3．プロジェクト実施上の諸問題

3－1　ポリオワクチンに係る進捗状況

3－1－1　技術移転の現状

1）Bia Farma 製単価ウイルス原液について

1992年4月より，試験製造開始以来の成果として，Bio Farma 製1型（BF102）36ℓ，2型（BF202）94ℓ，3型（BF301）62ℓの単価ウイルス原液が製造され，今回それらが製品として使用可能か調査した。いずれも全ての試験を完了していないが，特に重要なサルによる神経毒力試験では1型は合格，2型は試験中，3型は病理標本を観察中で，近く成績がまとまる。他の試験では問題はないようである。1993年8月末に，これらのウイルス原液を混合して Bio Farma 製第1ロット製造に向って始動できるものと考える。

2）最終製品用安定剤

Bio Farma 側と検討した結果3 W/V % Sucrose とすることに決った。

3）最終製品第1ロット（目標120万 doses）製造を8月末に設定し，それ迄に準備・訓練すべき点につき指導した。

4）製造用仔カニクイザルの確保

Bio Farma は現在次の2つの方法で仔ザルを得る方法を確立しつつある。

①野生ザルの中から妊娠ザルを選択的に購入

②新動物棟にて雌雄成熟ザルを同居させて繁殖する

妊娠ザルは捕獲後環境の変化による stress のため流産死産する頻度が高く，問題があるようであるが，妊娠経験ザルとして②の自家繁殖に使用出来るので，予想以上に早く仔ザル自家繁殖が確立されるであろう。

ちなみに1993年5月26日現在確保されている仔ザルは21頭，飼育中の妊娠ザルは26頭で Foamy ウイルス抗体陰性成熟ザルは34頭である。この様に，製造用には仔ザルを重要視する事が現実に進行している。年間製造用仔ザルの数として我々はとりあえず50頭を目標とするよう指示をした。

5）神経毒力試験

8月に予定されている Bio Farma の TOPV 第一ロットのコンポーネントとして Bio Farma 製の1型，3型（2型は試験中）の単価バルクが使用可能か否かを検討した。全ての病理標本を観察したのではないが結果は次頁の如くであった。

	1型	3型
WHO参照ウイルス	N.O (1.26)	1.02
Bio Farma 〃	1.21 (1.36)	N.O
単価バルク	0.89 (1.09)	1.04

( ) 内は Bio Farma のカウンターパートの観察結果

N.O.＝Not yet observation

数字は病変数値 (Lesion score)

この様に1型 (BF102) は問題なく使用可能である。また，3型 (BF301) は WHO 参照ウイルスより僅かに病変数値が高いが，この程度は充分 WHO の合格基準内であり，これも使用可能と判断した。2型 (BF202) の試験については，病理標本を日本に送り，日本で確認する事とした。

3－1－2　Bio Farma のポリオワクチン製造のための技術的達成度

①製造に関して

製造用サルの選択と繁殖→洗浄・準備・滅菌→Media の調整→細胞培養→ウイルス培養→単価バルクの調整→Blending 分注→包装，工程中，Blending 分注と包装は未経験であるが，サルに関しては50%，他の工程は75～80%の達成度と考えられ，1994年8月迄の本 project 終了までには，どの工程も90%近くは達成出来よう。

②品質管理に関して

Inprocess として進められる品質管理は，大別してウイルス含量試験，同定試験，外来性因子否定試験，ウイルスの遺伝的性状 (マーカー) 試験，サルによる神経毒力試験があげられ，いずれも60%程度の達成度と思われる品質管理に係わる試験は，ウイルス学的基礎知識を背景に，応用問題的判断を要する Case が多く，この点に関しては数年間実地に経験を積むことが肝要である。

3－1－3　WHO 査察受け入れ態勢つくり

1993年8月に予定される WHO 生物学的製剤管理責任者の査察に備え，受け入れ時の points について討議した。特に，サル⇄ヒト間の感染症防止対策，製造手技，製造・試験記録の管理，情報の伝達の確立が大切であることを指導した。

3－1－4　人員の配置

現在ポリオ関係の職員は，administrator である Drs. Benny, Kartimi, Ina を除き，製造関係15名，品質管理関係15名，サル管理7名，はしかとの共通部門としての media 調整3名，製造関係洗浄室8名，品質管理洗浄室8名で，必要とする人員はスケールアップに応じて増員されており，Bio Farma 中枢の理解と職員の熱意が感じられ，ほぼ計画通りに技術移転が進んでいる。

3－1－5 問題点

1）Foamy ウイルス抗体陽性ザルの処理

Bio Farma は地の利を生かして野生成熟ザルや妊娠ザルを購入するルートを拓き，Clean な親ザル→野生妊娠ザルから得た仔ザル→自家繁殖仔ザルへと Clean なサル供給の道が確立されつつあるが，野生成熟ザルで Foamy ウイルス抗体陽性サルが出る頻度は80%程度で，そのサルの処置に苦慮している。

2）消耗器材の補充

製造の規模が増大するに従って，消耗器材の消耗が目立ち，自国製品に切り換えようにも infrastructure が育ってないため，自助努力にも限りがあり，製造を継続するには援助する側にも今後特別の配慮が必要であろう。

3－2 麻疹ワクチンに係る進捗状況

1．業務内容

次の各項目についての移転状況を調査・検討し，今後の対応について打合せ。

1）原液製造

2）最終製品製造

3）品質管理

4）原材料の調達

3－2－1 技術移転の現状

1）原液製造（資料1）

1992年1月より，作業員のトレーニングを目的に小規模で製造を開始，比較的順調に進んだが，工程中の細菌混入あるいは，ワクチンウイルスの対照細胞への混入等の失敗を経験した。これらの失敗がトレーニングを一層効果的にしたものと考えられる。1992年6月以降は問題はなく1992年11月までは徐々に規模を拡大して，翌12月より計画当初の目的規模まで上げることができた。それ以降目的規模で生産を続け現在に到っている。現在すでにワクチン原液の手持量は1～2年分をストックしている。現在の製造規模は月間約400万人分であり，目的の年間750万～1,000万人分の最終製品を作るための原液製造期間は工程中のロスを見ても年間3～4か月で十分である。

尚，原液製造用種ウイルスも，Bio Farma で調製し向う20～30年間製造可能であり，原液製造に関する技術移転は完了したものと思う。

2）最終製品の製造（小分・凍結乾燥工程）（資料1）

小分，凍結乾燥工程は，1991年6月～12月にトレーニングを兼ねた試作ワクチンの製造を6ロット行った。使用した資材（ゴム栓）の前処理が不十分なため3ロットは失敗した

が，問題解決後の３ロットは成功した。1992年１月より現在まで合計25ロットを製造し結果は，一部試験中のものを除き，全ての試験に合格した。この中から初始の５ロットについては，（財）阪大微研会でも検査を行ったが，Bio Farma の成績と一致し，全て満足する結果であった。1992年10月下旬からの生産は，凍結乾燥機の能力100％の規模で本格的な生産態勢に入っている。

現在までに製造した凍結乾燥完了品は553万人分であり内134万人分は包装も完了し出荷待ちの状態にある。以前に輸入したワクチンの在庫のなくなる1993年６月から出荷が予定されている。

目的の年間750万～1,000万人分の完成品を製造するためには，約６～８か月を必要とする。

以上の状況と，この Bio Farma 製ワクチンで実施された試験結果から，Bio Farma は，インドネシア保健省から製造販売に関する承認を1993年２月18日付で得ている。以上の状況から判断して，この分野の技術移転は完了したものと思う。

３）品質管理

品質管理に必要な試験に関する技術は移転終了し，原液製造工程での初期の失敗，さらに小分，凍結乾燥工程に於いても初期のいくつかの失敗を品質管理側の検査結果で明らかにすることができた。この失敗の原因究明を行い，対策を検討して，問題を解決することも経験した。今後も失敗することが予想されるが，その頻度は極めてまれであり，内容もこれまでに経験したものであると考えられる。いずれにしても，失敗の原因は，設備機器の故障，原材料に帰因するもの，作業従事者の失敗の三つである。

これからは，自から経験を積んで行くことが品質管理を一層充実させることになる。但し常に，作業員の教育訓練，原材料の管理，設備機器の管理を充実に実行し続けることが必要である。

４）原材料の調達

①Specific phathogen free（SPF）ニワトリ胎児。（資料１）

アイソレーター内での小群飼育方式による，SPF ニワトリを維持することを確立して（1991年），現在に到っているが，途中で，次世代の準備をおこたり，SPF ニワトリ種卵の生産量の減少を経験した。現在は週200～300個を生産している。その有精率は70％以上である。これは，製造，品質管理に十分量である。

SPF 鶏群のモニタリングの結果，SPF であることを証明されているが，モニタリングの方法については多少の検討が必要であり，現在継続中である。

品質管理に使用する一定の遺伝子形質（C/O）を持つ SPF 鶏群の確立は現在進行中であり，まもなく確立されるものと思われる。

②牛血清（細胞培養用培地に使用）

使用可能な牛血清は現地調達が可能であることがわかり，現在原地産牛血清の規格試験の技術移転中である。

③小分・包装材料

現地調達品で十分であることが実証され，供給される実績もできて，今後の問題はないものと思う。

3－2－2　今後の対策

原液の製造，最終製品の製造，品質管理に関する基本技術は全て移転終了したことが確認された。（資料2）

現在，原材料としてのSPFモニタリング用試薬の調製，現地牛血清の供給とその品質管理に関する技術移転が進行中であり，本プロジェクトの期間中には終了する見込みである。

設備，機器のメインテナンスを十分行なわれるよう，システム作りが必要であるが，岩本長期専門家により完成するものと考えられる。

PROGRESS REPORT OF MEASLES VACCINE PRODUCTION

I. PRODUCTION RESULTS.

1. JULY - DECEMBER 1991.

- SINGLE HARVEST : 7 BATCHES FROM 13 BATCHES (= 53%).
- CLARIF.OF BULK : 5 BATCHES FROM 7 BATCHES (= 71%).
- FINAL PRODUCT (=VACCINE) : 3 BATCHES FROM 6 BATCHES (= 50%).

2. JANUARY - DECEMBER 1992.

- SINGLE HARVEST : 30 BATCHES FROM 34 BATCHES (= 88.2%).
- CLARIF.OF BULK : 22 BATCHES FROM 24 BATCHES (= 91.6%).
- FINAL PRODUCT (=VACCINE): 18 BATCHES FROM 18 BATCHES (=100%).

3. JANUARY - MAY 1993.

- SINGLE HARVEST : 22 BATCHES.
- CLARIF.OF BULK : 5 BATCHES.
- FINAL PRODUCT (=VACCINE): 7 BATCHES.

II. TENTATIVE ANNUAL ROUTINE PRODUCTION.

1. TARGET OF VACCINE PRODUCTION : 1,000,000 VIAL / YEAR.

x 3 ml

↓

2. PREPARATION OF FINAL BULK : 3,000,000 ml

: 10 (DILUTION RATE)

↓

3. PREPARATION OF BULK : 300,000 ml (= 300 L).

FOR SPARE : + 50%

↓

450 L / YEAR.

↓

IF 20 L / BATCH OF SINGLE HARVEST

↓

4. EXPLANTATION OF EGG : 22.5 (= 23) BATCHES / YEAR.

↓

23 WEEKS (= 6 MONTHS) / YEAR.

↓

5. SPF EGGS NEEDED : 23 x 100 EGGS = 2,300 EGGS /YEAR.

III. STOCK OF BULK.

1. BULK MATERIAL : 283 L.

IV. STOCK OF MEASLES VACCINE.

1. FREEZE DRIED (UNDER TEST) : 143,000 VIALS.
2. FREEZE DRIED (PASSED TEST) : 276,000 VIALS.
3. LABELLED & PACKAGED : 134,000 VIALS.

TOTAL : 553,000 VIALS.

BANDUNG, MAY 25,1993.

DEPARTMENT OF
MEASLES VACCINE PRODUCTION

資料－2

MEASLES VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
A. TARGET			
1. Preparation of Guideline & S.O.P (Standard Operation Procedure) for Production and Quality Control. ---------→		90 %	Almost accomplished
1-2. Transfer of Basic Technology for Production and Quality Control. ---------→	Accomplished		
2. Establishment and Maintenance of SPF Chicken Flocks. ---------→	Accomplished		
3. Establishment and Supply of Local Calf Serum. ---------→		10 %	QC Test not yet established
4. Quality Control Tests and Establishment of Working Seed Lots.---→	Accomplished		
5. Bulk Production. ---------→	Accomplished		
6. Dispensing, Freeze Drying, Capping and Packaging of Vaccine.---→		80 %	
7. Quality Control Tests and Quality Assurance. ---------→			
7-2. Field Clinic Trials of Measles Virus produced from the strain of Measles Virus approved in Japan for Acceptance.→	Accomplished		
7-3. Test Use of the Pilot Product in Fields. ---------→	Accomplished		
8. Put Vaccine on the market. ---------→			Will begin on June 1993
9. Preparation of Materials for SPF Monitoring and Quality Control Test. ---------→		75 %	Still studying in Guning Sindur and Biken
10. On the job Technology Transfer for Routine Production. ---------→		75 % 75 %	Still some problems has to be overcome

3－3 供与資機材の利用状況

・平成4年度実施した巡回指導調査時に，既供与機材の台帳は整備されていることを確認しているが，わが方は協力終了後を想定し，現在プロジェクトで必要な消耗品，スペアパーツのリストを作成中である。これらのリストをもとに機材にかかわるランニングコストを算出し，先方に対し予算化を要求して行く予定である。現在作成途上のリストを資料に示す。同時にサプライルートについても整備中である。（資料参照）

・供与機材の利用状況は極めて良好である。なお昨年度（平成4年度），機器メインテについてカウンターパート2名の本邦研修を実施しており，現在（平成5年5月）当カウンターパートを中心に，プロジェクト専属のメインテチームが結成され活動を行っている。また平成5年6月以降，機材メインテナンスの長期専門家を派遣することとなっており，修理技術及び機材管理についてメインテナンスチームに対し指導をおこなう予定である。常時，ワクチン製造を行って行くためには，技術協力により供与された機材以外に無償資金協力により整備された高額機材も対象とし，保守管理記録の徹底，定期点検といった，予防的なメインテナンス体制を構築することが必要である。

RECAPITULATION LIST OF REQUIREMENT ON SPARE PARTS
FOR POLIO-MEASLES PRODUCTION AND
QUALITY CONTROL BUILDING AND ANIMAL HOUSE
FISCAL YEAR - 1993

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

1

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
1	AIR SHOWER Phase 1	1) Tube Lamp 20w/220v 2) Gelatin mat. 380 mm x 707 mm	-	10 pcs 43 sets	
2	AIR SHOWER Phase 2	-	-	-	full stock
3	LAMINAR FLOW Phase 1	1) UV Lamp, 6L-15/100V 2) Tube Lamp, FL-40SD/100V	-	68 pcs 50 pcs	
4	LAMINAR FLOW Phase 2	1) UV Lamp, 6L-15/100V 2) Tube Lamp, FL-40SD/100V	-	10 pcs 4 pcs	
5	COLD ROOM Phase 1	1) UV Lamp, 6TW 1520 6T/100V 2) Tube Lamp, FL-40W/220V 3) Recorder Paper 100m, CHINO (0-50°C) 4) Gas Freon R-22	- - -	14 pcs 14 pcs 73 pcs 1 tube	
6	COLD ROOM Phase 2	1) Tube Lamp 40W/220v 2) Freon Gas R-22	-	6 pcs 1 tube	
7	AUTOCLAVE Phase 1	1) Steam filter, PALL MBS 1001M020 2) Exhaust Filter, PALL AB1FR7PVH4 3) Cassette Ribbon B9565	-	3 pcs 1 pce 1 pce	

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
8	AUTOCLAVE Phase 2	1) Steam filter PALL MBS1001M020	-	6 pcs	
9	DRYING OVEN Phase 1	1) Chart Paper, 100 mm, CHINO (0-200°C)	-	15 pcs	
10	DRYING OVEN Phase 2	-	-	-	full stock
11	DRYER Phase 1 & 2	-	-	-	full stock
12	PASS BOX Phase 1	1) Tube Lamp, NEC 15W/220V 2) UV Lamp, NEC GL-15/220V	-	9 pcs 15 pcs	
13	PASS BOX	1) UV Lamp, NEC 15/220V	-	28 pcs	
14	INCUBATOR ROOM Phase 1	1) Chartpaper 100mm CHINO 0-50°C 2) Tube Lamp, 40W/220V 3) UV Lamp, GTW 1520GT/100V	-	25 pcs 10 pcs 10 pcs	
15	INCUBATOR ROOM Phase 2	1) Tube Lamp, 40W/220V	-	4 pcs	
16	FREEZER - 20	1) Chart paper 100 mm, (-50°C-50°C)	-	12 pcs	

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
17	FREEZER - 80 Phase 2	1) Chart paper No. 2L-10040 2) Pen Cartridge 3) Battery SUM-2(5) 1,5V	-	30 pcs 5 pcs 5 pcs	
18	FREEZER - 80 Phase 1	1) Chart paper No. 2L-10040 2) Pen Cartridge 3) Battery SUM-2(5) 1,5V	-	48 pcs 8 pcs 8 pcs	
19	TUBE LAMP	All Facility	-	1550 pcs	
20	UV LAMP	All Facility	-	223 pcs	
21	WATER TREATMENT M.H - 1	1) Anthacite 2) Sand 3) Gravel 4) Ferrecite - U 5) ferrecity - AH 6) Gravel	-	120 ltr 100 ltr 120 ltr 1200 ltr 160 ltr 204 ltr	
22	WATER TREATMENT M.R - 5	1) IR - 120 B 2) IRA - 410 3) RO Element Cell NTR 759HR-S4 4) Micropore - 1N Nominal 1µm 5) UV Sterilizer 636T6 6) UV Quartz Glass G36S 7) Battery C200H-MR-431 8) Organo CR17335SE (3V)	-	80 ltr 100 ltr 21 pcs - 2 pcs 4 pcs 2 pcs	Filtering Material Resin Catcher

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
23	UF-WATER Phase 1	1) UF-Module SIP-3023, 594060 2) UV-Lamp G36T6L 3) Air Filter - II SARTOFROL-II, 5182307T1-0.2μ	-	2 pcs 10 pcs 1 pcs	
24	UF-WATER Phase 2	1) UF-Module SIP-3023, 594060	-	2 pcs	
25	DESTILATION SYSTEM	1) Air Filter CVGB71TPS-0.2μ 2) Conductivity Recording paper Chart No. 53822, CO-200°c 3) Pressure gauge 6kg SUS 304.20405294 4) Pressure gauge 1285590	-	2 pcs 2 pcs 1 pce 1 pce	
26	PRE FILTER for AHU	Pre filter	-	1 X 280 m	
27	V-BELT for AHU M.R - 5	1) B - 98" 2) B - 75" 3) B - 93" 4) B - 75" 5) B - 106" 6) B - 76" 5) A - 46" 6) A - 75" 7) A - 89" 8) A - 45" 9) A - 44" 10) A - 54" 11) B - 89" 12) B - 44" 13) A - 50" 14) A - 62"	-	3 pcs 3 pcs 4 pcs 3 pcs 5 pcs 3 pcs 5 pcs 2 pcs 2 pcs 2 pcs 2 pcs 3 pcs 1 pce 1 pce 2 pcs 1 pce	

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
28	AHU	1) Cell Type Filter Full Size #9-2424-12AM Half Size #9-1224-12AM	-	 158 pcs 82 pcs	
29	SAVIC CONTROL Yamatake Honeywell	1) Chart paper 2) Battery, medium 1,5V 3) Fuse 2A, cartridge 4) Fuse 0,5A, cartridge	-	12 pcs 12 pcs 2 pcs 20 pcs	
30	VACUM DRYING OVEN	1) Genuine vaccum oil type SMR - 100 ULVAC	-	20 ltr	
31	LABELLING MAMCHINE	1) Stempet 2) Tinta	-	2 bxs 200 cc	
32	CLEAN BENCH Phase 1	1) UV Lamp, 6L-15/220V 2) TL Lamp, 15W/220V	-	16 pcs 16 pcs	
33	CLEAN BENCH Phase 2	1) UV Lamp, 6L-15/220V 2) TL Lamp, 15W/220V	-	12 pcs 12 pcs	
34	INCUBATOR CABINET	1) Chart paper 180mm CHINO (0-100°C)	-	12 pcs	
35	FILLING & CAPPING Phase 2	1) Mobile Vactra Oil 2) Mobile DTE Oil Light 3) Mobilux EP-1 4) Mobil plex 46/47 5) Mobil Gear 630	-	15 ltr 15 ltr 1 kg 1 kg 1 kg	

SPARE PARTS FOR POLIO-MEASLES PRODUCTION & QUALITY CONTROL BUILDING AND ANIMAL HOUSE

NO.	ITEM	SPARE PARTS	PRODUCT	QUANTITY	REMARKS
36	GILOWY Phase 2	1) Mobilux Grease 2) Mobile Gear 3) Recorder Paper	-	1 kg 1 kg 10 pcs	

4．　評価調査のための準備

・今般専門家チームにあたって，平成6年度初頭に予定している評価調査のための事前打合せを行った。評価のインディケーター案は資料1のとおりである。内容的にはほぼ双方で了解しており，来年度の評価調査実施の際には本案が用いられる見込みである。

また，日本側に対しBio Farmaからプロジェクト終了後も，引き続き協力の要望があったが，先方へは評価調査後にプロジェクトの終了後の対処方針を決めることを説明し，了解を得ている。

・なお参考までに現在までの日本側投入実績を金額ベースで資料2のとおり取り纏めた。

MEASLES VACCINE PRODUCTION

A. TARGET

1. Preparation of Guideline & S.O.P (Standard Operation Procedure) for Production and Quality Control.

1-2. Transfer of Basic Technology for Production and Quality Control.

2. Establishment and Maintenance of SPF Chicken Flocks.

3. Establishment and Supply of Local Calf Serum.

4. Quality Control Tests and Establishment of Working Seed Lots.

5. Bulk Production.

6. Dispensing, Freeze Drying, Capping and Packaging of Vaccine.

7. Quality Control Tests and Quality Assurance.

7-2. Field Clinic Trials of Measles Virus produced from the strain of Measles Virus approved in Japan for Acceptance.

7-3. Test Use of the Pilot Product in Fields.

8. Put Vaccine on the market.

9. Preparation of Materials for SPF Monitoring and Quality Control Test.

10. On the job Technology Transfer for Routine Production.

MEASLES VACCINE PRODUCTION

B. TERMS of REFERENCE of EXPERTS DISPATCHED

1. Production Control and Basic Technology.

2. Preparation of Guideline and Standard Operation Procedure (SOP).

3. Quality Control Tests and Establishment of Working Seed Lots.

   (1). Preparation of Working Seed for the use of five years to go Quality Control Tests; Control and Establishment of Working Seed Lots.

   (2). Technology of Large Scale Tissue Culture.

4. Production and Monitoring of SPF Eggs.

5. Bulk Production

6. Dispensing, Freeze Drying, Capping and Packaging of Vaccine on the mass-production scale.

7. Preparation of Quality Control Materials.

8. Sero-Epidemological Methods.
   (1). Many kinds of Antigen and Anti-serum for the Q.C Tests of Measles Vaccine as well as for SPF Monitoring.

9. On the job Technology Transfer for Routine Production.

10. Basic Technology of GMP Control.
    GMP (Good Manufacturing Practice) Documentation and Establishment of Bio Farma's GMP Control System.

POLIO VACCINE PRODUCTION

A. TARGET

1. Preparation of Software for (Good Manufacturing Practice) GMP.

2. Establishment of Procurement of clean Cynomolgus Monkey for the Polio Vaccine Production.

3. Poliomyelitis Vaccine Production Control and Basic Technology.

4. Preparation of Anti-Polio Rabbit Sera.

5. Establishment of Cell and Virus Culture Techniques.

6. Establishment of in-process Quality Control Technigues.

7. Preparation of Seed Viruses.

8. Accumulation of Neurovirulence Test Data for Neurovirulence reference Viruses.

9. Production of Pilot Product.

10. Test use of the Pilot Product in Fields.

B. TERMS of REFERENCE of EXPERTS DISPATCHED

1. Production and Quality Control in General [I].

(1). Seed Virus, preparation of Seed Cell.

(2). Standardization of Antiserum against Polio Virus.

(3). Establishment of Technology for Production and Quality Control.

(4). Preparation of Standard Operating Procedure.

POLIO VACCINE PRODUCTION

2. *Tissue Culture and Preparation of Media for Virus Culture.*

   (1). Preparation of Sub-Materials such as Torypsin, Disparze, antibiotic etc.

   (2). Mass-production of Media for Tissue Culture and Virus Culture.

   (3). Quality Control Technology of Enzyme and Midia etc.

   (4). Chemical Tests of Materials.

3. *Establishment and Adjustment of Operation Technique of Equipments for the Production and Quality Control.*

   (1). Operation of Washing Machine, Autoclave, Pure Water Operatus Incubator etc.

   (2). Establishment of Washing Process of Equipments

4. *Production and Quality Control in General [II].*

   (1). Measurement Skill of Anti-bodyy against SV40, Helpes and Measles Viruses.

   (2). Preparation of Monovalent Bulk of Type I, II, and III.

   (3). Skill of Pooling and Filtration with big Tank.

   (4). Skill of Filling.

   (5). Test of Stabilizer for Polio Vaccine Production.

   (6). Production of Pilot Product (Trivalent Oral Poliomyelitis Vaccine - TOPV).

POLIO VACCINE PRODUCTION

5. *Selection of Monkey for Production and Neurovirulence Test.*

   (1). Selection Technology of Monkey for Production.

   (2). Technology of Neurovirulence Test.

   Infection Clinical Observation, Autopsy, Making of Pathological Sample and the Assesment by Observation of Sample.

6. *Technology of Quality Control ~~~ Preparation for Mass-Production Stage.*

   (1). Quality Control in General.

   (2). Tissue Culture, Virus Culture for Q.C. purpose.

   (3). Preparation of High Titer Polio Virus Antigen.

   (4). Concentration and Purification of Polio Virus Antigen.

   (5). Preparation and Standardization of Rabbit Antiserum.

7. *Complementary Technology.*

   (1). Preparation of Antigen for Diagnosis of SIV, Foamy Virus contamination of monkey used for production.

   (2). Control of Seed Virus.

   (3). On the Job Training of Production of Final Product and in-process Quality Control Tests.

インドネシア生ワクチン製造基盤技術プロジェクト実績　1

予算費目	平成元年		平成２年		平成３年		平成４年	
	当年度	繰越	当年度	繰越	当年度	繰越	当年度	繰越
（事項）調査実施に必要な経費	602,586	2,635,448	0	0	1,161,253	3,251,534	823,030	1,879,047
（目）調査諸費	65,920	2,635,448	0	0	297,921	3,251,534	356,364	1,879,047
事前調査	0	0	0	0	124,321	0	0	0
（節）調査諸費	0	0	0	0	0	0	0	0
（節）現地調査費	0	0	0	0	0	0	0	0
（節）資機材購送費	0	0	0	0	0	0	0	0
（節）報告書作成費	0	0	0	0	124,321	0	0	0
実施協議	65,920	2,635,448	0	0	0	0	0	0
（節）調査諸費	0	2,135,448	0	0	0	0	0	0
（節）現地調査費	0	500,000	0	0	0	0	0	0
（節）資機材購送費	0	0	0	0	0	0	0	0
（節）報告書作成費	65,920	0	0	0	0	0	0	0
計画打合せ	0	0	0	0	173,600	3,251,534	0	0
（節）調査諸費	0	0	0	0	0	2,806,534	0	0
（節）現地調査費	0	0	0	0	0	445,000	0	0
（節）資機材購送費	0	0	0	0	0	0	0	0
（節）報告書作成費	0	0	0	0	173,600	0	0	0
巡回指導	0	0	0	0	0	0	356,364	1,560,047
（節）調査諸費	0	0	0	0	0	0	0	319,000
（節）現地調査費	0	0	0	0	0	0	0	0
（節）資機材購送費	0	0	0	0	0	0	168,080	0
（節）報告書作成費	0	0	0	0	0	0	127,980	0
（目）所属先補填経費	536,666	0	0	0	863,332	0	466,666	0
（事項）専門家派遣に必要な経費	18,297,251	0	62,137,145	0	64,584,124	0	65,572,213	0
（目）派遣諸費	13,576,871	0	43,322,881	0	64,584,124	0	65,572,213	0
専門家	13,576,871	0	43,322,881	0	64,584,124	0	65,572,213	0
（節）派遣費	11,382,532	0	22,253,761	0	38,631,392	0	44,856,023	0
（細節）赴帰任旅費	4,146,948	0	8,852,671	0	23,754,942	0	21,337,044	0
（細節）滞在費	2,683,168	0	8,462,385	0	10,134,350	0	13,004,250	0
（細節）住居手当	4,552,416	0	4,938,705	0	4,742,100	0	9,526,541	0
（細節）語学手当	0	0	0	0	0	0	988,188	0
（節）携行機材費	2,194,339	0	20,788,500	0	25,841,192	0	20,716,190	0
（細節）購入	1,354,244	0	18,695,515	0	21,409,958	0	17,297,712	0
（細節）輸送	840,095	0	2,092,985	0	4,431,234	0	3,418,478	0
（節）一時帰国旅費	0	0	180,620	0	111,540	0	0	0
（目）所属先補填経費	2,650,533	0	14,240,264	0	17,348,162	0	30,625,996	0
（節）国内俸	0	0	3,989,966	0	4,608,000	0	10,355,000	0
（節）所属先給与	2,650,533	0	10,250,298	0	12,683,363	0	20,270,996	0
（節）所属先諸経費	0	0	0	0	56,799	0	0	0
（目）技術費	0	0	0	0	0	0	13,021,260	12,413,560

インドネシア生ワクチン製造基盤技術プロジェクト実績　2

予算費目	平成元年		平成２年		平成３年		平成４年	
	当年度	繰越	当年度	繰越	当年度	繰越	当年度	繰越
（目）現地業務費	2,069,847	0	4,674,000	0	4,443,378	0	4,095,000	0
（節）一般現地業務費	1,069,847	0	3,600,000	0	4,443,378	0	4,095,000	0
（細節）専門家	100,000	0	680,000	0	0	0	0	0
（細節）一般現地業務費	90,347	0	1,820,000	0	902,098	0	1,170,000	0
（細節）現地研究費	300,000	0	1,100,000	0	2,386,438	0	1,531,000	0
（細節）貧困国対策費	300,000	－	－	－	1,154,842	－	1,394,000	－
（節）現地研究費	500,000	－	－	－	－	－	－	－
（節）貧困国対策費	500,000	－	－	－	－	－	－	－
（節）応急対策費			1,074,000					
（事項）機材供与に必要な経費	887,465	0	72,532,292	149,607,500	104,477,678	76,577,980	40,320,425	0
（目）機材供与費	887,465	0	72,532,292	149,607,500	104,477,678	76,577,980	40,320,425	0
（節）一般機材供与	0	0	70,613,570	149,607,500	104,477,678	44,151,980	37,689,425	0
（細節）購入費	0	0	69,010,000	149,607,500	93,029,600	44,151,980	33,100,080	0
（細節）輸送費	0	0	1,603,570	0	11,448,078	0	4,589,345	0
（節）機材修理費	0	0	105,715	0	0	0	0	0
（節）機材仕様書等作成費	887,465	0	1,165,007	0	0	0	0	0
現地調達機材費	0	0	648,000	0	0	32,426,000	2,631,000	
（事項）プロジェクト実施に必要な経費	179,988	0	364,013	0	560,088	0	430,054	0
（目）実施計画諸費	179,988	0	364,013	0	560,088	0	430,054	0
（節）プロジェクト運営費	179,988	0	364,013	0		0	430,054	0
（細節）プロジェクト運営費	111,510	0	353,893	0	52,080	0	223,140	0
（細節）プロジェクト会議費	65,478	0	10,120	0	86,108	0	60,514	0
（細節）連会・開催	会議費　3,000	0	0	0	421,900	0	146,400	0
年度小計	19,967,290	2,635,448	135,033,450	149,607,500	170,783,143	79,829,514	107,145,722	1,879,047
年度合計	22,602,738		284,640,950		250,612,657		109,024,769	
							総計	666,881,114

資料

1)　Bio Farmaからの現状レポート

PREPARATION FOR JICA EXPERT TEAM (MEASLES)

1. Present situation.
   - Measles Vaccine Production (enclosed).
   - Measles Vaccine Quality Control (enclosed).
   - SPF Egg Production (enclosed).

2.A.Opinian concerning Technical Acquirement Level

a.Production.
- Cell culture and virus culture mostly already mastered.
- Problems : virus titer become low (less than $10^{7.0}$PFU/ml).
- Need expert for for trouble shooting.
- Final product : already acquired.

b.Quality Control.
- Basic Technology for in process and final control already achieved.
- Preparation of antigen for SPF monitoring not yet completed.

c.SPF Chicken Egg.
- Establishment and Maintenance of SPF Chicken Flocks has already been accomplished.

d.Local Calf Serum Supply.
- Not yet established, still studying in Gunung Sindur and Biken.

e.-GMP internal Inspection by Dr.Erman B. and Drs.Juliman on May 5,1993.

	OK no.of item/ no.of items.	Procentage
1.Personal qualification	10/11	91 %
2.Building & facilities	23/27	85 %
3.Equipment	8/13	62 %
4.Product process control	26/32	81 %
5.Records and reports	26/31	84 %
6.System control	17/18	94 %
Total :	110/132	83 %

-GMP for Measles Vaccine Production (Indonesia language).
1.SOP of Production : finished (100%).
2.Working sheet of Production : finished (100%).
3.Specification of materials : not yet (50%).
4.SOP of equipments : not yet (50%).

-GMP for Measles Quality Control (Indonesia language).
1.SOP of Production : finished (100%).
2.Working sheet of Production : finished (100%).
3.Specification of materials : not yet (50%).
4.SOP of equipments : not yet (50%).

2.B.-Dispatchment of experts for Production for 1994.

a.Bulk of Measles Vaccine, especially for treatment of virus culture and clarification.

b.Final Bulk, especially for mixing process.

c.Request dispatchment of expert : Mr.Kuniyaki Koyama.

-Dispatchment of expert for Quality Control for 1994.

a.Virological test, preparation of antigen and antibody for QC and SPF-monitoring and establishment of QC for local calf serum supply.

b.Request dispatchment of expert : Mr.Tadashi Ando.

-Counterpart training in Japan for 1994.

a.Production : Treatment of virus culture, Clarification and Mixing process of final bulk and Evaluation.
Requested : Dr.Erman Boedisetianto.

b.Quality Control: Preparation of antigen and antibody for quality control and SPF monitoring.
Requested : Dra.Antik Tjantika.

3. Equipment requested.

- 20L glass bottle (ex KOKURA) : 100 bottles.
- Vibrator , specification -Transducer : P.Z.T.
  -Frequency : 28 kHz.
  -Dimention : 450 x 450 x 95(H)mm.
  -Weight : 16kg.

  Used for Ultrasonic Generator DP-1200 (1200W), NISSEI, Nihonseiki Kaisha Ltd.

Head of Viral Vaccine Production

(Dr.Benny Kaligis, MPH)

PREPARATION FOR JICA EXPERT TEAM (POLIO)

Present situation

1. Result report as of April, 1993 (enclosed)
   - Polio vaccine production and quality control
   - Monkey report

2.A. Opinion concerning technical acquirement level:

a. Production
   - Cell culture and virus culture technique are almost completely acquired.
   - Preparations of monovalent bulk are also had been per formed without presence of JICA expert.
   - Preparation of trivalent vaccine (mixing, filling and capping) has not been started yet. According to the schedule, it will be performed on August 1993 with the assistance of JPRI's expert.
   - Choice of stabilizer will be decided during the expert team visit.

b. Quality Control
   - In general, basic technology regarding in process control has been acquired except several problems has not been settled yet, such as :
     a) RCT-marker test, d-marker test and cell culture technique.
     b) Antigen preparation for SIV, Foamy virus, SV5, Herpes virus, and SV40.
     c) Quality of antiserum produced not yet give satisfactory results, sometime problems occurred.
     d) Screening monkey against SIV, SV40
     e) Sensitivity test for medium in sterility test not yet established.

c. Medium preparation
   Already accomplished

d. Neurovirulence test (NVT)
   - Technology of NVT mostly already acquired.
   - Accumulating NVT data not yet completed, need time to achieve.

e. Monkey
   - Clean cynomolgus monkey kidney supply for production is still not enough. Requirement for 1993 : 188 monkeys.
   - Monkeys for NVT enough supply.
   - Breeding cynomolgus monkey need larger quality of monkey for breeding.
   - African green monkey : not yet established.

e. GMP

GMP Internal Inspection by Dr. Benny kaligis and Drs. Mahendra on May 3, 1993 :

	OK no. of items/ no. of items	Percentage
1. Personal qualification	10/11	91 %
2. Building & facilities	21/27	78 %
3. Equipment	9/13	69 %
4. Product process control	27/32	84 %
5. Records & reports	27/31	87 %
6. System control	18/18	100 %
Total	112/132	85 %

- Manual SOP by Dr. Karazawa (in English)
- GMP in Indonesian language
  a) Standard Operating Procedures
  b) Working sheet
  3) Specification
  4) Equipment

  ] almost completed both for production and quality control

2.B. Requirement of technical cooperation for 1994

1. Dispatchement of experts
   a. Production : Mr. H. Yamamoto (routine production of single harvest, bulk, and mixing/filling)
   b. Quality Control : Mr. Horie (routine QC)
   c. NVT :
   d. Monkey breeding : } Dr. S. Abe
   e. GMP : Dr. Y. Doi

2. Counterpart training in Japan for 1994
   a. Production : Mr. Ahmad Hasnan
      Mr. Yudi Kusmayudi
   b. QC and NVT : Ms. Endang Suryo (Veterinary)
      Ms. Atik Sariningsih

3. Equipment requested for 1994 (see enclosure)

Head of Viral Vaccine Production

(Dr. Benny Kaligis MPH)

資料

2)　同自己評価レポート

MEASLES VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
A. TARGET			
1. Preparation of Guideline & S.O.P (Standard Operation Procedure) for Production and Quality Control. ---------→		90 %	Almost accomplished
1-2. Transfer of Basic Technology for Production and Quality Control. ---------→	Accomplished		
2. Establishment and Maintenance of SPF Chicken Flocks. ---------→	Accomplished		
3. Establishment and Supply of Local Calf Serum. ---------→		10 %	QC Test not yet established
4. Quality Control Tests and Establishment of Working Seed Lots.---→	Accomplished		
5. Bulk Production. ---------→	Accomplished		
6. Dispensing, Freeze Drying, Capping and Packaging of Vaccine.---→		80 %	
7. Quality Control Tests and Quality Assurance. ---------→			
7-2. Field Clinic Trials of Measles Virus produced from the strain of Measles Virus approved in Japan for Acceptance.→	Accomplished		
7-3. Test Use of the Pilot Product in Fields. ---------→	Accomplished		
8. Put Vaccine on the market. ---------→			Will begin on June 1993
9. Preparation of Materials for SPF Monitoring and Quality Control Test. ---------→		75 %	Still studying in Guning Sindur and Biken
10. On the job Technology Transfer for Routine Production. ---------→		75 % 75 %	Still some problems has to be overcome

MEASLES VACCINE PRODUCTION

B. TERMS of REFERENCE of EXPERTS DISPATCHED	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
1. Production Control and Basic Technology. ---------→	Accomplished		
2. Preparation of Guideline and Standard Operation Procedure (SOP). ---------→		75 %	
3. Quality Control Tests and Establishment of Working Seed Lots. ---→	Accomplished		
(1). Preparation of Working Seed for the use of five years to go Quality Control Tests; Control and Establishment of Working Seed Lots. ---------→	Accomplished		
(2). Technology of Large Scale Tissue Culture. ---------→	Accomplished		
4. Production and Monitoring of SPF Eggs. ---------→	Accomplished		
5. Bulk Production ---------→	Accomplished		
6. Dispensing, Freeze Drying, Capping and Packaging of Vaccine on the mass-production scale. ---------→		80 %	
7. Preparation of Quality Control Materials. ---------→		50 %	Need more experience for monitoring medium, trypsin, calf serum, chemical test, etc.
8. Sero-Epidemological Methods. (1). Many kinds of Antigen and Anti-serum for the Q.C Tests of Measles Vaccine as well as for SPF Monitoring. ---------→		50 %	
9. On the job Technology Transfer for Routine Production. ---------→		50 %	
10. Basic Technology of GMP Control. GMP (Good Manufacturing Practice) Documentation and Establishment of Bio Farma's GMP Control System. ---------→		50 %	

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
A. TARGET			
1. Preparation of Software for (Good Manufacturing Practice) GMP.		80 %	In progress
2. Establishment of Procurement of clean Cynomolgus Monkey for the Polio Vaccine Production.		60 %	Assurance to achieve of the target FAT (-) is doubtful
3. Poliomyelitis Vaccine Production Control and Basic Technology.		80 %	RCT Test and d marker not yet
4. Preparation of Anti-Polio Rabbit Sera.		75 %	Quality not yet satisfactory
5. Establishment of Cell and Virus Culture Techniques.	100 %		
6. Establishment of in-process Quality Control Technigues.		75 %	Still several problems has to be overcome
7. Preparation of Seed Viruses.			We receive Seed Virus ready for use
8. Accumulation of Neurovirulence Test Data for Neurovirulence reference Viruses.		80 %	Type III just two times
9. Production of Pilot Product.		75 %	Bulk Type 1, 2, 3 already prepared Final Product not yet
10. Test use of the Pilot Product in Fields.		0	Not yet decidad
B. TERMS of REFERENCE of EXPERTS DISPATCHED			
1. Production and Quality Control in General [I].			
(1). Seed Virus, preparation of Seed Cell.			We receive ready for use
(2). Standardization of Antiserum against Polio Virus.		90 %	Need confirmation
(3). Establishment of Technology for Production and Quality Control.		80 %	
(4). Preparation of Standard Operating Procedure.		75 %	

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
2. *Tissue Culture and Preparation of Media for Virus Culture.* ----→			
(1). Preparation of Sub-Materials such as Torypsin, Disparze, antibiotic etc. ----------→	Accomplished		
(2). Mass-production of Media for Tissue Culture and Virus Culture. ---------→	Accomplished		
(3). Quality Control Technology of Enzyme and Midia etc. -------→		Not yet	
(4). Chemical Tests of Materials. ---------→		Not yet	
3. *Establishment and Adjustment of Operation Technique of Equipments for the Production and Quality Control.* ---------→			
(1). Operation of Washing Machine, Autoclave, Pure Water Operatus Incubator etc. ---------→	Accomplished		
(2). Establishment of Washing Process of Equipments ---------→	Accomplished		
4. *Production and Quality Control in General [II].* ---------→			
(1). Measurement Skill of Anti-bodyy against SV40, Helpes and Measles Viruses. ---------→		70 %	SV40 test just started
(2). Preparation of Monovalent Bulk of Type I, II, and III. ----→		80 %	Waiting for QC test
(3). Skill of Pooling and Filtration with big Tank. ---------→	Accomplished		
(4). Skill of Filling. ---------→		80 %	No experience yet
(5). Test of Stabilizer for Polio Vaccine Production. ---------→		40 %	Result not yet satisfactory
(6). Production of Pilot Product (Trivalent Oral Poliomyelitis Vaccine - TOPV). ---------→		0	

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
5. *Selection of Monkey for Production and Neurovirulence Test.*			
(1). Selection Technology of Monkey for Production.		80 %	Not yet satisfactory
(2). Technology of Neurovirulence Test.		80 %	Almost satisfactory
Infection Clinical Observation, Autopsy, Making of Pathological Sample and the Assesment by Observation of Sample.			
6. *Technology of Quality Control ~~ Preparation for Mass-Production Stage.*			
(1). Quality Control in General.		80 %	
(2). Tissue Culture, Virus Culture for Q.C. purpose.		80 %	
(3). Preparation of High Titer Polio Virus Antigen.		90 %	
(4). Concentration and Purification of Polio Virus Antigen.		90 %	
(5). Preparation and Standardization of Rabbit Antiserum.		75 %	
7. *Complementary Technology.*			
(1). Preparation of Antigen for Diagnosis of SIV, Foamy Virus contamination of monkey used for production.		0	Not yet
(2). Control of Seed Virus.		0	Not yet
(3). On the Job Training of Production of Final Product and in-process Quality Control Tests.		0	Not yet

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
A. TARGET			
1. Preparation of Software for (Good Manufacturing Practice) GMP.		80 %	In progress
2. Establishment of Procurement of clean Cynomolgus Monkey for the Polio Vaccine Production.		60 %	Assurance to achieve of the target FAT (-) is doubtful
3. Poliomyelitis Vaccine Production Control and Basic Technology.		80 %	RCT Test and d marker not yet
4. Preparation of Anti-Polio Rabbit Sera.		75 %	Quality not yet satisfactory
5. Establishment of Cell and Virus Culture Techniques.	100 %		
6. Establishment of in-process Quality Control Technigues.		75 %	Still several probleas has to be overcome
7. Preparation of Seed Viruses.			We receive Seed Virus ready for use
8. Accumulation of Neurovirulence Test Data for Neurovirulence reference Viruses.		80 %	Type III just two times
9. Production of Pilot Product.		75 %	Bulk Type 1, 2, 3 already prepared Final Product not yet
10. Test use of the Pilot Product in Fields.		0	Not yet decided
B. TERMS of REFERENCE of EXPERTS DISPATCHED			
1. Production and Quality Control in General [I].			
(1). Seed Virus, preparation of Seed Cell.			We receive ready for use
(2). Standardization of Antiserum against Polio Virus.		90 %	Need confirmation
(3). Establishment of Technology for Production and Quality Control.		80 %	
(4). Preparation of Standard Operating Procedure.		75 %	

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
2. *Tissue Culture and Preparation of Media for Virus Culture.* ----→			
(1). Preparation of Sub-Materials such as Torypsin, Disparze, antibiotic etc. ----------→	Accomplished		
(2). Mass-production of Media for Tissue Culture and Virus Culture. ---------→	Accomplished		
(3). Quality Control Technology of Enzyme and Midia etc. -------→		Not yet	
(4). Chemical Tests of Materials. ---------→		Not yet	
3. *Establishment and Adjustment of Operation Technique of Equipments for the Production and Quality Control.* ---------→			
(1). Operation of Washing Machine, Autoclave, Pure Water Operatus Incubator etc. ---------→	Accomplished		
(2). Establishment of Washing Process of Equipments ---------→	Accomplished		
4. *Production and Quality Control in General [II].* ---------→			
(1). Measurement Skill of Anti-bodyy against SV40, Helpes and Measles Viruses. ---------→		70 %	SV40 test just started
(2). Preparation of Monovalent Bulk of Type I, II, and III. ----→		80 %	Waiting for QC test
(3). Skill of Pooling and Filtration with big Tank. ---------→	Accomplished		
(4). Skill of Filling. ---------→		80 %	No experience yet
(5). Test of Stabilizer for Polio Vaccine Production. ---------→		40 %	Result not yet satisfactory
(6). Production of Pilot Product (Trivalent Oral Poliomyelitis Vaccine - TOPV). ---------→		0	

POLIO VACCINE PRODUCTION

	REMARKS		
	Already Accomplished	Not Yet; How %	Comments
5. *Selection of Monkey for Production and Neurovirulence Test.*			
(1). Selection Technology of Monkey for Production.		80 %	Not yet satisfactory
(2). Technology of Neurovirulence Test.		80 %	Almost satisfactory
Infection Clinical Observation, Autopsy, Making of Pathological Sample and the Assesment by Observation of Sample.			
6. *Technology of Quality Control === Preparation for Mass-Production Stage.*			
(1). Quality Control in General.		80 %	
(2). Tissue Culture, Virus Culture for Q.C. purpose.		80 %	
(3). Preparation of High Titer Polio Virus Antigen.		90 %	
(4). Concentration and Purification of Polio Virus Antigen.		90 %	
(5). Preparation and Standardization of Rabbit Antiserum.		75 %	
7. *Complementary Technology.*			
(1). Preparation of Antigen for Diagnosis of SIV, Foamy Virus contamination of monkey used for production.		0	Not yet
(2). Control of Seed Virus.		0	Not yet
(3). On the Job Training of Production of Final Product and in-process Quality Control Tests.		0	Not yet

資料

3) 最新（平成5年4月）製造レポート

Summary of Measles Vaccine Production (1992. 1～1993. 3)

Single Harvest					Final Product
Code No.	No. of Embryo used	Date of Harvest	Volume(L)	Titer(Log_{10})	
9201	38	1－17	3.9	7.7	
02	28	1－17	4.3	?	
03	88	Bacteria contamination			
04	94	3－26	13.5	7.9	CA0807 (×15.1dil)
05	146	4－02	13.7	7.7	CA0808 (×11.5dil)
06	100	4－22	12.4	7.2	CA0909 (×17.8dil)
07	106	4－30	13.8	7.4	Contamination in control cell
08	71	5－08	11.4	7.4	Domestic Bovine serum
09	94	5－14	24.0	7.4	Bacterial contamination
10	78	5－21	11.3	7.5	Contamination in control cell
11	102	5－29	22.2	7.8	CA1011, CA1012, CA1013 (×24dil)
12	75	6－04	16.8	7.5	CA1216 (×11.5dil)
13	76	6－11	17.7	7.5	CA1014, CA1115 (×20dil)
14	77	6－18	16.3	7.4	CA1217, CA1218 (×14.8dil)
15	74	6－26	17.7	7.4	

Single Harvest					BULK (MB)			
Code No.	No. of Embryo used	Date of Harvest	Volume(L)	Titer(Log_{10})	Code No.	Volume(L)	Titer(Log_{10})	
9216	75	7-03	16.4	7.8	9214	15.6	7.6	CA250013
17	75	7-10	19.6	7.6	15	18.7	7.5	CA250023 (X15dil)
18	70	7-18	14.7	7.2	16	13.5	7.0	
19	72	7-24	16.2	7.2	17	16.0	7.0	
20	71	7-31	15.4	7.4	18	14.5	7.8	
21	71	8-14	14.7	7.6	19	13.3	7.5	
22	60	8-21	13.9	7.2	20	13.0	7.1	
23	53	9-04	11.0	6.9	21	10.3	7.0	
24	62	9-26	12.0	7.5	22	12.0	7.3	
25	49	10-02	12.8	7.2	23	12.0	7.3	
26	26	10-30	4.0	7.7	24	21.5	7.5	
27	50	11-06	7.9	7.7				
28	60	11-13	10.5	7.5				
29	78	11-20	17.5	7.3	MVB	60.0	7.4	
30	99	11-27	22.0	7.4	013			
31	96	12-04	21.6	7.3				
32	98	12-11	21.5	7.4	MVB	63.0	7.2	
33	100	12-18	21.7	7.2	023			
34	99	12-25	21.5	6.9				

	Single Harvest				Bulk (MVB)
	No. of Embryo used	Date of Harvest	Volume(L)	Titer(Log_{10})	
MVC013	99	93. 1.15	21.3	6.9	
023	98	93. 1.18	21.0	6.8	MVB023 (62L700)
033	97	93. 1.23	21.0	6.8	Titer 6.8
043	100	93. 1.25	21.5	7.3	
053	97	93. 1.29	21.8		
063	94	93. 2. 5	21.5	7.4	
073	96	93. 2.12	21.7	6.7	
083	99	93. 2.15	21.0	6.9	
093	101	93. 2.19			
103	98	93. 2.25			
113	84	93. 3. 1			
123	102	93. 3. 6		7.4	
133	99	93. 3.19			
143	98	93. 3.22		7.3	
153	53				

Lot. No.	Date of Completed	Vials／10Doses	Freeze Dried	
			Pre	Post
CA 705	92. 7.24	5,038	6.6	5.8
706	92. 7.31	12,122	6.5	5.8
807	92. 8.07	32,262	6.5	5.8
808	92. 8.21	31,604	6.3	5.7
909	92. 9.03	32,547	6.3	5.4
910	92. 9.09	—— 停電事故 ——		
1011	92.10.09	31,661	6.3	5.2
1012	92.10.16	17,874	6.1	5.5
1013	92.10.23	32,595	6.3	5.4
1014	92.10.30	33,070	6.3	5.5
1115	92.11.06	33,124	6.3	5.5
1216	92.12.04	33,174	6.1	5.4
1217	92.12.18	33,191	6.2	5.4
1218	92.12.25	33,201	6.2	5.5
250013	93. 1.22	33,219	6.4	5.7
250023	93. 1.29	33,179	6.4	5.5
Total		427,861		

THE RESULTS OF ROUTINE PRODUCTION OF MEASLES VACCINE

(Table-1); The Production Record of Single Cell Culture.

April 30,1993

Code No.	Date	Age of Embryo (days)	No.of Egg Used	No. of Embryo Used	Volume of Cell Suspension (ml)	Cell Number x10^6/ml	Cell Susp / Embryo (ml)	Cell Culture					Observation	
								No.of Bot.	Medium	Vol/bot.	Temp.	Days	OK	NO
MCC163	Apr.05	11	100	99	18,000	1,20	181	177	MEM+5%Gibco	100 ml	37 °C	2	177	-
MCC173	Apr.07	11	114	106	19,500	1,30	183	192	MEM+5%Gibco	100 ml	37 °C	2	192	-
MCC183	Apr.12	11	100	94	18,000	1,30	191	177	MEM+5%Gibco	100 ml	37 °C	2	177	-
MCC193	Apr.19	11	124	114	21,000	1,30	184	209	MEM+5%Gibco	100 ml	37 °C	2	209	-
MCC203	Apr.26	11	88	86	18,000	1,30	209	178	MEM+5%Gibco	100 ml	37 °C	2	178	-

(Table-2) ; The Production Record of Virus Culture and Single Harvest.

Code No.	Virus Inoculation (Inoc.Vol; 10ml/Bot.)						Virus Culture (29oC, 100ml/Bot.)				Harvest			Single Harvest		
	Cell Culture Code No	Date	Seed V Code No.	Seed V Dilution.	No. of Roux Bottle	No.of Contrl Cell C	Culture Medium	Date of Medium Change	Culture Medium after MC	Term of Virus Culture	Code No.	Date	No.of Harvest Bottle	Code No.	Date	Volume (ml)
MVC093	MCC093	Peb.10	MWS-1A	x 90	193	10	MEM+3%Gibco	Peb.16	TCM-199	9 days	MVH093	Peb.19	190	MSH093	Mar.17	22,000
MVC103	MCC103	Peb.17	MWS-1A	x 90	200	11	MEM+3%Gibco	Peb.23	TCM-199	9 days	MVH103	Peb.25	193	MSH103	Apr.22	22,400
MVC113	MCC113	Peb.19	MWS-1A	x 90	169	10	MEM+3%Gibco	Peb.25	TCM-199	10 days	MVH113	Mar.01	158	MSH113	Apr.23	18,000
MVC123	MCC123	Peb.24	MWS-1A	x 90	201	10	MEM+3%Gibco	Mar.02	TCM-199	10 days	MVH123	Mar.06	196	MSH123	Apr.26	22,700
MVC133	MCC133	Mar.10	MWS-1A	x 90	201	10	MEM+3%Gibco	Mar.16	TCM-199	9 days	MVH133	Mar.19	200	MSH133	Apr.27	23,300
MVC143	MCC143	Mar.12	MWS-1A	x 90	199	19	MEM+3%Gibco	Mar.18	TCM-199	10 days	MVH143	Mar.22	200	MSH143	N.Y	-
MVC153	MCC153	Mar.31	MWS-1A	x 90	70	10	MEM+3%Gibco	Apr.06	TCM-199	9 days	MVH153	Apr.09	70	MSH153	N.Y	-
MVC163	MCC163	Apr.07	MWS-1A	x 50	166	10	MEM+3%Gibco	Apr.13	TCM-199	9 days	MVH163	Apr.16	164	MSH163	N.Y	-
MVC173	MCC173	Apr.09	MWS-1A	x 50	180	10	MEM+3%Gibco	Apr.15	TCM-199	10 days	MVH173	Apr.19	180	MSH173	N.Y	-
MVC183	MCC183	Apr.14	MWS-1A	x 50	166	10	MEM+3%Gibco	Apr.20	TCM-199	9 days	MVH183	Apr.23	151	MSH183	N.Y	-
MVC193	MCC193	Apr.21	MWS-1A	x 50	198	10	MEM+3%Gibco	Apr.27	TCM-199	9 days	MVH193	Apr.30	191	MSH193	N.Y	-
MVC203	MCC203	Apr.28	MWS-1A	x 50	167	10	MEM+3%Gibco	N.Y.	TCM-199	-	MVH203	N.Y.	-	MSH203	N.Y	-

(Table-3); Production Record of Virus Pool and Bulk.

April 30,1993

Virus Pool					Clarification		Bulk Material			Remark
Code No.	Single Harvest		Date	Volume after Sampling	Date	Volume after Clarif.	Code No.	Volume after Sampling	Storage Deep Freezer (-80°C)	
	Code No.	Volume								
MVP043	MSH-043 MSH-063 MSH-073	21,500 ml 21,500 ml 21,000 ml	Apr.16	63,500 ml	Apr.16	62,000 ml	MVB043	61,800 ml	3,000 ml x 19 2,900 ml x 1 1,900 ml x 1	-
MVP053	MSH-053 MSH-083 MSH-093	21,750 ml 21,000 ml 22,000 ml	Apr.30	64,350 ml	Mar.04	62,400 ml	MVB053	62,300 ml	3,000 ml x 20. 2,300 ml x 1.	-

(Table-4) : Production Record of Final Product.

Code No. of Final Product	Final Bulk						Filling		Term of Freeze Drying	Stoppering/Capping		Remark
	Code No.	Date	Bulk Code No.	Volume of Bulk (ml)	Dilution	Vol.of Final Bulk(ml)	Date	No. of Vials Filled		Date	No.of Vials Capped	
250033	25033	Apr.13	MB-9203	3,000	x 20	60,000	Apr.13	18,901	Apr.13-16	Apr.16	18,746 vials	-
250043	25043	Apr.20	MB-9215	3,200	x 26	86,000	Apr.20	27,714	Apr.20-23	Apr.23	27,475 vials	-
250053	25053	Apr.27	MB-9210	5,500	x 18	99,200	Apr.27	31,542	Apr.27-30	Apr.30	31,200 vials	-

THE PRODUCTION & INCUBATION RESULT OF SPF EGGS AND C/O TYPE EGGS

Tabel -1 :SPF Egg (1)

Type of Egg	Code No.	Term of Lay Eggs	Number of Eggs	Eggs / Week	No.of Incubation	Date Inc Stert	Embryonated		Use for Bulk Pro 11 days	Use for Q C		Use for Other	Remarks
							Number	%		5 days	11 days		
SPF	SE-9301	Dec.24 - Dec.30'92	315	315	130	Jan.02	115	88	110	0	0	0	
	SE-9302	Dec.31 - Jan.06'93	295	295	295	Jan.07	257	87	102	0	151	0	
	SE-9303	Jan.07 - Jan.13'93	296	296	294	Jan.14	250	85	100	126	10	12	
	SE-9304	Jan.14 - Jan.20'93	289	289	165	Jan.21	136	82	82	45	0	0	
	SE-9305	Jan.14 - Jan.20'93	289	289	120	Jan.23	108	90	105	0	0	0	
	SE-9306	Jan.21 - Jan.27'93	301	301	294	Jan.28	232	79	103	114	8	0	
	SE-9307	Jan.28 - Feb.03'93	298	298	177	Feb.04	150	84	99	0	8	37	
	SE-9308	Jan.28 - Feb.03'93	298	298	116	Feb.06	89	76	86	0	0	0	
	SE-9309	Feb.04 - Feb.10'93	267	267	260	Feb.11	221	85	104	50	44	0	
	SE-9310	Feb.11 - Feb.17'93	252	252	249	Feb.25	187	75	102	50	23	0	
	SE-9311	Feb.18 - Feb.24'93	246	246	138	Feb.27	123	89	105	0	0	17	
	SE-9312	Feb.18 - Feb.24'93	246	246	74	Mar.18	20	27	20	0	0	34	
	SE-9313	Feb.25 - Mar.03'93	233	233	66	Mar.18	32	48	27	0	0	0	
	SE-9314	Feb.25 - Mar.03'93	233	233	140	Mar.20	57	41	53	0	0	0	
	SE-9315	Mar.04 - Mar.10'93	218	218	183	Mar.25	98	54	90	0	2	0	
	SE-9316	Mar.11 - Mar.17'93	202	202	173	Mar.27	117	68	114	0	0	0	
	SE-9317	Mar.18 - Mar.24'93	171	170	170	Apr.01	130	76	110	0	0	15	
	SE-9318	Mar.25 - Mar.31'93	161	161	59	Apr.03	51	86	0	0	0	100	
	SE-9319	Apr.01 - Apr.07'93	161	161	155	Apr.08	123	79	124	0	0	0	
	SE-9320	Apr.08 - Apr.14'93	146	146	116	Apr.15	91	78	85	0	0	30	
	SE-9321	Apr.15 - Apr.22'93	153	153	103	Apr.22	86	83	80	4	0	50	
	SE-9322	Apr.23 - Apr.29'93	130	130	129	Apr.29							

THE PRODUCTION & INCUBATION RESULT OF SPF EGGS AND C/O TYPE EGGS

Tabel -2 :C/O Egg (2)

Type of Egg	Code No.	Term of Lay Eggs	Number of Eggs	Eggs / Week	No.of Incubation	Date Inc Stert	Embryonated		Use for Bulk Pro 11 days	Use for Q C		Use for Other	Remarks
							Number	%		5 days	11 days		
C/O	SO-9301	Dec.31 - Jan.06'93	80	80	79	Jan.07	51	65	0	10	41	0	
	SO-9302	Jan.07 - Jan.14'93	66	66	66	Jan.14	39	59	0	24	13	0	
	SO-9303	Jan.14 - Jan.20'93	66	66	65	Jan.21	34	52	18	0	16	0	
	SO-9304	Jan.21 - Jan.27'93	65	65	65	Jan.28	37	57	0	26	11	0	
	SO-9305	Jan.28 - Feb.03'93	60	60	60	Feb.04	31	51	1	0	29	0	
	SO-9306	Feb.04 - Feb.10'93	63	63	63	Feb.11	32	50	0	0	31	0	
	SO-9307	Feb.11 - Feb.17'93	66	66	66	Feb.18	27	40	0	8	19	0	
	SO-9308	Feb.18 - Feb.24'93	68	68	68	Feb.25	40	58	0	0	36	0	
	SO-9309	Feb.25 - Mar.03'93	63	63	53	Mar.18	17	32	8	0	8	0	
	SO-9310	Mar.04 - Mar.10'93	64	64	60	Mar.25	22	34	10	0	10	0	
	SO-9311	Mar.11 - Mar.17'93	63	63	63	Apr.01	32	51	0	0	0	27	Hatched
	SO-9311	Mar.18 - Mar.24'93	54	54	52	Apr.01	38	73	0	0	15	15	
	SO-9312	Mar.25 - Mar.31'93	53	53	20	Apr.02	9	45	0	9	0	0	
	SO-9313	Mar.25 - Mar.31'93	53	53	31	Apr.03	24	77	0	0	0	24	Hatched
	SO-9314	Apr.01 - Apr.07'93	56	56	56	Apr.08	31	55	0	0	31	0	
	SO-9315	Apr.08 - Apr.14'93	45	45	20	Apr.12	15	75	0	0	15	0	
	SO-9316	Apr.08 - Apr.14'93	45	45	24	Apr.15	16	67	3	0	12	0	
	SO-9317	Apr.15 - Apr.22'93	46	46	42	Apr.22	29	69	3	26	0	0	
	SO-9318	Apr.23 - Apr.29'93	36	36	20	Apr.27							
	SO-9319	Apr.23 - Apr.29'93	36	36	16	Apr.29							
	SO-9320												
	SO-9321												

Breeding Condition of SPF Chicken

Table - 3 Mei, 03 1993. Now

Kind of Chicken	Isolator	Male ♂	Female ♀	Number of Chicken	Date of Hatch, Remarks
New tion F3	24	1	4	♂ : 2206 ♀ : 2486.2453.2220.2225	10 Dec.1992
	29	1	4	♂ : 2470 ♀ : 2214.2476.2219.2215	3 Dec.1992
	5	1	4	♂ : 2442 ♀ : 2228.2229.2495.2213	10 Dec.1992
	30	1	4	♂ : 2226 ♀ : 2433.2233.2439.2465	3 Dec.1992
	13	1	4	♂ : 2231 ♀ : 2224.2209.2232.2201	10 Dec.1992
	36	1	4	♂ : 2467. ♀ : 2461.2469.2496.2468.	3 Dec.1992
	4	2	4	♂ : 2251.2270 ♀ : 2260.2277.2256.2299	30 Dec.1992
	31	1	4	♂ : 2280 ♀ : 2252.2295.2292	3 Dec.1992
	14	1	4	♂ : 2210 ♀ : 2216.2497.2221.2475	30 Dec.1992
	35	1	4	♂ : 2258 ♀ : 2266.2268.2264.2259	30 Dec.1992
	37	1	4	♂ : 2255. ♀ : 2257.2286.2243.2282	3 Dec.1992
	3	1	3	♂ : 2443 ♀ : 2446.2445.2432	3 Dec. 1992
	8	2	4	♂ : 2492 ♀ : 2431.2478.2419.2474	3 Dec.1992
	34	1	4	♂ : 2247 ♀ : 2274.2267.2281.2289	30 Dec.1992
	33	1	4	♂ : 2471 ♀ : 2466.2472.2480.2493	30 Dec.1992
	17	1	4	♂ : 2279 ♀ : 2262.2300.2290.2273	10 Dec.1992
TOTAL		18	67		
New gene-ration C/O F3	16	3	2	♂ : 2238.2246.2248 ♀ : 2249.2239	30 Dec.1992
	11	1	3	♂ : 2242 ♀ : 2250.2241.2245	30 Dec.1992
TOTAL		4	5		
New gene ration C/O F3	38	51			23 April 1993

Breeding Condition of SPF Chicken

Table - 4 MEI 03.1993. Now

Kind of Chicken	Isolator	Male ♂	Female ♀	Number of Chicken	Date of Hatch, Remarks
SPF New Gene ration	10	1	4	♂ :2180. ♀:2181 2195.2185.2179	April 1992
	1	1	3	♂:2416. ♀ :2150 2140.2141	"
	26	1	2	♂ 2175. ♀ :2182 .2176	"
	20	1	4	♂ 2188. ♀: 2176 2168.2173.2171	"
	22	1	4	♂ 2138. ♀ :2144 2147.2151.2146	"
	23	1	3	♂: 2450.♀:2435 2451.2447.	"
	21	1	4	♂ : 2448.♀: 2403 2405.2409.2410	"
	19	1	4	♂:2424.♀:2169 2170.2172.2174	"
	6	1	4	♂ :2402.♀:2456 2454.2441.2440	"
Total		9	32	-	-
New gene-ration for C/O F2	2	1	3	♂:2153. ♀: 2165 2161.2157.	April 1992
	25	1	4	♂: 2123 .♀:2158 2159.2160.2163	"
	9	1	4	♂ :2156.♀: 2162 2164.2421.2412	"
	7	1	2	♂ :2152 ♀ :2404.2408	
	TOTAL	4	13	-	-

April, 19

Table 1-3 ; Test on control of cell culture-1 (3)

Code No.	1-1. Test for Haemadsorbing			1-2. Test on Cell Culture for Non- Haemadsorbing Viruses									Remark
				Simian cells			Human cells			CEF Cell			
	Type of R.B.C	Date of test	Result	Type of cells	Date of inoc.	Result	Type of cells	Date of inoc.	Result	Method	Date of inoc.	Result	
MC-9226	0.5% GP	Nov. 4	Passed	Vero	Nov. 18	Passed	FI	Nov. 18	Passed	RIF. COFAL	Feb. 1	Passed	
MC-9227	0.5% GP	Nov. 11	Passed	Vero	Nov. 18	Passed	FI	Nov. 18	Passed	RIF. COFAL	Feb. 15	Passed	
MC-9228	0.5% GP	Nov. 18	Passed	Vero	Nov. 25	Passed	FI	Nov. 25	Passed	RIF. COFAL	Feb. 15	Passed	
MC-9229	0.5% GP	Nov. 25	Passed	Vero	Dec. 9	Passed	FI	Dec. 9	Passed	RIF. COFAL	Mar. 29	NY	
MC-9230	0.5% GP	Dec. 2	Passed	Vero	Dec. 9	Passed	FI	Dec. 9	Passed	RIF. COFAL	Mar. 29	NY	
MC-9231	0.5% GP	Dec. 9	Passed	Vero	Jan. 19	Passed	FI	Jan. 19	Passed	RIF. COFAL	Apr. 12	NY	
MC-9232	0.5% GP	Dec. 16	Passed	Vero	Jan. 19	Passed	FI	Jan. 19	Passed	RIF. COFAL	Apr. 12	NY	
MC-9233	0.5% GP	Dec. 24	Passed	Vero	Jan. 19	Passed	FI	Jan. 19	Passed	RIF. COFAL	Apr. 26	NY	
MC-9234	0.5% GP	Dec. 30	Passed	Vero	Jan. 19	Passed	FI	Jan. 19	Passed	RIF. COFAL	Apr. 26	NY	
MCC-013	0.5% GP	Jan. 21	Passed	Vero	Feb. 3	Passed	FI	Feb. 3	Passed	RIF. COFAL			
MCC-023	0.5% GP	Jan. 25	Passed	Vero	Feb. 3	Passed	FI	Feb. 3	Passed	RIF. COFAL			
MCC-033	0.5% GP	Jan. 27	Passed	Vero	Feb. 3	Passed	FI	Feb. 3	Passed	RIF. COFAL			
MCC-043	0.5% GP	Jan. 29	Passed	Vero	Feb. 3	Passed	FI	Feb. 3	Passed	RIF COFAL			
MCC-053	0.5% GP	Feb. 3	Passed	Vero	Feb. 24	Passed	FI	Feb. 24	Passed	RIF. COFAL			
MCC-063	0.5% GP	Feb. 10	Passed	Vero	Feb. 24	Passed	FI	Feb. 24	Passed	RIF. COFAL			

ND ; not done ; NY ; not yet done or resulted

Table 1-3 ; Test on control of cell culture-1 (4)

April, 199

Code No.	1-1. Test for Haemadsorbing			1-2. Test on Cell Culture for Non-Haemadsorbing Viruses									Remark
				Simian cells			Human cells			CEF Cells			
	Type of R.B.C	Date of test	Result	Type of cells	Date of inoc.	Result	Type of cells	Date of inoc.	Result	Method	Date of inoc.	Result	
MCC-073	0.5% GP	Feb.17	Passed	Vero	Feb.24	Passed	FI	Feb.24	Passed	RIF, COFAL			
MCC-083	0.5% GP	Feb.19	Passed	Vero	Feb.24	Passed	FI	Feb.24	Passed	RIF, COFAL			
MCC-093	0.5% GP	Feb.24	Passed	Vero	Apr.7	Passed	FI	Apr.7	Passed	RIF, COFAL			
MCC-103	0.5% GP	Mar.3	Passed	Vero	Apr.7	Passed	FI	Apr.7	Passed	RIF, COFAL			
MCC-113	0.5% GP	Mar.5	Passed	Vero	Apr.21	NY	FI	Apr.21	NY	RIF, COFAL			
MCC-123	0.5% GP	Mar.10	Passed	Vero	Apr.21	NY	FI	Apr.21	NY	RIF, COFAL			
MCC-133	0.5% GP	Mar.24	Passed	Vero			FI			RIF, COFAL			
MCC-143	0.5% GP	Mar.26	Passed	Vero			FI			RIF, COFAL			
MCC-153A	0.5% GP	Apr.14	Passed	Vero			FI			RIF, COFAL			
MCC-153B	0.5% GP	Apr.16	Passed	Vero			FI			RIF, COFAL			
MCC-163	0.5% GP	Apr.21	Passed	Vero			FI			RIF, COFAL			
MCC-173	0.5% GP	Apr.23	Passed	Vero			FI			RIF, COFAL			
MCC-183	0.5% GP	Apr.28	Passed	Vero			FI			RIF, COFAL			
MCC-	0.5% GP			Vero			FI			RIF, COFAL			
MCC-	0.5% GP			Vero			FI			RIF, COFAL			

ND : not done ; NY : not yet done or resulted

April, 1993

Table 2-3 ; Test on single harvest-1 (5)

Code.No.	2-1. Sterility Test						2-2. Test for Virus Concentration				Remark
	for Bacteria		for Fungi		for Mycoplasma		PFU/ml		TCID50/ml		
	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result (log 10)	Date of test	Result (log 10)	
MVH-093	Feb.22	Passed	Feb.22	Passed		ND		ND		ND	
MSH-043	Mar.1	Passed	Mar.1	Passed	Mar.1	Passed	Mar.12	7.27		ND	
MVH-103	Mar.1	Passed	Mar.1	Passed		ND		ND		ND	
MVH-113	Mar.2	Passed	Mar.2	Passed		ND		ND		ND	
MSH-063	Mar.4	Passed	Mar.4	Passed	Mar.4	Passed	Mar.12	7.41		ND	
MSH-073	Mar.9	Passed	Mar.9	Passed	Mar.9	Passed	Mar.12	6.72		ND	
MSH-083	Mar.12	Passed	Mar.12	Passed	Mar.12	Passed	Mar.12	6.84		ND	
MVH-123	Mar.16	Passed	Mar.16	Passed		ND	Mar.12	7.42		ND	
MSH-093	Mar.19	Passed	Mar.19	Passed	Mar.19	Passed	Mar.31	6.85		ND	
MVH-133	Mar.29	Passed	Mar.29	Passed		ND		ND		ND	
MVH-143	Apr.14	Passed	Apr.14	Passed		ND		ND		ND	
MSH-053	Apr.2	Passed	Apr.2	Passed	Apr.2	NY	Apr.28	NY		ND	
MVH-153A	Apr.12	Passed	Apr.12	Passed		ND	Apr.28	NY		ND	
MVH-153B	Apr.12	Passed	Apr.12	Passed		ND	Apr.28	NY		ND	
MVH-163	Apr.19	NY	Apr.19	NY		ND		ND		ND	

Table 2-3 ; Test on single harvest-1 (6)

April, 19

Code. No.	2-1. Sterility Test						2-2. Test for Virus Concentration				Remark
	for Bacteria		for Fungi		for Mycoplasma		PFU/ml		TCID50/ml		
	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result (log 10)	Date of test	Result (log 10)	
MVH-173	Apr. 21	NY	Apr. 21	NY		ND		ND		ND	
MSH-103	Apr. 23	NY	Apr. 23	NY	Apr. 23	NY	Apr. 28	NY		ND	
MVH-183	Apr. 27	NY	Apr. 27	NY		ND	Apr. 28	NY		ND	
MSH-113	Apr. 26	NY	Apr. 26	NY	Apr. 27	NY	Apr. 28	NY		ND	
MSH-123	Apr. 27	NY	Apr. 27	NY	Apr. 27	NY	Apr. 28	NY		ND	
MSH-133	Apr. 29	NY	Apr. 29	NY	Apr. 29	NY				ND	
										ND	
										ND	
										ND	
										ND	
										ND	
										ND	
										ND	
										ND	
										ND	

Apr. 1 1993

Table 3-1-2 ; Test on Virus Pool-1 (2)

Code No.	3-1. Sterility Test								3-2. Test for Virus Concent.				Remark
	for Bacteria		for Fungi		for Mycoplasma		for Mycobact.		PFU/ml		TCID50/ml		
	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result (log 10)	Date of test	Result (log 10)	
MP-9215	Aug. 20	Passed	Aug. 20	Passed	Aug. 20	Passed	Aug. 20	Passed	Aug. 26	7. 37	Aug. 26	7. 58	
MP-9216	Aug. 27	Passed	Aug. 27	Passed	Aug. 27	Passed	Aug. 27	Passed	Sep. 2	7. 06	Sep. 2	7. 06	
MP-9217	Sep. 4	Passed	Sep. 4	Passed	Aug. 4	Passed	Sep. 4	Passed	Sep. 4	7. 19	Sep. 4	7. 34	
MP-9218	Sep. 18	Passed	Sep. 18	Passed	Sep. 18	Passed	Sep. 18	Passed	Sep. 16	7. 73	Sep. 16	7. 57	
MP-9219	Sep. 17	Passed	Sep. 17	Passed	Sep. 17	Passed	Sep. 17	Passed	Sep. 25	7. 64	Sep. 25	7 57	
MP-9220	Sep. 24	Passed	Sep. 24	Passed	Sep. 24	Passed	Sep. 24	Passed	Sep. 25	7. 27	Sep. 25	7. 49	
MP-9221	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	7. 12	Oct. 2	7. 16	
MP-9222	Oct. 16	Passed	Oct. 16	Passed	Oct. 16	Passed	Oct. 16	Passed	Oct. 21	7. 32	Oct. 21	7. 47	
MP-9223	Oct. 22	Passed	Oct. 22	Passed	Oct. 22	Passed	Oct. 22	Passed	Oct. 23	7. 55	Oct. 23	7. 57	
MP-9224	Dec. 30	Passed	Dec. 30	Passed	Dec. 30	Passed	Dec. 30	Passed	Jan. 6	7. 42		ND	
MVP-013	Feb. 5	Passed	Feb. 5	Passed	Jan. 22	Passed	Jan. 22	Passed	Jan. 27	7. 47		ND	
MVP-023	Feb. 22	Passed	Feb. 22	Passed	Feb. 22	Passed	Feb. 22	Passed	Feb. 24	7. 24		ND	
MVP-033	Mar. 5	Passed	Mar. 5	Passed	Mar. 5	Passed	Mar. 5	Passed	Mar. 12	6. 86		ND	
MVP-043	Apr. 21	NY	Apr. 21	NY	Apr. 22	NY	Apr. 21	NY	Apr. 29	NY			

Table 3-2-2 ; Test on Virus Pool 2 (2)

Apr. 1 1993

Code No.	3-3. Test in Cell Culture of Neutralized Virus Pool						3-4. Test in Embryos of Fertilized Chicken Eggs						Remark
	Simian cells			Human cells			By Allantoic route			By Yolk Sac route			
	Type of cells	Date of inoc.	Result	Type of	Date of	Result	No & age of eggs	Date of test	Result	No & age of eggs	Date of test	Result	
MP-9215	Vero	Sep. 30	Passed	FI	Sep. 30	Passed	22, 11d	Nov. 16	Passed	22, 6d	Nov. 12	Passed	
MP-9216	Vero	Sep. 30	Passed	FI	Sep. 30	Passed	21, 11d	Nov. 16	Passed	22, 6d	Nov. 12	Passed	
MP-9217	Vero	Oct. 7	Passed	FI	Oct. 7	Passed	21, 11d	Nov. 16	Passed	22, 6d	Nov. 12	Passed	
MP-9218	Vero	Oct. 7	Passed	FI	Oct. 7	Passed	25, 11d	Nov. 13	Passed	27, 6d	Nov. 19	Passed	
MP-9219	Vero	Apr. 7	Passed	FI	Apr. 7	Passed	28, 11d	Dec. 7	Passed	27 6d	Nov. 19	Passed	
MP-9220	Vero	Apr. 7	Passed	FI	Apr. 7	Passed	22, 11d	Nov. 30	Passed	25, 6d	Nov. 26	Passed	
MP-9221	Vero	Apr. 21	NY	FI	Apr. 21	NY	24, 11d	Nov. 30	Passed	21, 6d	Jan. 28	Passed	
MP-9222	Vero	Apr. 21	NY	FI	Apr. 21	NY	24, 11d	Nov. 30	Passed	22, 6d	Jan. 28	Passed	
MP-9223	Vero			FI			24, 11d	Nov. 30	Passed	27, 6d	Feb. 4	Passed	
MP-9224	Vero			FI			30, 11d	Jan. 4	Passed	28, 6d	Feb. 4	Passed	
MVP-013	Vero			FI			25, 11d	Feb. 8	Passed	26, 6d	Feb. 4	Passed	
MVP-023	Vero			FI			40, 11d	Feb. 22	Passed	40, 6d	Feb. 19	Passed	
MVP-033	Vero			FI			40, 11d	Mar. 8	Passed	40, 6d	Mar. 5	Passed	
MVP-043	Vero			FI			22, 11d	Apr. 21	Passed				
	Vero			FI									

April 1993

Table 4-1-2 ; Test on Bulk 1 (2)

Code No.	4-1. Sterility Test								4-2. Test for Virus Concent.				Remark
	for Bacteria		for Fungi		for Mycoplasma		for. Mycobact.		PFU/ml		TCID50/ml		
	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result	Date of test	Result (log 10)	Date of test	Result (log 10)	
MB-9215	Aug. 20	Passed	Aug. 20	Passed	Aug. 20	Passed	Aug. 20	Passed	Aug. 26	7. 52	Aug. 26	7. 46	
MB-9216	Aug. 27	Passed	Aug. 27	Passed	Aug. 27	Passed	Aug. 27	Passed	Sep. 2	6. 97	Sep. 2	7. 10	
MB-9217	Sep. 4	Passed	Sep. 4	Passed	Sep. 4	Passed	Sep. 4	Passed	Sep. 4	7. 00	Sep. 4	7. 47	
MB-9218	Sep. 15	Passed	Sep. 15	Passed	Sep. 15	Passed	Sep. 15	Passed	Sep. 16	7. 81	Sep. 16	7. 69	
MB-9219	Sep. 18	Passed	Sep. 18	Passed	Sep. 18	Passed	Sep. 18	Passed	Sep. 25	7. 54	Sep. 25	7. 62	
MB-9220	Sep. 24	Passed	Sep. 24	Passed	Sep. 24	Passed	Sep. 24	Passed	Sep. 25	7. 07	Sep. 25	7. 51	
MB-9221	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	Passed	Oct. 2	6 98	Oct. 2	6. 74	
MB-9222	Oct. 16	Passed	Oct. 16	Passed	Oct. 16	Passed	Oct. 16	Passed	Oct. 21	7. 30	Oct. 21	7. 50	
MB-9223	Oct. 22	Passed	Oct. 22	Passed	Oct. 22	Passed	Oct. 22	Passed	Oct. 23	7. 33	Oct. 23	7. 21	
MB-9224	Dec. 30	Passed	Dec. 30	Passed	Dec. 30	Passed	Dec. 30	Passed	Jan. 6	7. 54		ND	
MVB-013	Feb. 5	Passed	Feb. 5	Passed	Jan. 22	Passed	Jan. 22	Passed	Jan. 27	7. 40		ND	
MVB-023	Feb. 22	Passed	Feb. 22	Passed	Feb. 22	Passed	Feb. 22	Passed	Feb. 24	7. 16		ND	
MVB-033	Mar. 5	Passed	Mar. 5	Passed	Mar. 5	Passed	Mar. 5	Passed	Mar. 12	6. 77		ND	
MVB-043	Apr. 21	NY	Apr. 21	NY	Apr. 22	NY	Apr. 21	NY	Apr. 28	NY		ND	

Table 4-2-2 ; Test on Bulk 2 (2)

April 1993

Code No.	4-3. Identity Tests TCID semi-micro (J-NIH) method		4-5. Test for Clarification		4-6. Test in small Laboratory Animals * (MP)						Remark
					Adult mice		Suckling mice		Guinea Pigs		
	Date of test	Result	Date of test	Result	Date of inject.	Result	Date of inject.	Result	Date of inject.	Result	
MB-9215	Aug. 26	Passed	Aug. 27	Passed	Sep. 11	Passed	Oct. 2	Passed	Oct. 15	Passed	
MB-9216	Sep. 2	Passed	Sep. 28	Passed	Sep. 11	Passed	Oct. 2	Passed	Oct. 15	Passed	
MB-9217	Sep. 4	Passed	Sep. 28	Passed	Sep. 11	Passed	Oct. 2	Passed	Oct. 15	Passed	
MB-9218	Sep. 16	Passed	Oct. 22	Passed	Sep. 28	Passed	Oct. 2	Passed	Nov. 9	Passed	
MB-9219	Sep. 25	Passed	Oct. 22	Passed	Sep. 28	Passed	Oct. 9	Passed	Nov. 9	Passed	
MB-9220	Sep. 25	Passed	Oct. 22	Passed	Sep. 29	Passed	Oct. 23	Passed	Nov. 9	Passed	
MB-9221	Oct. 2	Passed	Oct. 22	Passed	Nov. 9	Passed	Oct. 23	Passed	Nov. 9	Passed	
MB-9222	Oct. 21	Passed	Oct. 22	Passed	Dec. 3	Passed	Oct. 23	Passed	Nov. 10	Passed	
MB-9223	Oct. 23	Passed	Nov. 5	Passed	Dec. 16	Passed	Dec. 16	Passed	Dec. 16	Passed	
MB-9224	Jan. 6	Passed	Jan. 21	Passed	Jan. 29	Passed	Jan. 29	Passed	Jan. 29	Passed	
MVB-013	Jan. 27	Passed			Feb. 12	Passed	Feb. 26	Passed	Feb. 12	Passed	
MVB-023	Feb. 24	Passed			Mar. 1	Passed	Mar. 1	Passed	Mar. 1	Passed	
MVB-033	Mar. 12	Passed			Apr. 2	Passed	Apr. 22	NY	Apr. 16	NY	
MVB-043	Apr. 29	NY			Apr. 26	NY	Apr. 22	NY	Apr. 26	NY	

April, 1993

Table-5 ; Test on Final Bulk (2)

Code No.	5-1. Sterility Tests				5-2. Test for Virus Concentration				5-3. Test for Residual Serum Proteins			5-4. Test for pH	
	for Bacteria		for Fungi		PFU/ml		TCID50/ml						
	Date of test	Result	Date of test	Result	Date of test	Result (log 10)	Date of test	Result (log 10)	Date of test	Contents (ug/ml)	Result	Date of test	Result
25023	Jan. 27	Passed	Jan. 27	Passed	Feb. 10	6.38	-	ND	Mar. 4	0.190	Passed	Mar. 4	7.02
25033	Apr. 16	NY	Apr. 16	NY	Apr. 28	NY	-	ND					
25043	Apr. 21	NY	Apr. 21	NY									
25053	Apr. 29	NY	Apr. 29	NY									

Table 6-1-3 ; Test on Final Product-1 (3)

April 1993

Lot. No.	6-1. Test for Virus Concentration				6-2-1. Test for Stability 37.C, 7days)						6-2-2. Test for Stability			
	PFU/ml		TCID50/ml		PFU/ml			TCID50/ml			PFU/ml		TCID50/ml	
	Date of test	Result (log 10)	Date of test	Result (log 10)	Date of test	Result (log 10)	Decrease	Date of test	Result (log 10)	Decrease	37.C 14days	37.C 28days	37.C 14days	37.C 28days
CA-1013 1	Nov. 4	5.44	Nov. 4	5.42	Nov. 4	4.81	0.63	Nov. 4	5.25	0.17	ND	ND	ND	ND
CA-1013 6	Nov. 4	5.39	Nov. 4	5.47	Nov. 4	4.75	0.64	Nov. 4	4.78	0.69	ND	ND	ND	ND
CA-1013 11	Nov. 4	5.29	Nov. 4	5.23	Nov. 4	4.66	0.63	Nov. 4	4.74	0.49	ND	ND	ND	ND
CA-1014 1	Nov.11	5.54	Nov.11	5.55	Nov.11	5.10	0.44	Nov.11	5.10	0.45	ND	ND	ND	ND
CA-1014 4	Nov.11	5.48	Nov.11	5.47	Nov.11	5.02	0.46	Nov.11	4.67	0.80	ND	ND	ND	ND
CA-1014 8	Nov.11	5.53	Nov.11	5.57	Nov.11	5.03	0.50	Nov.11	4.70	0.87	ND	ND	ND	ND
CA-1014 11	Nov.11	5.46	Nov.11	5.26	Nov.11	5.12	0.34	Nov.11	4.94	0.32	ND	ND	ND	ND
CA-1015 1	Nov.11	5.53	Nov.11	5.49	Nov.18	4.78	0.75	Nov.18	5.06	0.43	ND	ND	ND	ND
CA-1015 6	Nov.11	5.39	Nov.11	5.40	Nov.18	4.88	0.51	Nov.18	5.10	0.30	ND	ND	ND	ND
CA-1015 11	Nov.11	5.44	Nov.11	5.43	Nov.18	4.83	0.61	Nov.18	4.74	0.69	ND	ND	ND	ND
CA-1216	Dec.30	5.37	-	ND	Dec.30	4.69	0.68	-	ND	ND	ND	ND	ND	ND
CA-1217	Dec.30	5.38	-	ND	Dec.30	4.76	0.62	-	ND	ND	ND	ND	ND	ND
CA-1218	Jan.6	5.46	-	ND	Jan.6	4.94	0.52	-	ND	ND	ND	ND	ND	ND
250013	Feb.3	5.69	-	ND	Feb.3	5.18	0.51	-	ND	ND	ND	ND	ND	ND
250023	Feb.10	5.50	-	ND	Feb.10	4.87	0.63	-	ND	ND	ND	ND	ND	ND
250033	Apr.28	NY	-	ND	Apr.28	NY		-	ND	ND	ND	ND	ND	ND

April, 1993

Table 6-2-3 ; Test on Final Product-2 (4)

Code No.	6-3. Identity Test TCID50 semi-micro (J-NIH) method		6-4. Test for Freedom from Abnormal Toxicity				6-5. Sterility Test				6-6. Test for Residual Moisture		
			Adult mice		Guinea Pig		for Bacteria		for Fungi				
	Date of test	Result	Date of inject.	Result	Date of inject.	Result	Date of test	Result	Date of test	Result	Date of test	Contents (M%)	Result
250033	Apr. 28	NY	Apr. 26	NY	Apr. 26	NY	Apr. 19	NY	Apr. 19	NY			
250043			Apr. 26	NY	Apr. 26	NY	Apr. 26	NY	Apr. 26	NY			

Table 6-2-3 : Test on Final Product-2 (4)

April '993

Code No.	6-3. Identity Test TCID50 semi-micro (J-NIH) method		6-4. Test for Freedom from Abnormal Toxicity				6-5. Sterility Test				6-6. Test for Residual Moisture		
			Adult mice		Guinea Pig		for Bacteria		for Fungi				
	Date of test	Result	Date of inject.	Result	Date of inject.	Result	Date of test	Result	Date of test	Result	Date of test	Contents (W/)	Result
250033	Apr. 28	NY	Apr. 26	NY	Apr. 26	NY	Apr. 19	NY	Apr. 19	NY			
250043			Apr. 26	NY	Apr. 26	NY	Apr. 26	NY	Apr. 26	NY			

PROGRESS RECORD OF POLIVIRUS TYPE 1 SINGLE HARVEST.

	Monkey Code No	Sex	Body Weight (Kg)	Date of Arrival	Monkey Origin	Anti bodies vs FV3	Anti bodies vs SV40	Production code	Date of Nephrect	Cortex Weight (gr)	Cells Suspension Vol(1) (..... x 10)	25 % Cell Control HAD D4	25 % Cell Control HAD D14	25 % Cell Control CPE (14D)	VCF VOL (Lt)	TEST ON SINGLE HARVEST Sterility	Indentification test 1	Indentification test 2	V.Titer CCID50/ml test 1	V.Titer CCID50/ml test 2	RCT MARKER(FPU/ml) Test1 36,0	Test1 39,0	Test1 39,5	Test1 36,0	Test1 39,0	Test1 39,5	ADVENTITION VIRUS TEST IN CELL CULTURE TCF - 0 Steril	MK Orig Cul	MK Sub Cul	VK Orig Cul	R K	Vero	TCF - 7 MK Orig Cul	VK Orig Cul	R K	Vero	TCF - 14 MK Orig Cul	VK Orig Cul	R K	Vero	VCF MK Orig Cul	MK Sub Cul	VK Orig Cul	R K	Vero
1	P12	M	1.48	09-02 92	Palembang (Mualim)	!		19301 A	01-06 93	5.6	8.1 (0.6)	-	-	-	5.9	ok	ok	ok	8.37 7.8	8.08 8.62	7.86	4.19	0.4				ok			ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			ok	ok	ok
2	P22	M	1.52	09-02 92	Palembang (Mualim)	!		19301 B	01-06 93	6.0	12 (0.6)	ND	ND	+	9.2		-																									
3	P23	M	1.18	09-02 92	Palembang (Mualim)	!		19302 A	01-11 93	4.2	7.2 (0.5)	ND	ND	+	-		-																									
4	Q41	M	1.17	09-09 92	Palembang (Mualim)	!		19302 B	01-11 93	5.0	12.2 (0.5)	ND	ND	+	-		-																									
5	R32	M	1.35	09-19 92	Palembang (Mualim)	!		19303 A	01-13 93	5.0	11.2 (0.5)	-	-	-	7.9	ok	ok	ok	8.0	7.85 8.78	7.95	4.25	1.2				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
6	S25	F	1.60	09-24 92	Palembang (Mualim)	!		19303 B	01-13 93	4.0	10.5 (0.5)	-	-	-	7.6	ok	ok	ok	8.33	8.58	8.16	4.29	1.6				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
7	U21	F	0.78	11-19 92	Baturaja (Mualim)	!		19304 A	01-18 93	3.0	10.2 (0.5)	-	-	-	7.5	ok	ok	ok	8.06	8.25	8.12	4.23	1.22				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
8	U22	M	0.86	11-19 92	Baturaja (Mualim)	!		19304 B	01-18 93	4.0	8.6 (0.5)	ND	ND	+	6.3		-																									
9	U5	F	0.94	11-19 92	Baturaja (Mualim)	!		19305 A	01-20 93	4.0	10.7 (0.5)	-	-	-	7.8	ok	ok	ok	8.39	8.78	8.07	4.31	1.2				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
10	U7	M	1.41	11-19 92	Baturaja (Mualim)	!		19305 B	01-20 93	8.3	14.8 (0.8)	-	ND	+	12.1		-																									
11	U15	M	0.83	11-19 92	Baturaja (Mualim)	!		19306 A	01-25 93	3.3	10.2 (0.5)	-	-	-	7.9	ok	ok	ok	8.20	8.52	8.12	4.31	1.25				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
12	U26	M	1.51	11-19 92	Baturaja (Mualim)	!		19306 B	01-25 93	6.0	13.2 (0.6)	-	ND	+	10.5		-																									
13	V3	F	1.26	11-24 92	Jambi (Mualim)	!		19307 A	01-27 93	5.2	10.0 (0.6)	-	-	-	7.7	ok	ok	ok	8.28	8.36	8.0	4.25	1.5				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
14	V29	M	1.37	11-24 92	Jambi (Mualim)	!		19307 B	01-27 93	5.2	12.0 (0.6)	-	-	+	10	ok	ok	ok	8.48	8.58	8.33	4.58	1.25				ok			ok		ok	ok	ok	ok	ok	ok	ok	ok	ok		ok	ok	ok
15	AA63	M	0.55	3 Month	Lampung	!		BCK IV 19307 C	01-27 93	1.5	4.4 (0.5)	-	-	-	29.7																											
16	H21	F	2.4	11-28 92	Lampung Purwanto			19308 A	02-01 93	9.2	14.0 (0.9)	ND	ND	+	-																											
17	AA19	F	0.8	3 month	Lampung	!		BCK V 19308 B	02-03 93	2.3	6.6 (0.5)	-	-	-	34.0																											

type1

PROGRESS RECORD OF POLIVIRUS TYPE 1 SINGLE HARVEST.

	Monkey Code No	Sex	Body Weight (kg)	Date of Arrival	Monkey Origin	Antibodies vs FVJ	Antibodies vs SV40	Production code	Date of Nephrect	Cortex Weight (gr)	Cells Suspention Vol(1) (..... x 10⁶)	25 % Cell Control HAD D4	25 % Cell Control HAD D14	25 % Cell Control CPE (14D)	VCF VOL (Lt)	TEST ON SINGLE HARVEST: Sterility	Indentification test 1	Indentification test 2	V.Titer CCID50/ml test 1	V.Titer CCID50/ml test 2	RCT MARKER(FPU/ml) Test1 36,0	Test1 39,0	Test1 39,5	Test2 36,0	Test2 39,0	Test2 39,5	ADVENTITION VIRUS TEST IN CELL CULTURE: TCF-0 Steril	TCF-0 MK Orig Cul	TCF-0 MK Sub Cul	TCF-0 VK Orig Cul	TCF-0 RK	TCF-0 Vero	TCF-7 MK Orig Cul	TCF-7 VK Orig Cul	TCF-7 RK	TCF-7 Vero	TCF-14 MK Orig Cul	TCF-14 VK Orig Cul	TCF-14 RK	TCF-14 Vero	VCF MK Orig Cul	VCF MK Sub Cul	VCF VK Orig Cul	VCF RK	VCF Vero
18	Y18	F	1.26	12-11 92	Palembang (Mualim)	+		19309 A	02-08 93	4.2	10.4 (0.6)	-	-	+	7.35																													
19	Y16	M	1.10	12-11 92	Palembang (Mualim)	+		19309 B	02-08 93	4.2	9.25 (0.6)	-	-	-	6.0	ok					8.07	4.24	1.69				ok	ok		ok	ok	ok		ok	ok		ok	ok		ok			ok	ok
20	Y10	M	0.95	12-11 92	Palembang (Mualim)			19310 A	02-10 93	3.6	10.0 (0.6)	-	-	-	6.8	ok											ok	ok		ok	ok	ok		ok	ok		ok	ok		ok			ok	ok
21	X19	M	1.03	12-12 92	Palembang (Mualim)			19310 B	02-10 93	4.5	10.4 (0.6)	-	-	-	7.2	ok											ok	ok		ok	ok	ok		ok			ok	ok					ok	ok
22	Z37	F	0.94	12-14 92	Palembang (Mualim)	+		19311 A	02-15 93	3.0	7.5 (0.6)	ND	ND	+																														
23	Z26	M	0.94	12-14 92	Palembang (Mualim)	+		19311 B	02-15 93	3.2	6.8 (0.6)	ND	ND	+																														
24	AB23	F	1.45	12-21 92	Palembang (Mualim)	+		19312 A	02-17 93	5.4	10.7 (0.7)	ND	ND	+	8.0																													
25	AC1	M	1.48	12-28 92	Cianjur (Sukri)	+		19313 A	02-22 93	7.8	12.0 (0.8)	-	-	+	9.5																													
26	AC4	M	1.40	12-28 92	Cianjur (Sukri)	+		19313 B	02-22 93	6.8	11.7 (0.7)	-	-	+	9.2																													
27	AC5	M	1.69	12-28 92	Cianjur (Sukri)	+		19314 A	02-24 93	8.0	11.3 (0.8)	-	-	-	7.5																													
28	Z44	M	0.32	2,5 month	Bio Farma	+		BCK VI 19314 B	02-24 93	1.3	2.7 (0.6)	-	-	-	16.8																													
29	AD12	M	0.82	12-30 92	Palembang (Mualim)	+		19315 A	03-01 93	4.3	8.8 (0.6)	-	+	-	6.0																													
30	AD07	F	0.75	12-30 92	Palembang (Mualim)	+		19315 B	03-01 93	3.0	5.8 (0.6)	ND	ND	+	4.0																													
31	AD08	M	1.29	12-30 92	Palembang (Mualim)	+		19316 A	03-31 93	5.1	11.2 (0.7)	ND	ND	+																														
32	AF07	F	1.38	01-12 92	Palembang (Mualia)	+		19317 A	04-07 93	5.9	12.0 (0.7)	-			8.3																													
33	211192 01	F	0.52	5 month	Bio Farma	+		BCK VII 19318 A	04-14 93	2.1	5.2 (0.6)																																	
34	AF01	M	1.34	01-12 93	Palembang (Mualia)	+		19319 A	04-19 93	5.8	12.4 (0.7)																																	

type1-1

PROGRESS RECORD OF POLIVIRUS TYPE 1 SINGLE HARVEST.

	Monkey Code No	Sex	Body Weight (Kg)	Date of Arrival	Monkey Origin	Antibodies vs FV3	Antibodies vs SV40	Production code	Date of Nephrect	Cortex Weight (gr)	Cells Suspension Vol(1) (.... x 10)	25 % Cell Control HAD D4	HAD D14	CPE (14D)	VCF VOL (Lt)	TEST ON SINGLE HARVEST: Sterility	Indentification test 1	Indentification test 2	V.Titer CCID50/ml test 1	V.Titer CCID50/ml test 2	RCT MARKER(FPU/ml) Test1 36,0	Test1 39,0	Test1 39,5	Test2 36,0	Test2 39,0	Test2 39,5	ADVENTITION VIRUS TEST IN CELL CULTURE: TCF-0 Steril	TCF-0 MK Orig Cul	TCF-0 MK Sub Cul	TCF-0 VK Orig Cul	TCF-0 RK	TCF-0 Vero	TCF-7 MK Orig Cul	TCF-7 VK Orig Cul	TCF-7 RK	TCF-7 Vero	TCF-14 MK Orig Cul	TCF-14 VK Orig Cul	TCF-14 RK	TCF-14 Vero	VCF MK Orig Cul	VCF MK Sub Cul	VCF VK Orig Cul	VCF RK	VCF Vero
35	AF12	M	1.83	01-12 93	Palembang (Mualim)	+		19319 B	04-19 93	6.9	14.6 (0.7)																																	
36	AF15	M	2.34	01-21 93	Palembang (Mualim)	+		19320 A	04-21 93	7.6	14.0 (0.8)																																	
37	AG27	M	0.81	01-21 93	Lampung Herwanto	+		19320 B	04-21 93	3.0	8.0 (0.6)																																	
38	AK53	F	1.53	17-02 93	Palembang (Mualim)	+		19321 A	04-26 93	6.2	12.0 (0.7)																																	
39	AL14	F	0.92	22-02 93	Lampung Herwanto	+		19321 B	04-26 93	3.7	7.8 (0.7)																																	
40	12019315	M	0.66	5 month	Bio Farma			BCK VIII 19322 A	04-28 93	3.5	7.4 (0.6)																																	

typeI-2

PROGRESS RECORD OF POLIOVIRUS MONOVALEN BULK

BONO-1

No	Bulk Code	Sterility	Myco test	TB Test	Identification Test 1	Identification Test 2	Virus.Titration CCID50/ml Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10	Virus.Titration PFU/ml Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	rct - marker (PFU/ml) Test1 36.0	39.0	39.5	40.0	Test2 36.0	39.0	39.5	40.0	d - marker Test 1 High Bic	Low Bic	Test 2 High Bic	Low Bic	Adventitious virus test in cell culture M K Orig	Sub	V K Orig	Sub	Vero Orig	Animal Test Rabbit	Guinea Pig	Adult Mice	Suck Mice	M V T
					GMK	PMK	GMK	GMK	GMK	GMK	GMK	GMK	PMK	PMK	PMK		GMK	GMK	GMK	PMK	PMK	PMK																						
1	BPo 101	ok		ok	-	-	8.39	8.39	8.45				7.83	8.07			8.12	8.14					-	-	-	-	-	-	-	-	-	-	-	-	ok	-	ok	-	ok	ok	ok	ok	ok	
							8.36	8.33					7.7	8.04			8.32																										
2	BF 101	ok	-	-		ok	8.39	8.62	8.12	8.28			7.77	8.2			8.06	8.27		8.1	7.96		7.96	-	-	<0.01	8.03			<0.01	7.53	<3			-	-	-	-	-	-	-	-	-	-
							8.45	8.2	8.39	8.2			7.91	7.93			8.27	8.0																										
3	BPo 102	ok	ok	ok	-	-	8.45	8.45					7.91	7.89			8.28	8.17					-	-	-	-	-	-	-	-	-	-	-	-	ok	-	ok	-	ok		ok	ok		
							8.2						7.7	8.45																												
							8.3																																				
							8.12																																				
							8.27																																				
4	BF 102	ok	-	-		ok	8.59	8.36	7.95	8.2	8.45		8.01	7.86			7.93	8.09		8.13	7.87		8.06	-	-	<0.01					8.04	<3			-	-	-	-	-	-	-	-	-	-
							8.45	8.31	8.04	8.45	8.28		7.95	8.04			8.25	8.05																										
									8.36																																		
									8.7																																		
									8.12																																		
									8.26																																		
5	BPo 201	ok		ok	-	-	7.95	7.86	8.2	8.54	8.01		8.12	8.2	7.78		8.11						-	-	-	-	-	-	-	-	-	-	-	-	ok	-	ok	-	ok	ok	ok	ok	ok	
							8.31	8.36	8.14	8.2	8.0		8.28		7.81		8.29																										
										8.20																																		
										8.75																																		
6	BF 201	ok	-	-	ok	ok	7.89	8.2	7.8	7.85	8.39	8.37	7.93	8.2	7.45		8.05			8.27																-	-	-	-	-	-	-	-	-	-
							8.36	8.36	8.49	8.31	8.20	8.12	7.83		7.45		8.0																										
									8.31	8.2	7.83				7.3																												
									8.33	8.2	8.04				7.45																												
7	BPo 202	ok					8.2	8.3	8.04				7.45																														
							8.2	7.99	8.36				7.62																														
								8.12																																			
								8.12																																			
8	BF 202	ok			ok		8.2	8.36	8.01				7.36																														
							7.95	8.01	8.09				7.36																														

PROGRESS RECORD OF POLIOVIRUS MONOVALEN BULK

mnblang

No	Bulk Code	Sterility	Mycotest	TB Test	Identification Test 1	Identification Test 2	Virus.Titration CCID50/ml Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10	Virus.Titration PFU/ml Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	rct - marker (PFU/ml) Test1 36.0	39.0	39.5	40.0	Test2 36.0	39.0	39.5	40.0	d - marker Test 1 High Bic	Low Bic	Test 2 High Bic	Low Bic	Adventitious virus test in cell culture M K Orig	Sub	V K Orig	Sub	Vero Orig	Animal Test Rabbit	Guinea Pig	Adult Mice	Suck Mice	N V T
					GMK	PMK	GMK	GMK	GMK	GMK	GMK	GMK	PMK	PMK	PMK		GMK	GMK	GMK	PMK	PMK	PMK																						
8	8F 202						8.28	8.12	8.2				7.01																															
							8.38	8.08	8.04				7.08																															
9	8Po 301	ok	ok	ok	-	-	8.36	8.7	8.78				8.32	8.54			8.48	8.06																									
							8.45		8.62				8.12				8.61																									
							8.54																																			
10	8F 301	ok			ok	ok	8.45	8.51	8.78	8.45			7.95	8.01			8.48	7.98		8.4																					
							8.48	8.56	8.39	8.45			7.95				8.67	7.73																							
							8.54	8.45		8.36																															
								8.45		8.12																															

Polio Type 1 : a. Have already monovalent bulk 36 L.
Now still waiting for QC results.

b. Have already made.
35 batches from negative FAT monkey.
5 batches baby monkey (passage).
Now still waiting for QC results.

Polio Type 2 : - Have already monovalent bulk 94 L
Still waiting for now QC results.

Polio Type 3 : Have already monovalent bulk 61.8 L .
Still waiting for QC results.

MONTHLY REPORT
MONKEY RECEIVING AND CONSUMPTION
POLIO PRODUCTION MONKEY BREEDING

APRIL 1993

DATE	RECEIVING				USING			
	FAT (-)	FAT (+)	BABY	REMARKS	FAT (-)	FAT (+)	BABY	REMARKS
March 31,93	20	224	4	Last Stock in March 31, 1993				
March 28,93	-	-	5	Born in Polio Animal Breeding	7	-	2	Polio production Nepherectomy
					-	-	-	For NVT
					-	5	-	Polio testing Nepherectomy
					-	77	-	Dead in stable horse in Animal Breeding
					2	27	-	Dead caused diarrhea
					-	-	-	Dead caused mother dead
	20	224	9	SUB TOTAL	9	109	2	SUB TOTAL
	20	115	7	Last stock in April 30, 1993				

Bandung April 30, 1993

(Drh. Samiarso Laksono)

LAPORAN BULANAN
PENERIMAAN DAN PENGELUARAN KERA
SARANA PEMELIHARAAN KERA PRODUKSI POLIO

Bulan : April 1993

Tanggal	Penerimaan (dalam ekor)				Pengeluaran (dalam ekor)			
	FAT (-)	FAT (+)	BAYI	Keterangan	FAT (-)	FAT (+)	BAYI	Keterangan
31/03/93	20	224	4	Stock Awal per tanggal : 31/03/93				
28/04/93	-	-	5	Kelahiran Di Sarana Breeding Kera Polio	7	-	2	Nephrectomy produksi Polio
					-	-	-	Untuk NVT
					-	5	-	Nephrectomy untuk Testing Polio
					-	77	-	Mati di Kandang Besar Bid.Pemeliharaan Hewan
					2	27	-	Mati karena diare
					-	-	-	Mati karena induk mati
	20	224	9	Sub Total	9	109	2	Sub Total
	20	115	7	Stock Akhir per tanggal : 30/04/93				

Bandung, 30 April 1993

(Drh. Samiarso Laksono)

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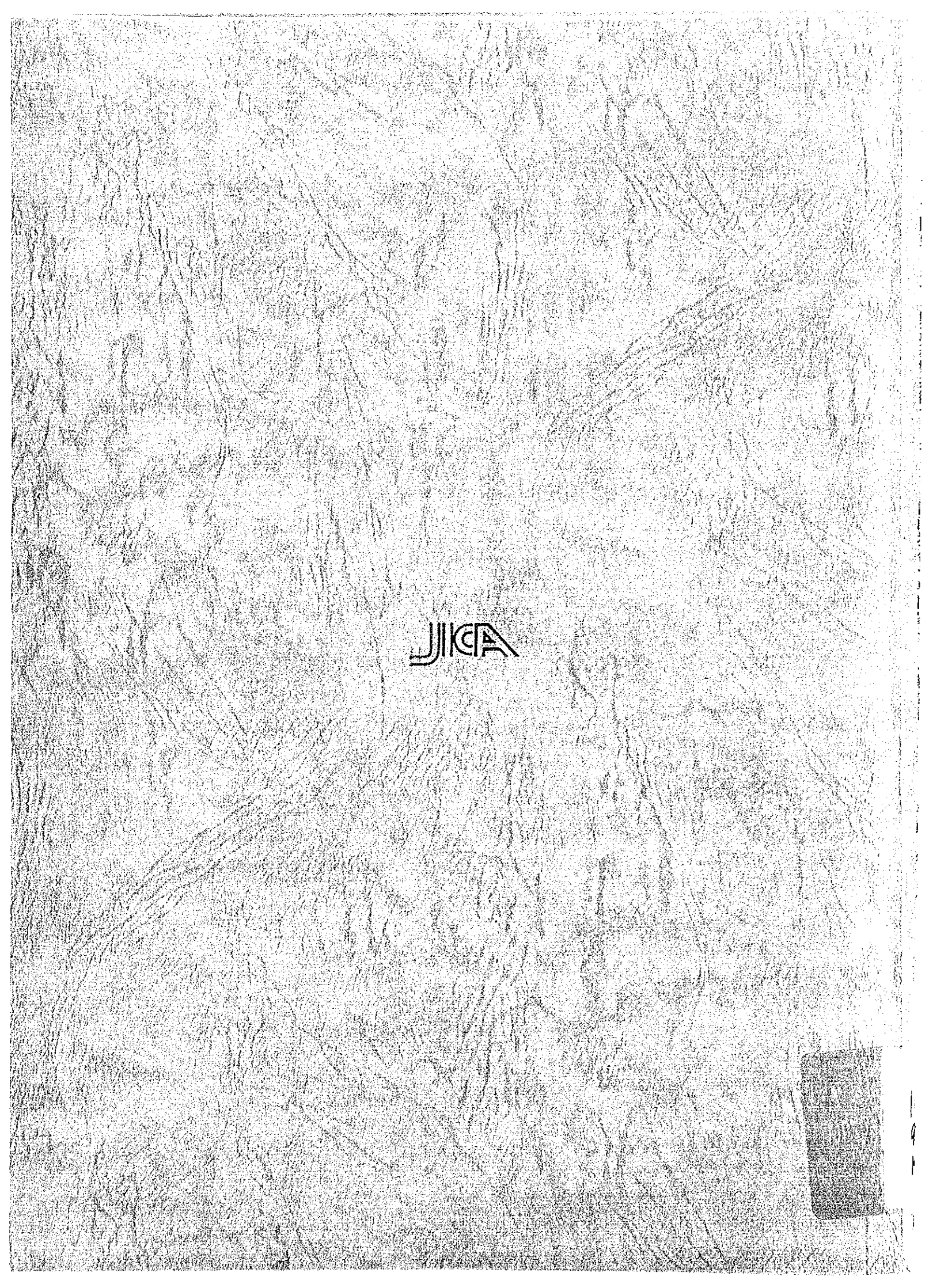
JICA