



Biological E. Limited

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S. S. D. Y. D.
19.07.19

CERTIFICATE OF ANALYSIS

Name of the Product: Final Lot of Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed)-0.5mL

A.R. No.	BEFL19000198	Inspection Lot. No.	40000048450
Batch No.	220104219C	Batch Size	296322 Vials
Mfg. Date	May 2019	Exp. Date	October 2021
Specification Id	103462	Date Of Release	14-06-2019 11:14

S. No.	TEST	SPECIFICATION	RESULT
1	Description	Whitish turbid liquid in which the mineral carrier tends to settle down slowly on keeping.	Whitish turbid liquid in which the mineral carrier settled down slowly on keeping.
2	pH	6.0 - 7.0	6.58
3	Identity for Diphtheria component	Sample should show flocculation with DAT	Sample showed flocculation with DAT
4	Identity for Tetanus component	Sample should show flocculation with TAT	Sample showed flocculation with TAT
5	Identity for Pertussis component	Should show Agglutination with Agglutinins 1, 2 and 3	Sample showed Agglutination with Agglutinins 1, 2 and 3
6	Identity for Hep.B. component	Should show reaction with Hepatitis-B antibody	Sample shows positive reaction with Hepatitis-B antibody.
7	Identity for Hib component	Sample should show agglutination	Complies
8	Thiomersal Content	NLT 0.085 mg/mL and NMT 0.115 mg/mL	0.087 mg/mL
9	Aluminium Content	NMT 1.25 mg/SHD	0.291 mg/SHD
10	Free Formaldehyde	NMT 0.2 g/L	<0.2 g/L
11	Sterility	No evidence of contamination with in 14 days of incubation period. This has to be confirmed by subsequent inoculation of initial media tubes in to fresh media tubes after 14 days and incubate the fresh tubes for 4 days.	No contamination found with in 14 days and subsequent 04 days of incubation period.
12	Total PRP	Not less than 80% of label claim (NLT 8.8 µg/SHD)	9.98 µg/SHD
13	Free PRP	Not more than 20 %	8 %
14	Specific toxicity for	a. At the end of day 3 the average	108.13 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Shiva.Shankar (Test In-charge (TI))	Reviewed By	MADHAV RAMESH.MADISE TTY (Sample in-chagre (SI))	Approved By	Santosh.Bandari (Manager (MGR))
Prepared On	12-06-2019 10:26	Reviewed On	14-06-2019 09:35	Approved On	14-06-2019 11:14
Printed by:	Bikki.venkata srinivasa rao		Printed on:		14-06-2019 11:16
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CIN: U01120TG1953PLC001095

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	Pertussis	weight of the group of vaccinated mice is not less than that preceding the injection. b. At the end of 7 days the average weight gain per mouse is not less than 60% and not more than 150% of that per control mouse. c. Not more than 5% of the vaccinated mice should die during the test.	
15	Potency-Diphtheria	Lethal challenge method: Lower limit of 95% confidence interval of estimated potency should not be less than 30 IU/SHD. If lower limit of 95% confidence interval of estimated potency is less than 30 IU/SHD then the limit of 95% confidence interval should be within 50-200% of the estimated potency.	Potency: 68.28 IU/SHD UCL: 119.46 IU/SHD LCL: 44.68 IU/SHD
16	Potency-Tetanus	Subcutaneous lethal challenge method in mice: Lower limit of 95% confidence interval of estimated potency should not be less than 60 IU/SHD. If lower limit of 95% confidence interval of estimated potency is less than 60 IU/SHD then the limit of 95% confidence interval should be within 50-200% of the estimated potency.	Potency: 928.23 IU/SHD UCL: 1607.33 IU/SHD LCL: 579.72 IU/SHD
17	Potency-Pertussis	The estimated potency of the vaccine should not be less than 4.0 IU/SHD and the lower fiducial limit (P = 0.95) of estimated potency should not be less than 2.0 IU.	Potency: 6.03 IU/SHD UCL: 12.25 IU/SHD LCL: 3.03 IU/SHD

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18	Potency-Hepatitis B (in-vitro)	In-vitro: Antigen content not less than 20 mcg/mL.	Antigen Content:36.50 mcg/mL
19	Osmolality	240 – 360 mOsm/Kg	281 mOsm/Kg
20	Extractable volume	Not less than nominal volume.	0.54 mL

Test Plan Remarks: --

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