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SUMMARY PROTOCOL FOR PRODUCTION AND TESTING OF MEASLES-MUMPS-RUBELLA COMBINED VACCINE (LIVE)

The following protocol is intended *for guidance*, and indicates the information that should be provided as a minimum.
The section concerning the final product must be accompanied by a sample of the label, a copy of the leaflet that accompanies the vaccine container, and a certificate from the national control authority of the country in which the vaccine was produced stating that the product meets national requirements as well as the Requirements published by WHO.

Information on blending

Measles component

Reference no.

_____

$CCID_{50}$ or PFU/ml

_____

Volume

_____

Mumps component

Reference no.

_____

$CCID_{50}$ or PFU/ml

_____

Volume

_____

Rubella component

Reference no.

_____

$CCID_{50}$ or PFU/ml

_____

Volume

_____

Final bulk of combined components (A.2.2)
Reference no. of final bulk

_____

Date of completion

_____

Total volume of final bulk

_____

Added substances (diluent, stabilizer)

_____

Residual animal serum proteins (A.2.2.1)
Date

_____

Method

_____

Results (indicate amount and nature
of serum protein(s) present per
human dose)

_____

Sterility tests (A.2.2.2)

bacteria fungi

mycoplasmas
Date of inoculation _____

_____ _____

Results _____

_____ _____

Filling and containers (A.3)
Name and address of manufacturer

_____

_____

Proprietary name of vaccine

_____

Reference no. of final lot

_____

Expiry date

_____

No. of containers in the lot

_____

No. of doses per container

_____

Lot no. of final bulk

_____

Date of filling of final containers

_____

Control tests on final product (A.4)

***Sterility tests* (A.4.1)**

	bacteria	fungi	mycoplasmas
Date of inoculation	_____	_____	_____
Results	_____	_____	_____

Virus concentration, thermostability and identity (A.4.2)

Record the results of virus titration and the thermostability test in the table opposite.

Identity test

	measles	mumps	rubella
Date of test	_____	_____	_____
Methods	_____	_____	_____
Results	_____	_____	_____

Virus concentration and thermostability test (A.4.2)

	Control (unheated) samples									Samples incubated at 37°C for 7 days								
	Measles			Mumps			Rubella			Measles			Mumps			Rubella		
	1	2	3	1	2	3	1	2	3	1	2	3	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 exposure (in $\log_{10}$ units)																		
Reference preparation																		
Identification																		
Theoretical titre																		
Actual titre																		

General safety tests (A.4.3)
Test in mice
Date of inoculation

_____

No. of mice tested

_____

Volume and route of injection

_____

Observation period

_____

Results (give details of deaths)

_____

Test in guinea-pigs
Date of inoculation

_____

No. of guinea-pigs tested

_____

Volume and route of injection

_____

Observation period

_____

Result (give details of deaths)

_____

Residual moisture (A.4.4)
Date

_____

Method

_____

Size of sample

_____

Moisture content (%)

_____

Inspection of final containers (A.4.5)
Date and result

_____

Submission addressed to national control authority for batch release

Number (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 measles-mumps-rubella combined vaccine (live) satisfies national requirements and/or Part A of the Requirements for Measles-Mumps-Rubella Combined Vaccine in Requirements for Biological Substances No. 47 (Requirements for Measles, Mumps and Rubella Vaccines and Combined Vaccine (Live)).

Signature

_____

Name (typed)

_____

Date

_____