

**SUMMARY PROTOCOL FOR PRODUCTION
AND
TESTING OF JAPANESE ENCEPHALITIS
VACCINE
(INACTIVATED) FOR HUMAN USE**

Identification of Final Lot

Name and address of manufacturer

Lot number of vaccine

Date of manufacture of final lot

Expiry date

Total volume of final lot

Control of Source Materials

Serum for cell cultures

Origin of serum used

Tests performed on serum

Results

Virus seed

Strain of virus

Name and short description of history

Date of preparation of master virus seed lot

Date of preparation of working virus seed lot

Number of passages between master and working virus seed lots

Number of subcultures between working seed lot and production

Tests for identification of the virus seed lot

Method used

Results

Tests for freedom from bacteria, fungi, and mycoplasmas

Method used

Results

Tests for adventitious agents

Tests in animals:

Methods used

Results

Tests in cell cultures:

Methods used

Results

Control of Vaccine Production

Control of single virus harvests

Sterility test

Method

Results

Test of virus content

Method

Results

Bulk material

Pooling of single virus harvests

Number of single harvests pooled

Volume of bulk material

Animal serum test

Method

Result

Inactivation

Agent and concentration

Temperature

Date of start of inactivation

Date of completion of inactivation

Test for effective inactivation

Method

Results

Purification of virus

Method of purification

Concentration

Potency test of bulk suspension

Method

Results

Final bulk

Preservatives and other substances

Concentrations

Sterility test

Method

Results

Final product

Potency test

Method

Results

Identity test

Method

Results

Sterility test

Method

Results

Innocuity test

Number of animals

Route of injection

Volume of injection

Date of injection

Date of end of test

Results

Protein content

Method

Results

Stability test

Method

Results

Pyrogenicity test

Method

Results

Residual moisture test (for freeze-dried vaccine)

Method

Results

Content of inactivating agent

Method

Results

Content of preservatives

Inactivation of virus

Method

Results

Certification

Name (typed) and signature of head of
Laboratory

Date

Certification by person taking overall responsibility for
production and control of the vaccine

I certify that lot No. of Japanese encephalitis
vaccine (Inactivated) meets the requirements of Part A of the
WHO Requirements for Biological Substances No. 43
(requirements for Japanese Encephalitis Vaccine (Inactivated)
for Human Use)

Name (typed)

Signature

Date
