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SUMMARY PROTOCOL FOR THE ROUTINE BATCH RELEASE OF VIRUS VACCINES

Good documentation is an essential part of quality assurance. Its aims are to define the specifications for materials and methods of manufacture and testing and to provide the information necessary for batch release, as well as an audit trail that will permit the investigation of any suspected defective batch. A summary protocol of production and processing and quality control should therefore be prepared for each lot and/or batch of vaccine on the basis of a master record.

The aim of this summary protocol is to indicate the type of information that should be provided to a national control authority for the routine batch release of viral vaccines (inactivated or live) , as well as the information that should be included in the release certification provided by a national control authority.

The more comprehensive summary protocol for the production and testing of a virus vaccine that is sometimes included as a part of the Requirements for individual products should be used for the purposes of licence application, as well as for the first submission of the product for batch release and whenever a change is made.

Control of final lot

International name and proprietary name of vaccine _____

Name and address of manufacturer _____

Lot no. of final product _____

Potency test _____

Method _____

Result _____

Reference no. of master seed lot _____

Reference no. of working seed lot _____

Tests on final bulk

Sterility tests

Method _____

Result _____

Test for chemical used in production (if applicable)

Method _____

Result _____

Potency test (if applicable)

Method _____

Result _____

Test for preservatives (if applicable)

Method _____

Result _____

Tests on final lot

Identity test

Method _____

Result _____

Sterility test

Method _____

Result _____

Potency test

Method _____

Result _____

Test for virus concentration and thermostability (if applicable)

Date of inoculation _____

Type of cell cultures _____

	Control samples maintained at usual storage temperature			*Heated samples (incubated at 37°C for ----------days)*		
	1	2	3	1	2	3
Virus concentration in each container (in PFU or $CCID_{50}$)						
Mean virus titre per human dose, with 95% fiducial limits						

Mean loss in titre due to heat (in $\log_{10}$ units) _____

Reference preparation used

Identification _____

Theoretical titre _____

Actual titre _____

General safety test

No. of animals tested _____

Volume and route of injection _____

Observation period _____

Results (give details of deaths) _____

Test for endotoxin (if applicable)

Method _____

Result _____

Pyrogen content (if applicable)

Method _____

Result _____

Test for preservatives

Method _____

Results _____

Protein content (if applicable)

Method _____

Result _____

Adjuvants (if applicable)

Method _____

Results _____

Nature and concentration of

adjuvant per single human dose _____

Residual moisture (if applicable)

Method _____

Result _____

Inspection of final containers

Method _____

Result _____

Submission addressed to national control authority for batch release

Name (typed) and signature of

head of production laboratory _____

_____

Date _____

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

I certify that lot no. _____ of _____ vaccine satisfies national requirements and/or Part A of the Requirements for _____ vaccine in Requirements for Biological Substances No. _____.

Signature _____

Name (typed) _____

Date _____