

Stabilizer of Live virus vaccine

	Measles	Rubella	varicella
Lactose	18 mg*	18 mg	—
D-sorbitol	5.4 mg	—	—
L-sodium glutamate	1.8 mg	1.8 mg	0.36 mg
Purified sugar	—	—	25.0 mg

* per dose

Prion --- BSE

BSE : Bovine Spongiform Encephalopathy
(Mad cow disease)

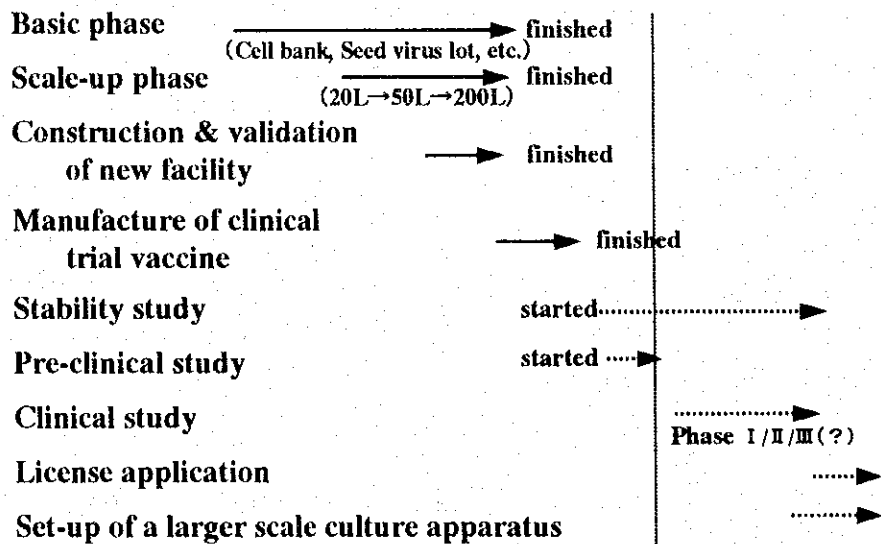
- Latent period 3 ~ 6year
- Recycling of animal protein(the internal organs or born)
- Creutzfeldt-Jakob disease (CJD)
- Gerstmann-Straussler-Scheinker syndrome
- Kuru

An Inactivated Japanese Encephalitis Vaccine

**Manufactured from the Virus-Infected
Microcarrier-Attached Vero cells:**

Time course of TC-JE vaccine development

1996 1997 1998 1999 2000 2001 2002 2003



Manufacturing cell bank system

Passage level

Original 121st
(ATCC.CCL81,Vero)

↓ 5 passages in stationary culture

Master cell bank 126th

↓ 4 passages in stationary culture

↓ 2 passages in microcarrier culture

Working cell bank 132nd

↓ 1 passage in stationary culture

↓ 4 passages in microcarrier culture

Manufacture 138th : microcarrier culture

Management of the seed virus

Original virus Beijing-1
(The seed virus for the mouse brain vaccine)

↓ 2 passages

Master seed virus Vero/2nd

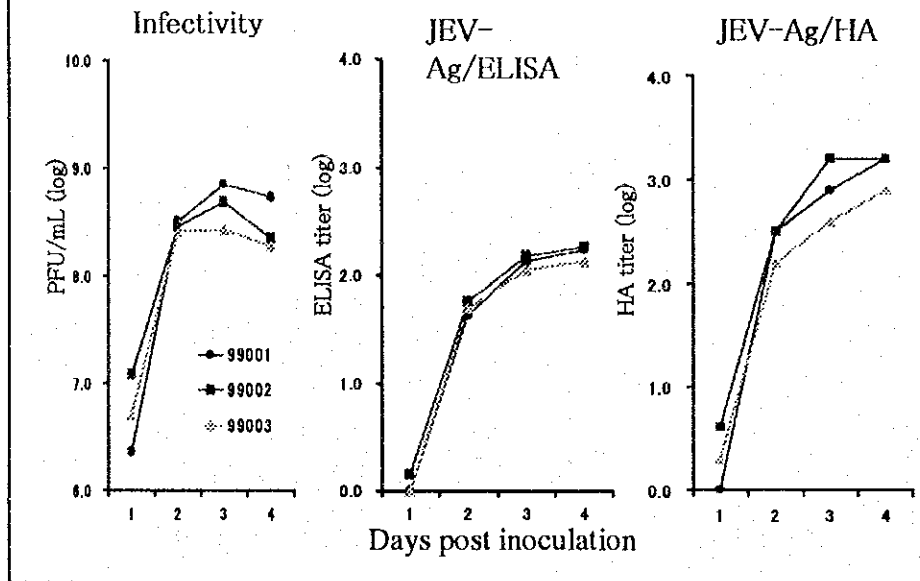
↓ 2 passages

Working seed virus Vero/4th

↓

Manufacture Vero/5th

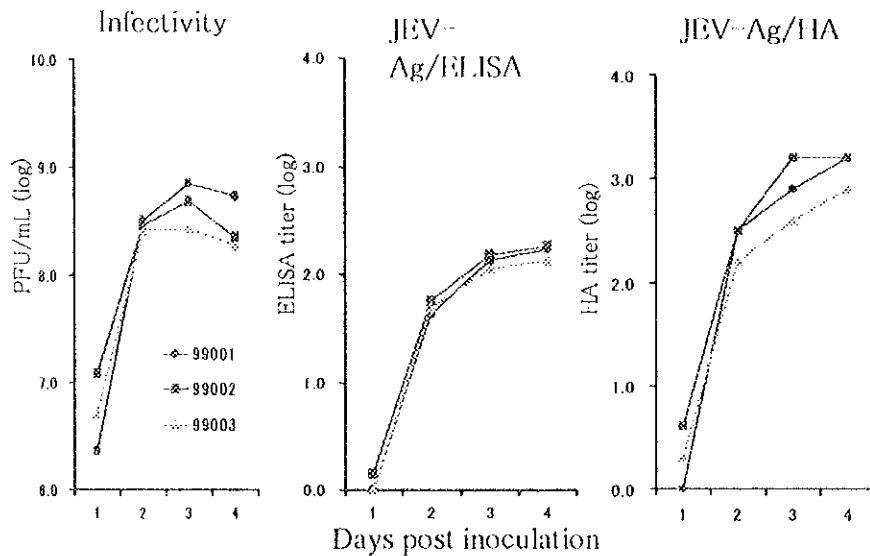
Virus growth in 3 consecutive lots of culture for preparation of clinical trial vaccine



Qualification of 3 lots of the bulk

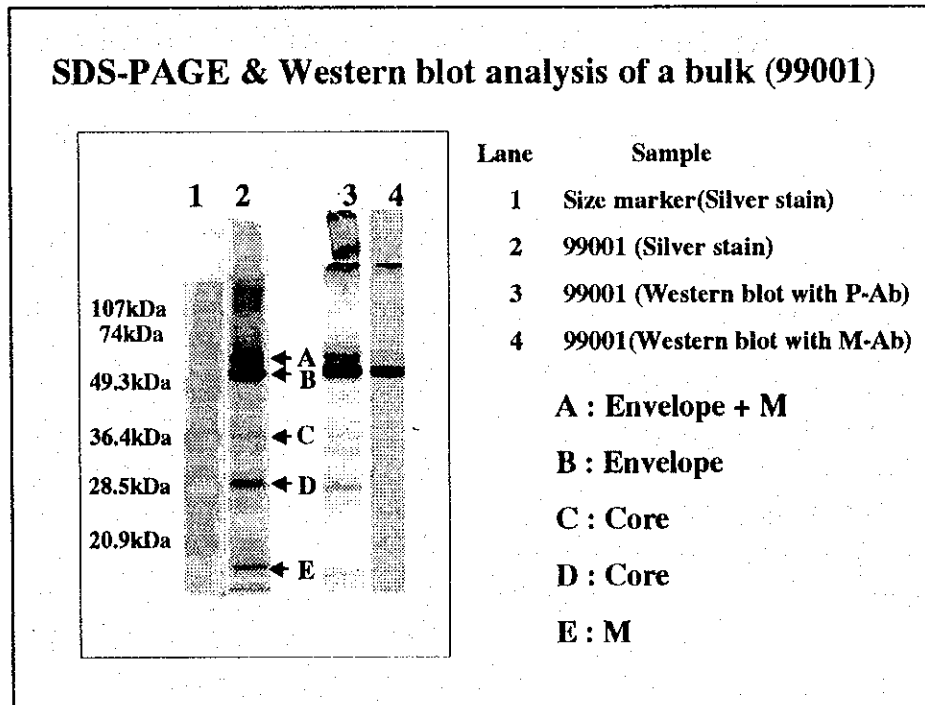
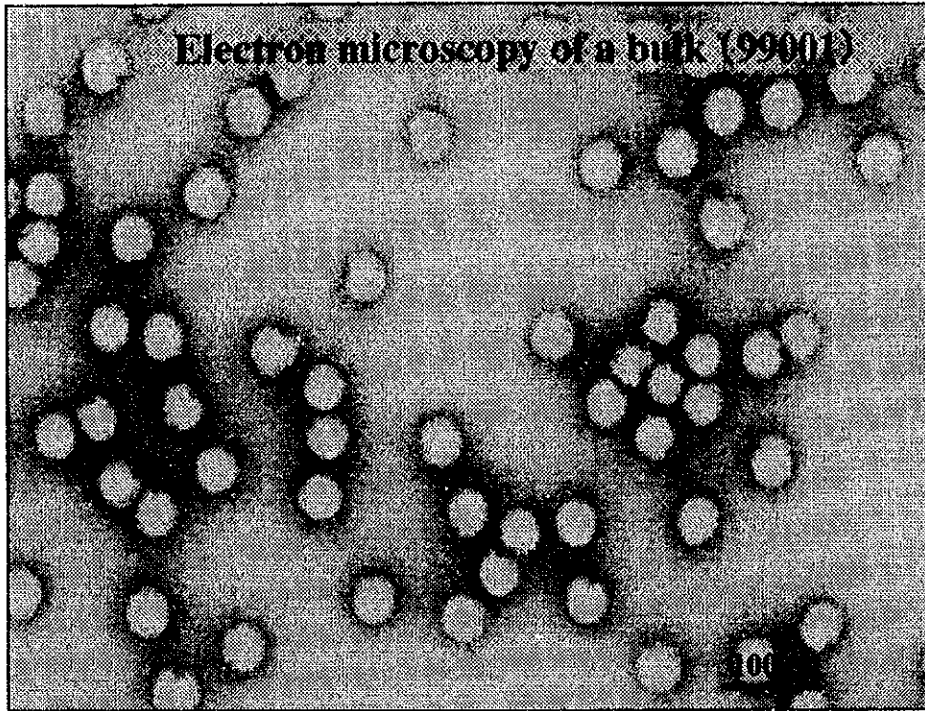
Test item	99001	99002	99003
Sterility	Pass	Pass	Pass
Staining	Pass	Pass	Pass
Inactivation	Pass	Pass	Pass
JEV-Ag : ELISA(M-Ab)	1,517	1,533	1,203
CF(P-Ab)	53.2	55.3	50.5
Protein content (μg/mL)	104	123	98
Potency (N antibody titer: log)	3.74	3.75	3.67
Residual CS protein (ng/mL)	<100	<100	<100
Residual cellular DNA(ng/mL)	<1	<1	<1
Electron microscopy	} see following slides		
SDS-PAGE			
HPLC			

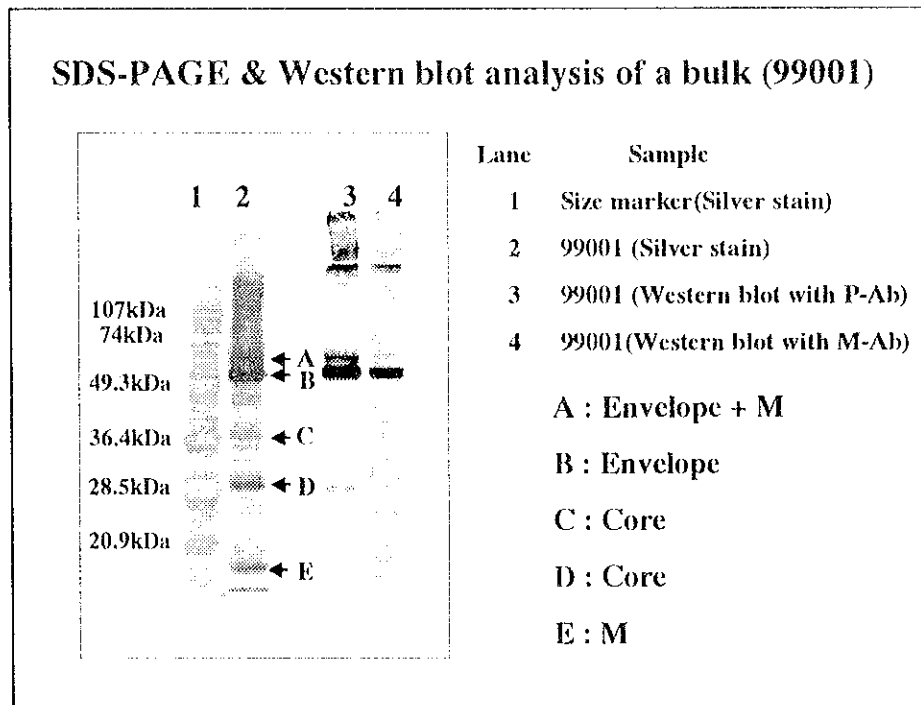
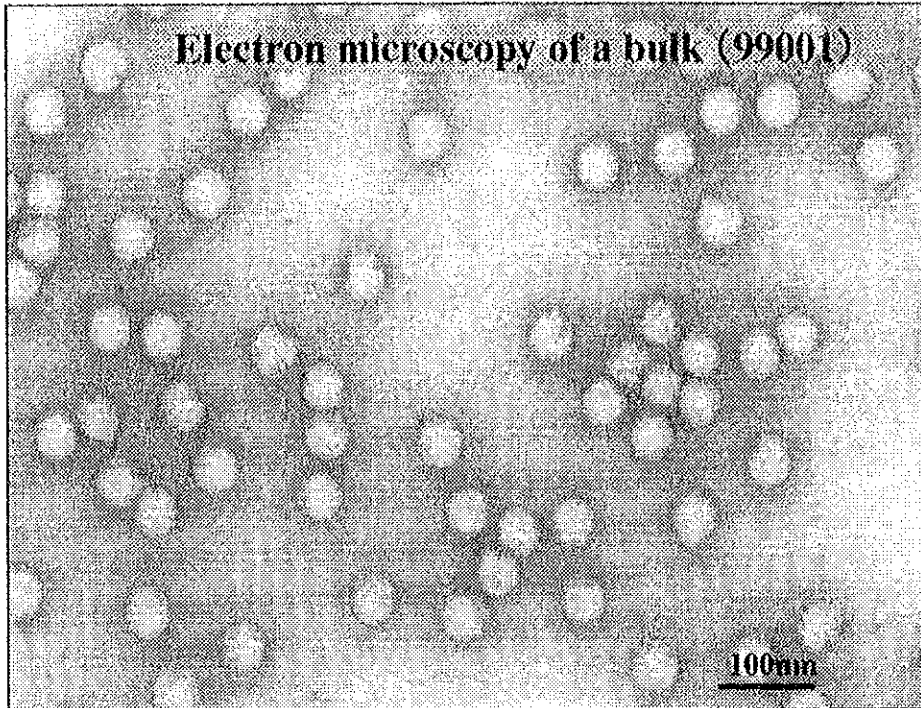
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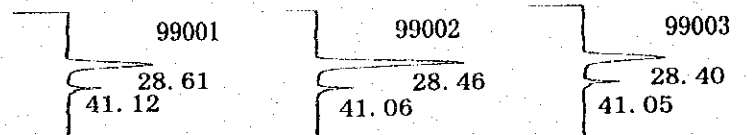
HPLC analysis of 3 lots of the bulk

Column : TOYO SODA TSK G6000PWXL

Buffer : M/75 PBS pH7.4 + 0.05% NaN₃

Flow rate : 0.3mL/min

Absorbance : OD280

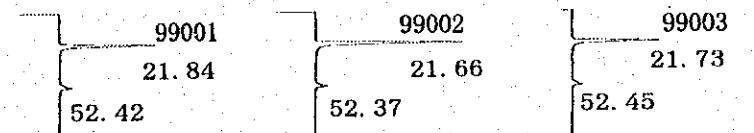


Column : TOYO SODA TSK G4000SWXL

Buffer : M/20 PBS pH7.0 + 0.3M NaCl + 0.05% NaN₃

Flow rate : 0.3mL/min

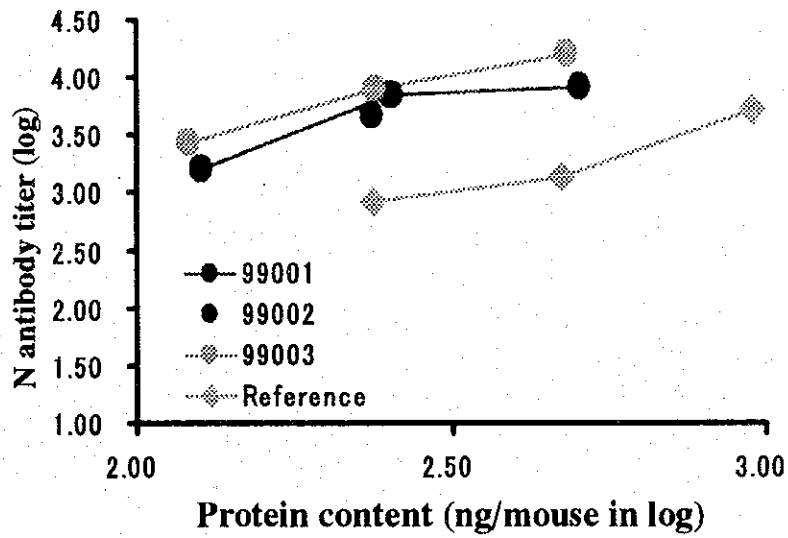
Absorbance : OD280



Qualification of the vial-filled vaccine

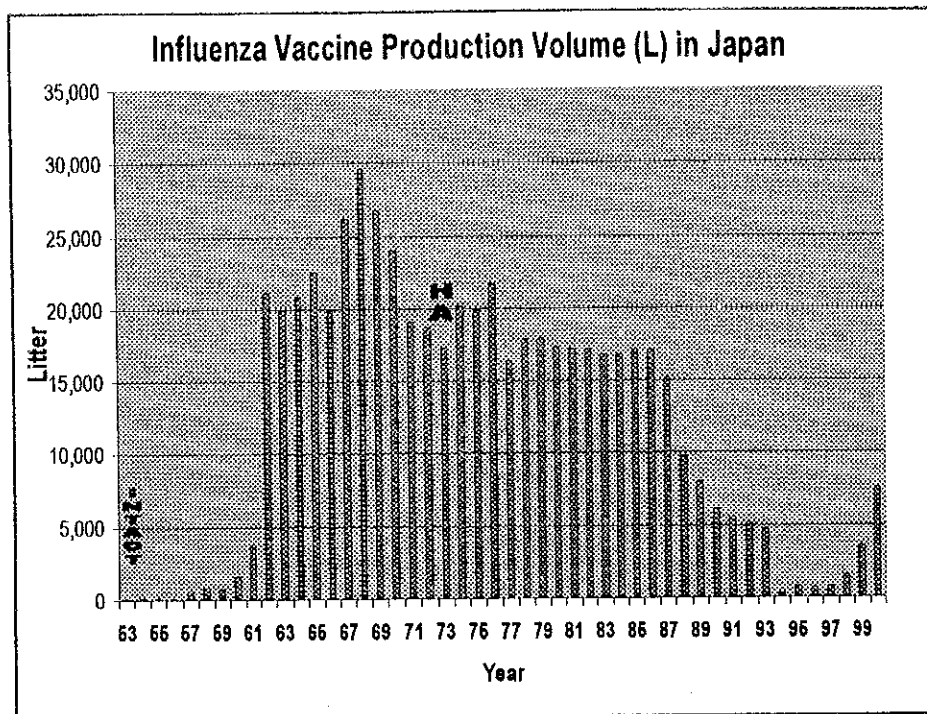
Test item	99001	99002	99003
Sterility	Pass	Pass	Pass
Staining	Pass	Pass	Pass
Moisture contents(%)	1.3	1.2	1.3
Inactivation	Pass	Pass	Pass
JEV-Ag Titer by ELISA (M-Ab)	120	103	116
TCA-protein (μ g/mL)	8.1	7.6	7.7
Potency (N Ab Titer in log)	3.85	3.66	3.89
pH	7.3	7.3	7.3
Residual CS proteins (ng/mL)	<10	<10	<10
Residual cellular DNA (pg/mL)	<100	<100	<100
Innocuity			
Guinea pig	Pass	Pass	Pass
Mouse	Pass	Pass	Pass

Potency of of the vial-filled vaccine



Measles-Rubella combined vaccine

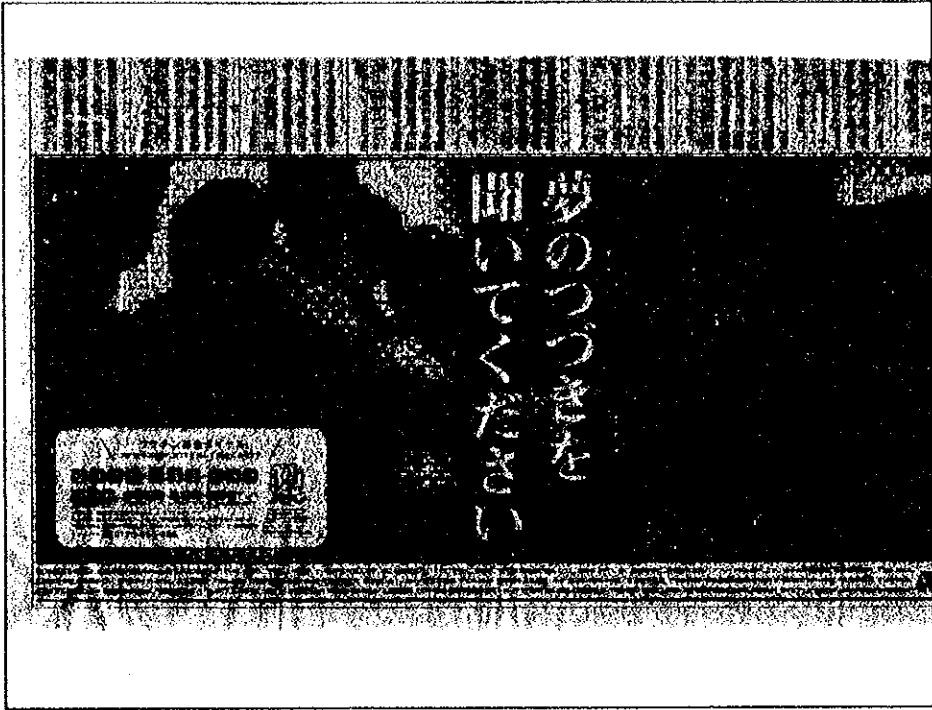
Now,
On clinical trial



Live varicella zoster vaccine

Seed Virus : OKA strain

Licensed to SKB and PM
SI(China)



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