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CERTIFICATE OF ANALYSIS

Name of the Product: Final lot of Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) for Export/ UNICEF, PAHO and other UN agencies - 5 mL

A.R. No.	BEFL19000004	**Inspection Lot. No.**	40000045284
Batch No.	221100518A	**Batch Size**	92880 Vials
Mfg. Date	January 2019	**Exp. Date**	December 2020
Specification Id	103764	**Date Of Release**	08-03-2019 15:58

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	**Identity for Tetanus**	Sample should show flocculation with Tetanus Antitoxin.	Sample showed flocculation with Tetanus Antitoxin.
3	**Identity for Diphtheria**	Sample should show flocculation with Diphtheria Antitoxin.	Sample showed flocculation with Diphtheria Antitoxin.
4	**Identity for Pertussis**	Sample should show the agglutination with agglutinin 1, 2, 3.	Sample showed the agglutination with agglutinins 1, 2 ,3.
5	**Sterility**	No evidence of contamination within 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 within 14 days and subsequent 04 days of incubation period.
6	**pH**	6.0 - 7.0	6.68
7	**Thiomersal content**	The amount is not less than 85 % and not greater than 115 % of the intended amount of 0.01 % w/v (0.085 to 0.115mg / mL)	0.090 mg/mL
8	**Aluminium content**	NMT 1.25 mg per single human dose.	0.378 mg/SHD
9	**Free Formaldehyde**	NMT 0.02% w/v (0.2 g / L).	<0.2 g/L
10	**Specific toxicity of Pertussis component**	a. At the end of day 3 the average weight of the group of vaccinated mice is not less than that preceding the injection.	67.20 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Jagadeesh.V (Sample in-chagre (SI))	Reviewed By	MADHAV RAMESH.MADISETTY (Sample in-chagre (SI))	Approved By	Santosh.Bandari (Manager (MGR))
Prepared On	07-03-2019 14:30	Reviewed On	07-03-2019 16:48	Approved On	08-03-2019 15:58

Printed by: Bikki.venkata srinivasa rao **Printed on: 08-03-2019 16:09**

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		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 inoculated mice should die during the test.	
11	**Potency for Tetanus component**	Subcutaneous lethal challenge method if carried in mice: The lower confidence limit (P=0.95) of estimated potency should not be less than 60 IU per single human dose.	Potency:99.08 IU/SHD UCL:153.33 IU/SHD LCL:65.96 IU/SHD
12	**Potency for Diphtheria component**	Lethal challenge method : Estimated potency should not be less than 30 IU per single human dose. If the lower limit of 95.0 per cent confidence interval of estimated potency is less than 30 IU per single human dose then the limits of the 95.0 per cent confidence interval should be within 50 – 200% of estimated potency.	Potency:72.78 IU/SHD UCL:121.64 IU/SHD LCL:48.84 IU/SHD
13	**Potency for Pertussis component**	The estimated potency of the vaccine should not be less than 4.0 IU per single human dose and the lower fiducial limit (P=0.95) of the estimated potency should not be less than 2.0 IU per single human dose.	Potency:6.25 IU/SHD UCL:12.23 IU/SHD LCL:3.40 IU/SHD
14	**Extractable volume**	Not less than nominal volume.	5.87 mL
15	**Extractable doses**	The multi dose container should yield a specific number of doses of a stated volume	10 doses
16	**Osmolality**	240 – 360 mOsm/Kg	277 mOsm/Kg

Remarks: APPROVED (Sample Conforms to above Specification)

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Test Plan Remarks: --

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CIN: U01120TG1953PLC001095
Plot No. 1, S.P. Biotech Park, Phase II, Kolthur Village, Shameerpet. Phone: +91 40 30213999
Fax: +91 40 27616715, e-mail: info@biologicale.com www.biologicale.com