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SUMMARY PROTOCOL FOR RABIES VACCINE (HUMAN) PRODUCTION AND TESTING

Identification of Final Lot

Name and address of manufacturer

_____

_____

_____

Lot number of vaccine

_____

Date of manufacture of final lot

_____

Expiry date

_____

Type of vaccine

_____

(animal brain/eggs/cell culture)

_____

Vaccine Virus Strain

Name and short description of history, origin, process of attenuation and adaptation

_____

Date of preparation of master seed virus

_____

Number of passages between isolation and master seed

_____

Date of preparation of working seed

_____

Number of passages between master and

working seed

_____

Virus Production Substrate

(Complete only the relevant part-----i.e., A, B, C, D or E.)

A. ***Animal neural tissue (brains)***

Animal species

_____

Adult/weanling/suckling

_____

Number of animals used

_____

Age of animals

_____

Quarantine period

_____

Period between inoculation and harvest

_____

Result of autopsy

_____

Result of sterility test on harvested tissue
(to be indicated by the terms “pass” or “fail”)

_____

B. Embryonated eggs

Animal species

_____

Origin of eggs

_____

Incubation period

_____

Period between inoculation and harvesting

_____

Number of eggs harvested

_____

Result of sterility test

_____

Other tests

_____

C. *Cell cultures/avian embryo*
Amount of cell suspension used in vaccine production

_____

Amount of cell suspension used to prepare control cultures (ml)

_____

Results of control tests

_____

Test for haemadsorbing viruses

_____

Tests for extraneous agents

_____

Test for avian leucosis viruses

_____

Test for adenoviruses

_____

Other tests (sterility, mycoplasma, etc.)

_____

D. *Cell cultures/human diploid or continuous*
Cells used for production

_____

Authority by which cell seed was approved

_____

Amount of cell suspension used in vaccine production

_____

Amount of cell suspension used to prepare control cultures (ml)

_____

Results of control tests

_____

Test for haemadsorbing viruses

_____

Tests for extraneous agents

_____

Identity test of cells

_____

Results of chromosome monitoring of cell seed at production level

_____

Other tests (sterility, mycoplasma, etc.)

_____

E. *Cell cultures/other cells*

Type of cell culture (including host species)

_____

Amount of cell suspension used

_____

Amount of control suspension investigated (ml)

_____

Results of control

_____

Test for haemadsorbing viruses

_____

Test for extraneous agents

_____

Test for viruses specific for the host species

_____

Other tests (sterility, mycoplasma, etc.)

_____

Virus Cultures

Number(s) of culture(s)

_____

Date of inoculation of virus

_____

Date of viral harvest

_____

Bulk Material

Numbers of viral harvests included

_____

_____

Date of pooling

_____

Sterility test

Have all the harvests included been tested for sterility?

_____

Results of these tests

_____

Control of inactivation

Nature of concentration and/or purification (if applied)

_____

Method of inactivation

_____

Date

_____

Temperature

_____

Test for inactivation—volume of material injected (including concentration)

_____

Number of mice injected

_____

Weight of mice

_____

Duration of observation

_____

Other animals (if used)

_____

Result of tests

_____

Result of virus amplification test (for cell

vaccines)

_____

Amount of vaccine tested (ml)

_____

Final Bulk

Preservatives, etc.

Concentration of phenol (if used)

_____

Other preservatives (type and concentration)

_____

Sterility tests

Date of test and result

_____

Other tests (chemical, biochemical)

Type of test

_____

Result

_____

Test on Final Lot

1. *Identity test*

Method used

_____

Result

_____

2. *Sterility tests*

Number of containers examined

_____

Method of test

_____

Date at start of test

_____

Date at end of test

_____

Result

_____

3. *Innocuity tests* *Mice*
Guinea-pigs
Number of animals _____ _____
Route of injection _____ _____
Volume of injection _____ _____
Date of injection _____ _____
Date of end of test _____ _____
Result _____ _____

4. *Chemical and biochemical tests*
Type of test

_____

Result

_____

5. *Potency test*
Type of test

_____

Date of test

_____

Immunization of mice
Date of start of test

_____

Reference vaccine (potency)

_____

Challenge strain

_____

Date of challenge

_____

ED_{50} test vaccine

_____

ED_{50} reference vaccine

_____

Calculated IU/single human dose

_____

Confidence limits

_____

Results of other potency tests

_____

6. Stability test for freeze-dried vaccine

Duration and temperature of incubation

_____

Result

_____

7. *Residual moisture test for freeze-dried vaccine*

Method used

_____

Result

_____

Signature of head of laboratory

_____

Certification by person taking overall responsibility for production of the vaccine. I certify that lot No. of the vaccine satisfies Part A (and, if HDC were used, Part C) of the WHO Requirements for Rabies Vaccine for Human Use.

Date

_____

Signature

_____

Name typed

_____

The protocol must be accompanied by a sample of the label and a copy of the leaflet.