

**Genome Valley, Turkapally, Shameerpet
 Hyderabad-500078, INDIA**

Department: Quality Control

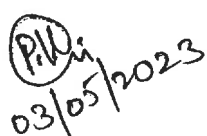
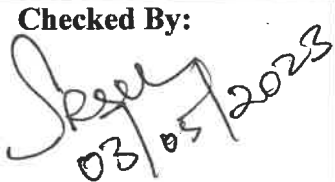

CERTIFICATE OF ANALYSIS

Product	: Bivalent Poliomyelitis Vaccine Type 1 & 3, Live (Oral), BIOPOLIO B1/3		
Batch Number	: 68D23040A	A.R. Number	: FP-68-23-083
Batch Size	: 115 L	Date of Receipt	: 17/04/2023
Mfg. Date	: 04/23	Qty. Sampled	: 77 Vials
Exp. Date	: 03/25	COA Release Date	: 03/05/2023
Specification No.	: FPS238		

TESTS	SPECIFICATIONS	RESULTS
Description	Clear liquid with a faint yellowish to pinkish/reddish color	Clear liquid with a faint pinkish color
Identification	Should comply with the Potency test	Complies
pH	6.50 to 7.20	6.84
MgCl ₂ content	NLT 0.980 M and NMT 1.020 M	1.000 M
Extractable volume a. By Density b. By Drop Counting	a. NLT 1.00 mL b. NLT 20 Drops	1.05 mL/Vial 23 Drops/Vial
Sterility	No growth should be observed (Sterile)	No growth observed
Thermal Stability at 37°C for 48 hrs	Loss in titre on exposure should not be greater than 10 ^{0.50} CCID ₅₀ /0.1mL	10 ^{0.25} CCID ₅₀ /0.1 mL
Assay : a. Virus Content for Individual components	a. NLT 10 ^{6.00} CCID ₅₀ /0.1mL for Type-1 NLT 10 ^{5.80} CCID ₅₀ /0.1 mL for Type-3.	10 ^{6.34} CCID ₅₀ /0.1 mL 10 ^{6.09} CCID ₅₀ /0.1 mL
b. Total Virus Content	b. NLT 10 ^{6.21} CCID ₅₀ /0.1 mL for TVC	10 ^{6.57} CCID ₅₀ /0.1 mL

COMPLIANCE STATEMENT:

Sample **COMPLIES**/ ~~DOES NOT COMPLY~~ as per specification No. FPS238

Prepared By:  03/05/2023	Checked By:  03/05/2023	Approved By:  03/05/2023 (Head - Quality Control)
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