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SUMMARY PROTOCOL FOR INFLUENZA VACCINE (INACTIVATED) (MASTER/WORKING SEED LOT TYPE A OR TYPE B)

The model summary protocol that follows is provided as general guidance to manufacturers. It is not intended to constrain them in the presentation of data relevant to the complete review of the quality-control tests performed on the vaccine. It is important to note that satisfactory test results do not necessarily imply that the vaccine is safe and effective, since many other factors must be taken into account, including the characteristics of the manufacturing facility.

Name and address of manufacturer

_____

Laboratory reference no. of lot

_____

Date when the processing was completed

_____

Information on manufacture

Virus used to inoculate eggs for the manufacture of the lot:

(a) strain and substrain

_____

(b) passage level

_____

(c) source and reference no.

_____

(d) remarks

_____

Results of sterility test

_____

Conditions of storage

_____

Monovalent virus pool Type A or Type B

Name and address of manufacturer

_____

Laboratory reference no. of virus pool

_____

Virus used to inoculate eggs:
(a) master seed strain and source

_____

(b) passage level of master seed

_____

(c) working seed lot, reference no. and source

_____

Date of inoculation

_____

Date of harvesting allantoic and amniotic fluids

_____

Storage conditions before inactivation

_____

Date of inactivation

_____

Time of inactivation

_____

Method of inactivation

_____

Concentration of inactivating agent

_____

Storage conditions after inactivation

_____

Concentration/purification procedure

_____

Antibiotics used during preparation, it any

_____

Tests on monovalent pool

Test for absence of viable influenza virus

_____

No. of eggs inoculated

_____

Incubation time and temperature

_____

Date of test

_____

Results

_____

Determination of haemagglutinin content

_____

Method

_____

Date of determination

_____

Results

_____

Tests for presence of neuraminidase (if performed)
Method

_____

Date of test

_____

Results

_____

Virus disruption (for Vaccinum Influenzae ex Virorum Fragmentis Praeparatum)
Method

_____

Date

_____

Results

_____

Surface antigen (for Vaccinum Influenzae ex corticis antigeniis praeparatum)
Method

_____

Date

_____

Results

_____

Identity tests
Method

_____

Date of test

_____

Results

_____

Final bulk

Name and address of manufacturer

_____

Identification of final bulk

_____

Identification of monovalent virus pool used to prepare final bulk

_____

Date of manufacture

_____

Control of final bulk

Preservative(s) added and concentration

_____

Any other substances added and concentration

_____

Determination of haemagglutinin content

Method

_____

Date of determination

_____

Results

_____

Sterility

Date of test

_____

Results

_____

Total protein content

Method

_____

Date of test

_____

Results

_____

Ovalbumin content
Method

_____

Date of test

_____

Results

_____

Tests for chemicals used

_____

Date of tests

_____

Results

_____

Final lot
Identity test
Method

_____

Date of test

_____

Results

_____

Sterility
Method

_____

Date of test

_____

Results

_____

Determination of haemagglutinin content
Method

_____

Date of determination

_____

Results

_____

Innocuity
No. and species of animals

_____

Doses injected

_____

Period of observation

_____

Date of test

_____

Results

_____

Endotoxin content
Method

_____

Date of test

_____

Results

_____

Inspection of final container
Results

_____

Other tests

_____

Additional comments (if any)

_____

A sample of a completed final container label and package insert shall be attached.

Certification by producer
Name of head of production of the final
vaccine

_____

Certification by head of the quality assurance department taking overall responsibility for production and control of the final vaccine:

I certify that lot no … of influenza vaccine (inactivated), whose number appears on the label of the final container, meets all

national requirements and satisfies Part A of the Requirements for Biological Substances No. 17, revised 1990.

Signature

_____

Name (typed)

_____

Date

_____