


MATERIAL SPECIFICATION

	HUMAN BIOLOGICALS INSTITUTE (A division of Indian Immunologicals Ltd.) Rakshapuram, Gachibowli Post, Hyderabad 500 032		Material Name MEASLES HARVEST (From POLYVAC)
			Department Quality Control
Status	IP/BP	Material Code	Effective Date
		NA	04 JUL 2018

TEST

SPECIFICATION

Control cells

Observation for control cells : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check (14 days)

Test for Haemadsorbing viruses : No detection of extraneous virus causing Haemadsorbance

Test for freedom from extraneous agents on FL cells : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Test for freedom from extraneous agents on Vero cell : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Tests for freedom from extraneous agents on chicken embryonic cell : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Tests for freedom from extraneous agents on chicken kidney cell : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Single harvest

Sterility test : Negative

Mycoplasma test : Negative

Potency : $\geq 5.6 \lg$ PFU/0.5mL(in house spec)





Test for freedom from extraneous agents on FL cells : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Test for freedom from extraneous agents on CEC cells : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

Test for freedom from extraneous agents on Vero cells : No CPE Observed
 Less than 20% of cells discarded due to nonspecific reason
 at final check

TEST	SPECIFICATION
Test for freedom from extraneous agents by inoculating into yolk sac	: No observation of pox virus in chicken embryonic membrane : Less than 20% of eggs died due to nonspecific reason at final check
Test for freedom from extraneous agents by inoculating into allantoic cavity	: No observation of virus causing chicken red blood agglutination : Less than 20% of eggs died due to nonspecific reason at final check
Bulk Material	
Identification*	: Should be identified as Measles virus
Sterility test for bacteria and fungi	: Negative
Mycoplasma test	: Negative
Confirm removal of cells	: No residual cells
Virus Concentration*	: Not less than 1×10^4 CCID ₅₀ / 0.5 mL
BSA residual test	: <50 ng/0.5mL
pH test	: 6.5-8.5

*Tests performed at HBI upon receipt,
Note: Remaining test results should be considered from vendor COA.

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Sign & Date	 04.07.17	 04.07.17	 04.07.17	 04.07.17

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ISSUED DATE
04 JUL 2018