 2 (second floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
19	UFW-⑤ SIP Temp.	TRSU-581	Sterilization room 3 (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
20	Condenser Outlet Temp.	TIRCA-6101	UFW generation system (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	21/01/2009	Pass	21/01/2010
21	WFI Cooler Outlet Temp.	TRA-6102		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
22	WFI Heater Outlet Temp.	TIRCA-7103	WFI distribution system (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.9°C 120°C ± 1.0°C 130°C ± 1.0°C	21/01/2009	Pass	21/01/2010
23	WFI Tank Temp.	TRS-7101		Thermal Cal equipment (Ametek ITC-320A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
24	WFI Return Temp.	TRS-7102		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010

NO.	Name of equipment	Code of equipment	Position	Calibrator	Criteria	Cal date	Pass/hot pass	Expried Date
25	WFI Generation Outlet SIP Temp.	TRS-7181	WFI distribution system (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
26	P-7101 SIP Temp.	TRS-7182		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
27	WFI Return SIP Temp.	TRS-7183		Thermal Cal equipment (Ametek ITC-320A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
28	HE-7101 Outlet SIP Temp.	TRS-7184		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
29	VE-7101 SIP Temp.	TRS-7185		Thermal Cal equipment (Ametek ITC-320A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
30	WFI-① SIP Temp	TRS-W181	Washing and sterilization room (the first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
31	LC-WFI2 SIP Temp.-1	TRS-W281	Washing room 3(first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
32	LC-WFI2 SIP Temp.-2	TRS-W282		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
33	LC-WFI3 SIP Temp.-1	TRS-W381		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
34	LC-WFI3 SIP Temp.-2	TRS-W382		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
35	LC-WFI2 SIP Temp.-3	TRS-W284	Filtration room (first floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010

NO.	Name of equipment	Code of equipment	Position	Calibrator	Criteria	Cal date	Pass/not pass	Expired Date
36	LC-WFI4 SIP Temp.-1	TRS-W481	Medium preparation room (the second floor)	Thermal Cal equipment (Ametek ITC-320A)	Temp. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
37	LC-WFI4 SIP Temp.-2	TRS-W482		Thermo Calibrator (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
38	WFI-5 SIP Temp	TRS-W581	Washing room (second floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
39	LC-WFI6 SIP Temp.-1	TRS-W681	Washing room 1 (second floor)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
40	LC-WFI6 SIP Temp.-2	TRS-W682		Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
41	UFW&WFI SIP Temp.	TRS-5101	PS Unit (1F)	Thermal Cal equipment (Ametek ITC-320A)	Temperature. 110°C ± 0.8°C 120°C ± 0.8°C 130°C ± 0.9°C	21/01/2009	Pass	21/01/2010
42	UFW Return Pressure	PICA-4101	UFW generation system	Pressure Cal equipment (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	21/01/2009	Pass	21/01/2010
43	Pure Steam Pressure	PICA-5101	PS Unit	Pressure Cal equipment (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	21/01/2009	Pass	21/01/2010
44	Pure Steam Pressure	PICA-6101	UFW generation system	Pressure Cal equipment (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	21/01/2009	Pass	21/01/2010
45	WFI Return Pressure	PICA-7101	WFI distribution system	Pressure Cal equipment (Ametek CPC200C)	Pressure 0.00MPa ± 0.01MPa 0.25MPa ± 0.02MPa 0.50MPa ± 0.02MPa	21/01/2009	Pass	21/01/2010

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Result of calibration for equipment in 2009

Updated date: 30/08/2009

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
1	QC	Autoclave B						
		Thermal sensor - Channel of measuring temperature in chamber	TE1-1	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.1	TE1-2	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	
		Thermal sensor - Channel of measuring temperature in chamber	TE3-1	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.2	TE3-2	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	
		Thermal sensor - channel to measure heat of waste water filter	TE4-1	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
		Thermal sensor - kênh ghi nhiệt bộ lọc nước thải CH.3	TE4-2	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	
		Thermal sensor - Channel of measuring temperature in chamber	TE5-1	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.4	TE5-2	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	
		Thermal sensor - Channel of recording temperature in chamber CH.5	TE 6	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
5	QC	Recorder of Incubator A						
		Thermal sensor - Channel of recording temperature in chamber	TE 7	111, 121, 131(°C)	02/01/2009	Pass	02/01/2010	1
		Loop to measure pressure in chamber	PE - 1-1	0,100,200,300,-90(kPa)	02/01/2009	Pass	02/01/2010	
		Loop to record pressure in chamber CH.12	PE - 1-2	0,100,200,300,-90(kPa)	02/01/2009	Pass	02/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE1-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE2-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE3-1	50,40,30(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal Sensor - Channel of recording temperature/khoang Incubator B 23oC (CH.5)	TE1	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber Incubator C 31oC (CH.1)	TE2	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber Incubator C 31oC (CH.4)	TE3	50,40,30(°C)	16/03/2009	Pass	16/03/2010	1
6	QC	Recorder of Incubator B, C						
		Thermal sensor - Channel of recording temperature in chamber Incubator C 58oC (CH.6)	TE4	50,40,30(°C)				1
		Channel to measure temperature	TE1	50,60,70	19/02/2009	Pass	19/02/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE1-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE2-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE3-1	50,40,30(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE1	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE2	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE3	50,40,30(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE4	50,40,30(°C)				1
7	QC	Vacuum dry oven						
		Thermal sensor - Channel of recording temperature in chamber	TE1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE2-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE3-1	50,40,30(°C)	23/01/2009	Pass	23/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE1	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE2	40,30,20(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE3	50,40,30(°C)				1
		Thermal sensor - Channel of recording temperature in chamber	TE4	50,40,30(°C)				1
		Channel to measure temperature	TE1	50,60,70	19/02/2009	Pass	19/02/2010	1
		Thermal sensor - Channel of recording temperature in chamber	TE1-1	40,30,20(°C)	23/01/2009	Pass	23/01/2010	1

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
9	CO2 Incubator A M02-15-03/03/03	Thermal sensor - Channel of recording temperature in chamber	30,40,50(oC)	At 30oC: ≤±0.5(oC) At 40oC: ≤±0.6(oC) At 50oC: ≤±0.7(oC)	23/03/2009	Pass	23/03/2010	1
		Sensor of CO2 concentration	3,5,7(%)	≤±1(%)	23/03/2009	Pass	23/03/2010	1
		Thermal sensor - Channel of recording temperature in chamber	30,40,50(oC)	At 30oC: ≤±0.5(oC) At 40oC: ≤±0.6(oC) At 50oC: ≤±0.7(oC)	11/03/2009	Pass	11/03/2010	1
10	CO2 Incubator B M02-15-01/03/03	Sensor of CO2 concentration	3,5,7(%)	≤±1(%)	11/03/2009	Pass	11/03/2010	1
		Thermal sensor- Channel of recording temperature in chamber	30,40,50(oC)	At 30oC: ≤±0.5(oC) At 40oC: ≤±0.6(oC) At 50oC: ≤±0.7(oC)	11/03/2009	Pass	11/03/2010	1
		Sensor of CO2 concentration	3,5,7(%)	≤±1(%)	11/03/2009	Pass	11/03/2010	1
11	Egg Incubator	Thermal sensor - Channel of recording temperature in chamber	30,40,50(oC)	≤±1(oC)	11/03/2009	Pass	11/03/2010	1
12	Lab. Autoclave for Chemical	Thermal sensor - Channel of recording temperature in chamber	110,120,130(oC)	≤±1(oC)	11/03/2009	Pass	11/03/2010	1
		Loop to measure pressure in chamber	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	19/02/2009	Pass	19/02/2010	1
		Thermal sensor - Channel of recording temperature in chamber	110,120,130(oC)	≤±1(oC)	18/02/2009	Pass	18/02/2010	1
13	Lab. Autoclave for Bio.	Loop to measure pressure in chamber	0.1, 0.12, 0.14(Mpa)	≤±0.01(Mpa)	18/02/2009	Pass	18/02/2010	1
		Thermal sensor- Channel of recording temperature in chamber	100,125,250(oC)	At 100: ≤±0.61(oC) At 125: ≤±0.64(oC) At 250: ≤±0.82(oC)	04/03/2009		04/03/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	100,125,250(oC)	At 100: ≤±0.57(oC) At 125: ≤±0.63(oC) At 250: ≤±0.92(oC)	04/03/2009		04/03/2010	1
14	Dry Oven	Thermal sensor - Channel of recording temperature in chamber	100,125,250(oC)	At 100: ≤±3.5(oC) At 125: ≤±3.5(oC) At 250: ≤±3.5(oC)	04/03/2009	Pass	04/03/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	100,125,250(oC)	At 100: ≤±3.5(oC) At 125: ≤±3.5(oC) At 250: ≤±3.5(oC)	04/03/2009	Pass	04/03/2010	1
		Pressure Sensor - channel to measure pressure in chamber	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	04/03/2009	Pass	04/03/2010	1
	Freezer : -30°C Qty: 4	Pressure Sensor - Channel to record pressure in chamber	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	04/03/2009		04/03/2010	1
		Pressure Sensor - channel to measure pressure in chamber	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	04/03/2009		04/03/2010	1
		Pressure Sensor - Channel to record pressure in chamber	0,150,300(Pa)	At 0: ≤±7(Pa) At 150: ≤±5(Pa) At 300: ≤±5.5(Pa)	04/03/2009		04/03/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Recorder	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Recorder	-30(oC)	≤±7(oC)	18/04/2009	Pass	18/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Recorder	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Recorder	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	-30(oC)	≤±7(oC)	18/04/2009		18/04/2010	1

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
	Freezer : -70°C Qty: 3	Thermal sensor- Channel of measuring temperature in chamber	TE1-1	-70(oC)	17/04/2009	Pass	17/04/2010	
		Thermal sensor- Recorder	TE1-2	-70(oC)	17/04/2009		17/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	TE2-1	-70(oC)	17/04/2009		17/04/2010	
		Thermal sensor- Recorder	TE2-2	-70(oC)	17/04/2009		17/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	TE3-1	-70(oC)	17/04/2009		17/04/2010	
		Thermal sensor- Recorder	TE3-2	-70(oC)	17/04/2009		17/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber	TE4-1	-70(oC)	17/04/2009		17/04/2010	
		Thermal sensor- Recorder	TE4-2	-70(oC)	17/04/2009		17/04/2010	1
		Thermal sensor- Channel of measuring temperature in chamber (incubator: 5030295)	TE1-1	5(oC)	2009/7/2		2010/7/2	
		Thermal sensor- Recorder (incubator: 5030295)	TE1-2	5(oC)	2009/7/2		2010/7/2	1
		Thermal sensor- Channel of measuring temperature in chamber (incubator: 5030295)	TE2-1	5(oC)	2009/7/2		2010/7/2	
		Thermal sensor- Recorder (incubator: 5030295)	TE2-2	5(oC)	2009/7/2		2010/7/2	1
19 Medium	Refrigerator : 5°C Qty: 2	Thermal sensor- Channel of measuring temperature in chamber	TE1-1	111 , 121 , 131(oC)	06/01/2009	Pass	06/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.1	TE1-2	111 , 121 , 131(oC)	06/01/2009		06/01/2010	
		Thermal sensor- Channel of measuring temperature in chamber	TE3-1	111 , 121 , 131(oC)	06/01/2009		06/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.2	TE3-2	111 , 121 , 131(oC)	06/01/2009		06/01/2010	
		Thermal sensor - channel to measure heat of waste water filter	TE4-1	111 , 121 , 131(oC)	06/01/2009		06/01/2010	1
		Thermal sensor - channel to measure heat of waste water filter CH.3	TE4-2	111 , 121 , 131(oC)	06/01/2009		06/01/2010	
		Thermal sensor- Channel of measuring temperature in chamber	TE5-1	111 , 121 , 131(oC)	06/01/2009		06/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.4	TE5-2	111 , 121 , 131(oC)	06/01/2009		06/01/2010	
		Thermal sensor - Channel of recording temperature in chamber CH.5	TE 6	111 , 121 , 131(oC)	06/01/2009		06/01/2010	1
		Thermal sensor - Channel of recording temperature in chamber CH.6	TE 7	111 , 121 , 131(oC)	06/01/2009		06/01/2010	1
		Loop to measure pressure in chamber	PE - 1-1	0,100,200,300,400,-900(RPa)	06/01/2009		06/01/2010	1
		Loop to record pressure in chamber CH.12	PE - 1-2	0,100,200,300,400,-900(RPa)	06/01/2009		06/01/2010	1

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
20	Medium	Dry Oven	Thermal sensor - Channel of measuring temperature in chamber	TE1-1	100,125,250(°C)	At 100: $\leq \pm 0.61(°C)$ At 125: $\leq \pm 0.64(°C)$ At 250: $\leq \pm 0.82(°C)$	2010/8/1	1
			Thermal sensor - Channel of recording temperature in chamber	TE1-2	100,125,250(°C)			1
			Thermal sensor - Channel of measuring temperature in chamber	TE2-1	100,125,250(°C)	At 100: $\leq \pm 0.57(°C)$ At 125: $\leq \pm 0.63(°C)$ At 250: $\leq \pm 0.92(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber	TE2-2	100,125,250(°C)			1
			Thermal sensor - Channel of measuring temperature in chamber	TE3-1	100,125,250(°C)	At 100: $\leq \pm 3.5(°C)$ At 125: $\leq \pm 3.5(°C)$ At 250: $\leq \pm 3.5(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber	TE3-2	100,125,250(°C)			1
			Pressure sensor - channel to measure pressure in chamber	PE1-1	0,150,300(Pa)	At 0: $\leq \pm 7(Pa)$ At 150: $\leq \pm 5(Pa)$ At 300: $\leq \pm 5.5(Pa)$		1
			Pressure sensor - channel to record pressure in chamber	PE1-2	0,150,300(Pa)			1
			Pressure sensor - channel to record pressure in chamber	PE2-1	0,150,300(Pa)	At 0: $\leq \pm 7(Pa)$ At 150: $\leq \pm 5(Pa)$ At 300: $\leq \pm 5.5(Pa)$		1
			Pressure sensor - channel to measure pressure in chamber	PE2-2	0,150,300(Pa)			1
21	BP	Autoclave A-2	Pressure sensor - channel to measure pressure in chamber	PE2-3	0,150,300(Pa)		05/01/2009	1
			Thermal sensor - Channel of measuring temperature in chamber	TE1-1	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber CH.1	TE1-2	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of measuring temperature in chamber	TE3-1	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber CH.2	TE3-2	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - channel to measure heat of waste water filter	TE4-1	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - channel to measure heat of waste water filter CH.3	TE4-2	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of measuring temperature in chamber	TE5-1	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber CH.4	TE5-2	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
			Thermal sensor - Channel of recording temperature in chamber CH.5	TE 6	111, 121, 131(°C)	$\leq \pm 0.5(°C)$		1
23	BP	Egg Incubator	Thermal sensor - Channel of recording temperature in chamber CH.6	TE 7	111, 121, 131(°C)	$\leq \pm 0.5(°C)$	06/01/2010	1
			Loop to measure pressure in chamber	PE - 1-1	0,100,200,300,-90(kPa)	$\leq \pm 5(kPa)$		1
			Loop to record pressure in chamber CH.12	PE - 1-2	0,100,200,300,-90(kPa)			1
			Thermal sensor - Channel of recording temperature in chamber	TE2	30,40,50(°C)	At 30°C: $\leq \pm 0.5(°C)$ At 40°C: $\leq \pm 0.6(°C)$ At 50°C: $\leq \pm 0.7(°C)$		1
			Humidity Sensor - Channel to measure humidity	HE1	70(%)	$\leq \pm 5(%)$		1
23	BP	Incubator for egg stock	Thermal sensor - Channel of recording temperature in chamber	TE1	10,15,20(°C)	$\leq \pm 1(°C)$	06/01/2009	1

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
24	BP	Dry Oven	TE1-1	100,125,250(oC)	08/01/2009	Pass	08/01/2010	1
			TE1-2	100,125,250(oC)	08/01/2009		08/01/2010	
			TE2-1	100,125,250(oC)	08/01/2009		08/01/2010	1
			TE2-2	100,125,250(oC)	08/01/2009		08/01/2010	
			TE3-1	100,125,250(oC)	08/01/2009		08/01/2010	1
			TE3-2	100,125,250(oC)	08/01/2009		08/01/2010	
			PE1-1	0,150,300(Pa)	08/01/2009		08/01/2010	1
			PE1-2	0,150,300(Pa)	08/01/2009		08/01/2010	
			PE1-3	0,150,300(Pa)	08/01/2009		08/01/2010	1
			TE1-2	-30(oC)	07/01/2009		07/01/2010	
			TE2-2	-30(oC)	07/01/2009		07/01/2010	1
			TE3-2	-30(oC)	07/01/2009		07/01/2010	
	BP	Freezer:-70°C Qty: 4 MDF-U581	TE4-2	-30(oC)	07/01/2009	Pass	07/01/2010	1
			TE1-2	-70(oC)	07/01/2009		07/01/2010	
			TE2-2	-70(oC)	07/01/2009		07/01/2010	1
			TE3-2	-70(oC)	07/01/2009		07/01/2010	
			TE4-2	-70(oC)	07/01/2009		07/01/2010	1
			TE1-2	-70(oC)	06/01/2009		06/01/2010	
			TE2-2	-70(oC)	06/01/2009		06/01/2010	1
			TE3-2	-70(oC)	06/01/2009		06/01/2010	
			B210	40,60,100(oC)	06/01/2009		06/01/2010	1
			PIA 110	950,500,0(kPa)	2008/10/12		2009/10/12	
			PIA 120	950,500,0(kPa)	2008/10/12		2009/10/12	1
			PIA 121	250,125,0(kPa)	2008/10/12		2009/10/12	
28	FP	Vial washing machine	PIA 130	950,500,0(kPa)	2008/10/12	Pass	2009/10/12	1
			TE 211	280,300,320(oC)	2008/10/12		2009/10/12	
			TE 213	280,300,320(oC)	2008/10/12		2009/10/12	1
			Channel to measure and record temperature in area 1	AI 280: ≤±2.0(oC) AI 300: ≤±2.2(oC) AI 320: ≤±2.4(oC)	2008/10/12		2009/10/12	
			Channel to measure and record temperature in area 2	AI 280: ≤±2.0(oC) AI 300: ≤±2.2(oC) AI 320: ≤±2.4(oC)	2008/10/12		2009/10/12	1
			Channel to measure pressure	≤±30(kPa)	2008/10/12		2009/10/12	
			Channel to measure pressure	≤±30(kPa)	2008/10/12		2009/10/12	1
			Channel to measure pressure	≤±30(kPa)	2008/10/12		2009/10/12	
			Channel to measure and record temperature in area 1	AI 280: ≤±2.0(oC) AI 300: ≤±2.2(oC) AI 320: ≤±2.4(oC)	2008/10/12		2009/10/12	1
			Channel to measure and record temperature in area 2	AI 280: ≤±2.0(oC) AI 300: ≤±2.2(oC) AI 320: ≤±2.4(oC)	2008/10/12		2009/10/12	
			Channel to measure pressure	≤±30(kPa)	2008/10/12		2009/10/12	1
			Channel to measure pressure	≤±30(kPa)	2008/10/12		2009/10/12	

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
30	FP	Autoclave A-1	TE1-1	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			TE1-2	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	
			TE3-1	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			TE3-2	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	
			TE4-1	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			TE4-2	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	
			TE5-1	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			TE5-2	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	
			TE 6	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			TE 7	111, 121, 131(°C)	≤±0.5(°C)	09/12/2008	09/12/2009	1
			PE - 1-1	0,100,200,300,-90(kPa)	≤±5(kPa)	10/12/2008	10/12/2009	1
			PE - 1-2	0,100,200,300,-90(kPa)	≤±5(kPa)	10/12/2008	10/12/2009	
			TE101	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE102	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	
30	FP	Freeze dryer	TE103	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	
			TE104	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	
			TE105	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE106	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE107	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE108	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE109	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE110	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE111	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE112	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE113	120,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE201	30,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			TE201A	30,20,0(°C)	≤±1(°C)	15/12/2008	15/12/2009	1
			Thermal sensor - Channel of recording temperature in chamber (product 1 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 2 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 3 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 4 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 5 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 6 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 7 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 8 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 9 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 10 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 11 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 12 temp)					
			Thermal sensor - Channel of recording temperature in chamber (product 13 temp)					
			Thermal sensor - Channel of recording temperature (silicic acid inlet temp)					
			Thermal sensor - Channel of recording temperature (silicic acid outlet temp)					

No.	Equipment	Item	Cal Point	Odd range	Cal date	Pass/not pass	Expired date	Frequency (year)
30	FP Freeze dryer	Thermal sensor- Channel of recording temperature(silicool oil outlet)	TE202	30,20,0(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender coil 1 temp)	TE203	30,20,0(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender coil 2 temp)	TE204	30,20,0(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender coil 3 temp)	TE205	30,20,0(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(chamber drain temp)	TE212	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender drain temp)	TE212A	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender drain temp)	TE213	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender drain temp)	TE213A	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(consender drain temp)	TE214	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(filter drain temp)	TE214A	130,120,110(oC)	≤±1(oC)	15/12/2008	15/12/2009	1
		Thermal sensor- Channel of recording temperature(filter drain temp)						
		Thermal sensor- Channel of recording temperature(filter drain temp)						

Result of calibration of equipment in 2009 by outside companies

Updated on: 30/08/2009

No.	Name of equipment	Quantity	Dept.	Manufacturer	Model	Serial	Cal frequency	Cal date 2009	Receive certificate of Equip.j
1	Integrity test	3	Final production	Millipore	XIY4S0001	IT40332	1	14/04/2009	X
			Môi trường	Millipore	XIY4S0001	IT40001		14/04/2009	X
			Bán thành phẩm	Millipore	XITXACTPI	W20855		14/04/2009	X
2	Particle counter A2400	3	Thành phẩm	Hach Ultra	A2400 LL	50601041	1	2009/4/1	x
			Bán thành phẩm	Hach Ultra		50601042			
			QC	Hach Ultra		50601043			
3	Particle counter (portable)227B	5	Final production	Hach Ultra	227B	51200047	1	2009/8/4	x
				Hach Ultra	227B				
				Hach Ultra	227B				
				Hach Ultra	227B	51200048			
				Hach Ultra	227B	51200049			
4	Air Sampler B (M Air T)	1	Medium	Millipore	Cat No.: ATBPUMP01	276	1	14/04/2009	X
5	Air Sampler A	3	Final production	Sartorius	MD8 Air port 16757		1	2009/4/2	x
			QC	Sartorius	MD8 Air port 16757				
			Bulk	Sartorius	MD8 Air port 16757	17601125			
6	Integrity test	1	Medium	Pall	Part No:FFSXC	22289326	1	2008/12/11	x
7	Surface temp. meter)	2	Medium	TES-Taiwan	TES-1304		1		
			Final production	TES-Taiwan	TES-1304	050500759	1	29/12/2008	x
8	Sensors in water system (Sensor to measure conductivity: CIRA-7101, CI1201; CI1202, CI1302, CIRA-4101, CIRA-6101; Sensor do TOC: TOC-7101; Sensor to measure water level of tank: LIA-7101, LIA-4101;)	9 (sensor)	Engineering	Melter và Yamatake			1		
9	Particle counter KC-01E	1	Engineering	Rion Japan	KC-01E		1	28/04/2009	x
10	Standard Thermometer	1	Engineering	Sato Japan	Code :0022 *Temp range: -50 to 0 degC		3		
11	Standard Thermometer	1	Engineering	Sato Japan	Code: 0022 *Temp range: 0 to 50 degC		3		
12	Standard Thermometer	1	Engineering	Sato Japan	Code: No.0022 *Temp range: 50 to 100 degC		3		
13	Standard Thermometer	1	Engineering	Sato Japan	Code: No.0022 *Temp range: 100 to 150 degC		3		
14	Hybrid Recorder	2	Engineering	Yokogawa Japan	DR232-12-00-1S/M1/H1	91FC57643	2	29/12/2008	x
			Engineering			91FC57644		29/12/2008	x
15	Temperature Calibrator	1	Engineering	JOFA/AMETEK DENMARK/EU	ITC-320 A 115/230V+PE	552656-00181	1	29/12/2008	x
16	Pressure Calibration	1	Engineering	JOFA/AMETEK DENMARK/EU	CPC200CC1NDG	9185017	1	29/12/2008	x
17	Thermo-Hygro Recorder	30	Engineering	T&D Japan	TR72U	có 30 thiết bị	2	29/12/2008	x
18	Digital temperature indicator	1	Engineering	AMETEK	DTI-1000	564803-00193	1	29/12/2008	x
19	Dry block temperature calibrator	1	Engineering	AMETEK	ITC-155A	560279-00634	1	29/12/2008	x
20	Anemometer	1	Engineering	KANOMAX	6541/6543	635537	1	29/12/2008	x
21	Micro manometer	1	Engineering	HALSTRUP KRONE COMPANY	KAL 84	9095.0208KH08073	1	29/12/2008	x
22	Particle counter 237B	1	Engineering	HACH ULTRA ANALYTICS	237B		1	2009/4/12	x
23	Pressure Sensor of freeze drying machine	3	Final production	Edward		076012021	2	25/11/2008	x
						66179601		25/11/2008	x
						66468721		25/11/2008	x

Annex 11: Summary of Issued Certificates

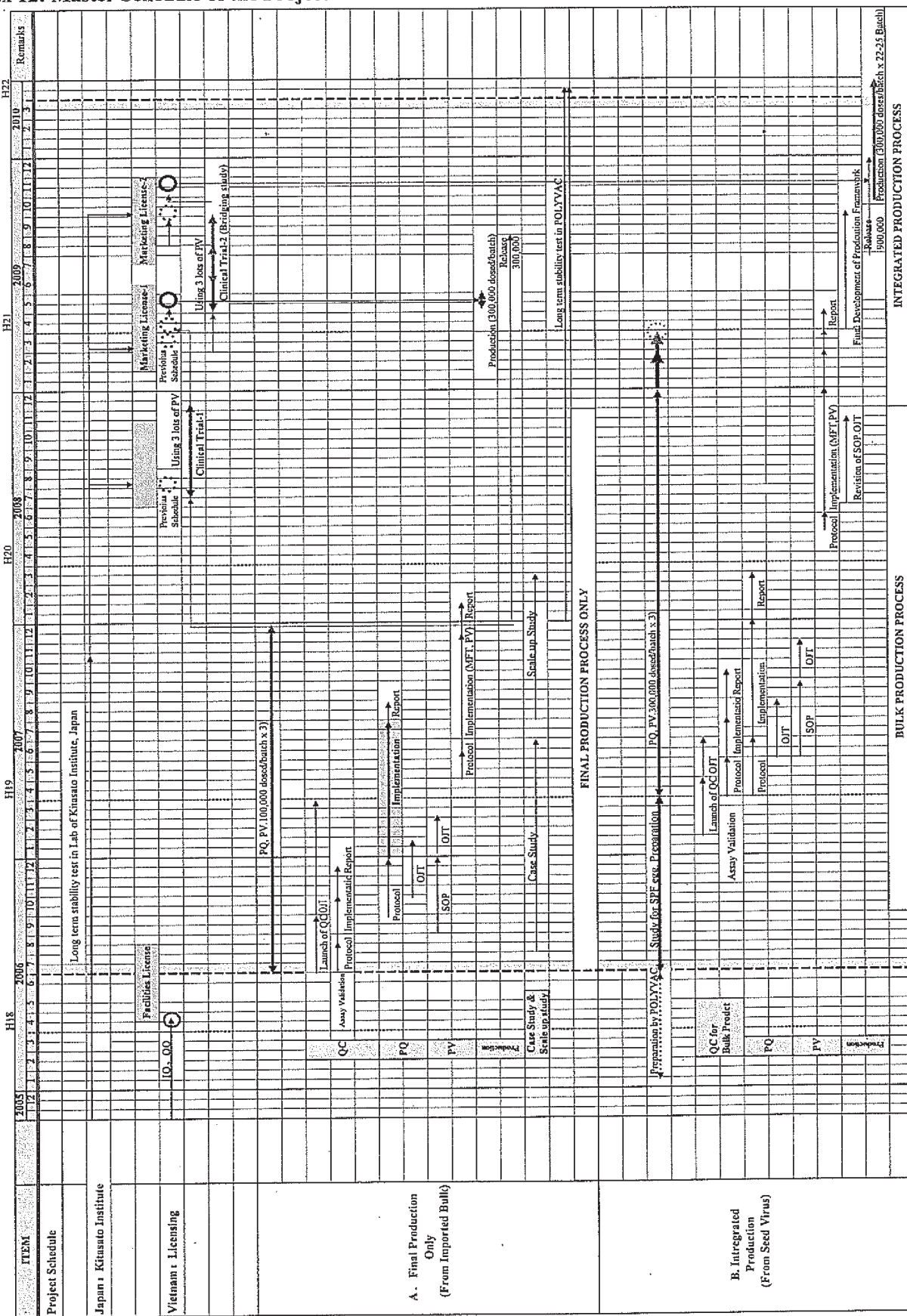
Name of Department/Year	Date of Issued	Date of Issued	Nos. of Process or Test	Nos. of Certificated Persons	Remarks
1. Final Production					
1.1 FY 2006	14 Jan. 2007	13	16	5	
	9 Mar. 2007	5	5	5	
	12 Mar. 2007	10	25	8	
1.2 FY 2007	19 Oct. 2007	40	102	14	
1.3 FY 2008	22 Oct. 2007	1	1	1	
1.4 FY 2008	16 Jan. 2009	19	28	28	
2. Medium Preparation					
2.1 FY 2006	14 Mar. 2007	16	16	5	
2.2 FY 2007	6 Jul. 2007	4	4	1	
	9 Jul. 2007	5	10	3	
	12 Jul. 2007	4	7	3	
	16 Jul. 2007	2	4	2	
	3 Oct. 2007	33	46	4	
	23 Jan. 2008	2	2	2	
3. Quality Control					
3.1 FY 2006 Biological	23 Oct. 2006	6	10	3	
	22 Dec. 2006	2	3	2	
	16 Mar. 2007	2	3	2	
3.2 FY 2007 Biological	24 Aug. 2007	11	11	1	
	11 Jan. 2008	10	13	2	
3.3 FY 2008 Biological	25 Jul. 2008	1	2	2	
	14 Nov. 2008	2	2	2	
3.4 FY 2009 Biological	14 Aug. 2009	3	3	2	
3.5 FY 2006 Chemical	20 Nov. 2006	12	104	2	
	24 Nov. 2006	5	33	3	
	6 Dec. 2007	1	20	1	
	7 Dec. 2007	1	8	1	
	8 Dec. 2007	9	36	1	
	1 Feb. 2007	2	28	2	
3.6 FY 2007 Chemical	27 Apr. 2007	1	2	1	
	3 May 2007	1	11	2	
	4 May 2007	1	9	1	
	12 May 2007	2	19	1	
	15 May 2007	1	20	1	
	16 May 2007	6	12	1	
	17 May 2007	8	38	2	
	18 May 2007	4	8	1	
	22 May 2007	6	26	3	
	15 Jun. 2007	5	20	1	
	31 Jul. 2007	4	5	2	
3.7 FY 2007 Animal-1	13 Jun. 2007	2	2	1	
3.8 FY 2007 Animal-2	13 Jun. 2007	3	6	2	
4. Bulk Production					
4.1 FY 2006	-	-	-	-	
4.2 FY 2007	14 Jun. 2007	10	2	2	
	15 Jun. 2007	10	2	2	
	29 Jun. 2007	10	20	2	
	3 Jul. 2007	8	22	4	
	6 Jul. 2007	2	5	5	
	12 Jul. 2007	5	10	2	
	14 Jul. 2007	9	19	4	

Annex 12: Master Schedule of the Project

Rev-9: 15 September 2001
Rev-8: 20 February 2009

Technical Cooperation Project for Strengthening Capacity for Measles Vaccine Production

Annex 12: Master Schedule of the Project



Annex 13: List of Working Groups

POLIVAC

LIST OF WORKING GROUPS

Date: 28 May 2009												
rev. 12												
Klasato												
Member												
No.	Code	Name	Leader	Sub Leader	BP	MP	FP	QA	QC	Eng	Supporting	
1	WG-1	Calibration/Validation	Nguyễn Đăng Anh	Nguyễn Thụy Hương	Nguyễn Xuân Hòa	Le Tuấn Anh	Le Quốc Hưng	Nguyễn Thụy Hương	Nguyễn Hu Anh Thu	Nguyễn Đăng Anh	Katsuda	
				Ha Hoàng Phương	Nguyễn Danh Bình	Ta Kim Quốc	Trần Tài Phương	Nguyễn Thị Nguyệt	Dang Anh Tuan	Nakashima		
				Le Văn Dung	Nguyễn Thái Học	Nguyễn Đăng Cường		Ngô Thị Thanh Hương	Nguyễn Mạnh Cường			
				Phạm Lê Tuấn		Nguyễn Berti Nguyễn			Cao Minh Đức			
2	WG-2	Formalin Fumigation	Nguyễn Xuân Hòa	Trần Thị Phương	Nguyễn Xuân Hòa	Nguyễn Thái Học	Le Quốc Hưng	Trần Thị Phương	Nguyễn Hu Anh Thu	Nguyễn Mạnh Cường	Sato	
				Ha Hoàng Phương	Nguyễn Danh Bình	Ta Kim Quốc	Phạm Thị Phương Thao	Nguyễn Thị Nga	Cao Minh Đức	Katsuda		
				Le Văn Dung	Le Trí Cảnh	Nguyễn Đăng Cường		Vũ Thị Hương				
					Le Tuấn Anh	Nguyễn Mạnh Hân		Ngô Thị Thanh Hương				
3	WG-3	Environmental Pollution Control	Nguyễn T. Mai Hương (Ms. Dung)	Trần Thị Phương	Lai Quỳnh Mai	Le Tuấn Anh	Trần Minh Tuấn	Trần Thị Phương	Nguyễn T. Mai Hương	Cao Minh Đức	Sato	
					Le Văn Dung	Nguyễn Thái Học	Nguyễn T. Thanh Văn		Le Thị Hương		Katsuda	
			Nguyễn Hu Anh Thu	Ha Hoàng Phương	Ha Hoàng Phương	Nguyễn Danh Bình	Dang Ngan Ha	Le Thị Hòa	Nguyễn Hu Anh Thu	Luu Van Chien	Sato	
					Phạm Văn Khôi	Nguyễn Thái Học	Nguyễn L. Ngọc Thanh		Phạm Anh Thu		Katsuda	
4	WG-4	Environmental Monitoring			Phạm Thanh Trường							
			Trần Trọng Hải (Mr. Hiep)	Le Thu Nga	Nguyễn Xuân Hòa	Le Trí Cảnh	Le Quốc Hưng	Nông Thị Thanh Văn	Nguyễn Thị Nguyệt	Cao Minh Đức	Myagawa	
					Ha Hoàng Phương	Le Tuấn Anh	Nguyễn Bình Nguyễn				Katsuda	
5	WG-5	Procurement Control			Vũ Thị Mai							
					Nguyễn Thị Khuyen							
			Nguyễn Mạnh Dũng (Mrs. Thuý)	Nguyễn Đăng Quỳnh	Nguyễn Xuân Hòa	Le Tuấn Anh	Nguyễn Đăng Quỳnh	Trần Thị Phương	Nguyễn Thị Nguyệt	Nguyễn Mạnh Cường	Myagawa	
					Le Văn Dung	Nguyễn Thái Học	Nguyễn Bình Nguyễn				Katsuda	
6	WG-6	Risk Management	Nguyễn Thụy Hương	Ha Hoàng Phương	Nguyễn Xuân Hòa	Le Tuấn Anh	Nguyễn Bình Nguyễn	Le Thu Nga	Nguyễn Thị Mai Hương	Dang Anh Tuan	Nakashima	
					Lai Quỳnh Mai	Nguyễn Danh Bình	Ta Kim Quốc	Ngô Thị Thanh Hương				
					Phạm Văn Khôi		Nguyễn Bình Nguyễn		Ngô Thị Mai Hương (P)			
7	WG-7	Document Control										
8	WG-8	Clinical trial	Nguyễn Hu Anh Thu	Nguyễn Thụy Hương	Nguyễn Đăng Hân	Nguyễn Tài Thanh Văn	Nguyễn L. Ngọc Thanh	Trần Thị Phương	Trần Bích Hạnh		Dr. Lee	
PIC for Department:			Dept.	Main	Sub	Dept.	Main	Sub				
	Bulk	Van Chi	QC	Heng	Van Chi							
	Medium	Phuong	QA	Van Chi	Al							
	Final	Cuc										
	Engineering	Phuong										