

**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.

CCID₅₀ or PFU/ml

Volume

Mumps component

Reference no.

CCID₅₀ or PFU/ml

Volume

Rubella component

Reference no.

CCID₅₀ 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.

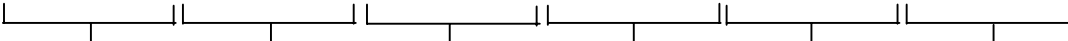
Identity test

	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