Biological E. Limited

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30.07.19

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.	BEFL19000206	**Inspection Lot. No.**	40000048606
Batch No.	220104419C	**Batch Size**	297074 Vials
Mfg. Date	May 2019	**Exp. Date**	October 2021
Specification Id	103462	**Date Of Release**	19-06-2019 14:06

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	6.54
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	0.088 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)	11.05 µg/SHD
13	**Free PRP**	Not more than 20 %	7 %
14	**Specific toxicity for**	a. At the end of day 3 the average	89.91 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Srivalli.Devi (Test In-charge (TI))	Reviewed By	MADHAV RAMESH.MADISETTY (Sample in-chagre (SI))	Approved By	Santosh.Bandari (Manager (MGR))
Prepared On	19-06-2019 09:31	Reviewed On	19-06-2019 12:32	Approved On	19-06-2019 14:06

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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:73.99 IU/SHD UCL:131.42 IU/SHD LCL:48.80 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:1124.83 IU/SHD UCL:2017.21 IU/SHD LCL:703.27 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:7.10 IU/SHD UCL:14.59 IU/SHD LCL:3.53 IU/SHD

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18	**Potency-Hepatitis B (in-vitro)**	In-vitro: Antigen content not less than 20 mcg/mL.	Antigen Content:34.20 mcg/mL
19	**Osmolality**	240 – 360 mOsm/Kg	280 mOsm/Kg
20	**Extractable volume**	Not less than nominal volume.	0.54 mL

Test Plan Remarks: --

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