

Laboratory	Central Drugs Laboratory, C.R.I. Kasauli, Himachal Pradesh		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Chemical Testing	Issue Date	19.11.2014
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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I. DRUGS & PHARMACEUTICALS				
A. Vaccines & Sera				
1.	Tetanus Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3143-49 & Clause 2.3.8 Page 95 WHO TRS 800 Page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
2.	Diphtheria & Tetanus Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3143-49 & Clause 2.3.8 Page 95 WHO TRS 800 Page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
3.	Diphtheria, Pertussis & Tetanus Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3143-49 & Clause 2.3.8 Page 95 WHO TRS 800 Page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
4.	Diphtheria, Pertussis, Tetanus Vaccine (Whole cell) & Hepatitis B Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3070-72 & Clause 2.3.8 Page 95 WHO TRS 800 Page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
5.	Diphtheria, Pertussis, Tetanus Vaccine (Whole cell) & Haemophilus Type-b Conjugate Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025 % to 0.025 % w/v
		b) Aluminum	IP,2014 Page 3070-72 & Clause 2.3.8 Page 95 WHO TRS 800 page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
6.	Diphtheria, Pertussis, Tetanus Vaccine (Whole cell) , Hepatitis-B (rDNA)& Haemophilus Type-b Conjugate Vaccine (Adsorbed)	a) Thiomersal	IP,2014 Page 3143-49 & Clause 2.3.48 Page 119-120, WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025 % to 0.025 % w/v
		b) Aluminum	IP,2014 Page 3070-72 & Clause 2.3.8 Page 95 WHO TRS 800 Page No.118 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3143-49 & Clause 2.3.20 Page 99 WHO TRS 800 Page No.118 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) pH	IP,2014 Page 3143-49 & Clause 2.4.24 Page 169-70 WHO TRS 800 Page No.118 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No. 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
7.	Typhoid Polysaccharide Vaccine	a) Phenol	IP,2014 Page 3154-56 Clause 2.3.36 Page 109 SOP No CDL/WI/031Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v
		b) pH	IP,2014 Page 3154-56 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed - Dt. 01-05-2013	1.0 to 10.0
		c) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
8.	Bacillus Calmette Guerin Vaccine (Freeze Dried)	a) pH	IP,2014 Page 3057-60 & Clause 2.4.24 Page 146 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
9.	Haemophilus Type-b Conjugate Vaccine (Freeze Dried))	a) Thiomersal	IP,2014 Page 3084-87 & Clause 2.3.48 Page 119-120 WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2104	0.0025 % to 0.025 % w/v

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Haemophilus Type-b Conjugate Vaccine (Freeze Dried))	b) pH	IP,2014 Page 3084-87 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		c) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
10.	Pneumococcal Polysaccharide Vaccine	a) Phenol	IP,2014 Page 3121-23 Clause 2.3.36 Page 109 SOP No CDL/WI/031 Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v
		b) pH	IP,2014 Page 3121-43 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		c) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
11.	Meningococcal Vaccine (Freeze Dried)	a) Thiomersal	IP,2014 Page 3107-14 & Clause 2.3.48 Page 119-120 WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025 % to 0.025 % w/v

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	Meningococcal Vaccine (Freeze Dried)	b) pH	IP,2014 Page 3107-14 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		c) Volume	IP,2014Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150% of the label claim
		d) Moisture	IP2014 Page No.3107-14 Clause 2.3.43 Page 113-115 WHO TRS 904, 2002 P No.58-62 SOP No CDL/WI/033 Ed -03 Dt. 01-05-2013	0.5 % to 4.5% w/w
		e) Molecular Size Distribution	IP2014 WHO TRS 904 , 2002 P No.58-62 SOP No CDL/WI/114 Ed -03 Dt. 01-05-2013	Qualitative (65 % of Group A polysaccharide eluted before K _D of 0.50)
12.	Hepatitis –A (Inactivated)	a) Aluminum	IP,2014 Page 3091-93 & Clause 2.3.8 Page 95 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		b) Formalin	IP,2014 Page 3091-93 & Clause 2.3.20 Page 99 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative

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	Hepatitis –A (Inactivated)	c) pH	IP,2014Page 3091-93 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		d) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
13.	Hepatitis –B (rDNA)	a) Thiomersal	IP,2014 Page 3088-91 & Clause 2.3.48 Page 119-120 WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3088-91& Clause 2.3.8 Page 95 SOP No CDL/WI/027 Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) pH	IP,2014Page 3088-91& Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		d) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
14.	Yellow Fever Vaccine	a) Protein	IP,2014 Page 3160-63 & Clause 2.3.49 Page 120 SOP No CDL/WI/030 Ed -03 Dt. 01-05-2013	1.0 % to 17% w/v
		b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
15.	Anti Rabies Vaccine (Cell Culture)	a) Thiomersal	IP,2014 Page 3133-37 & Clause 2.3.48 Page 119-120 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025 % to 0.025% w/v
		b) Protein	IP,2014 Page 3133-37 & Clause 2.3.49 Page 120 SOP No CDL/WI/028 Ed -03 Dt. 01-05-2013	1.0 % to 17 % w/v
		c) Moisture	IP IP,2014 Page 3133-37 & Clause 2.3.43 Page 113-115 SOP No CDL/WI/033 Ed -03 Dt. 01-05-2013	0.5 % to 4.5 % w/w
		d) pH	IP,2014 Page 3133-37 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0

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	Anti Rabies Vaccine (Cell Culture)	e) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
16.	Japanese Encephalitis Vaccine (Inactivated)	a) Thiomersal	IP,2014 Page 3101-03 & Clause 2.3.48 Page 119-120 WHO TRS 800 Page No.118 SOP No CDL/WI/025 Ed -03 Dt. 01-05-2013	0.0025% to 0.025% w/v
		b) Aluminum	IP,2014 Page 3101-03 & Clause 2.3.8 Page 95 SOP No CDL/WI/027Ed -03 Dt. 01-05-2013	0.4 mg/ml to 1.5 mg/ml
		c) Formalin	IP,2014 Page 3101-03 & Clause 2.3.20 Page 99 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		d) Protein	IP,2014Page 3101-03 & Clause 2.3.49 Page 120 SOP No CDL/WI/029 Ed -03 Dt. 01-05-2013	1.0 % to 17 % w/v
		e) pH	IP,2014Page 3101-03 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0

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	Japanese Encephalitis Vaccine (Inactivated)	f) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
17.	tOPV Trivalent Poliomyelitis Vaccine(Oral)	a) pH	IP,2014 Page 3128-33 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
18.	mOPV I Monovalent Poliomyelitis Vaccine Type I (Oral)	a) pH	IP,2014 Page 3128-33 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03	1.0 to 10.0
		b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
19.	mOPV III Monovalent Poliomyelitis Vaccine Type III (Oral)	a) pH	IP,2014 Page 3128-33 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0

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	mOPV III Monovalent Poliomyelitis Vaccine Type III (Oral)	b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
20.	bOPV I&III Bivalent Poliomyelitis Vaccine Type I & III (Oral)	a) pH	IP,2014 Page 3128-33 & Clause 2.4.24 Page 169-70 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		b) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
21.	Inactivated Polio Vaccine	a) Formalin	IP2014 Page No. 3123-27 Clause 2.3.20 Page 99 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/032 Ed -03 Dt. 01-05-2013	Qualitative
		b) Protein	IP2014 Page No. 3123-27 Clause 2.3.49 Page 120 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/029 Ed -03 Dt. 01-05-2013	1.0 % to 17 % w/v
		c) pH	IP2014 Page No. 3123-2 Clause 2.4.24 Page 169-70 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0

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	Inactivated Polio Vaccine	d) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
22.	Tetanus Antitoxin	a) Phenol	IP,2014 Page 3142-43 Clause 2.3.36 Page 109 SOP No CDL/WI/031Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v
		b) Protein	IP2014 Page 3142-43 Clause 2.3.49 Page 120 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/028 Ed -03 Dt. 01-05-2013	1.0 % to 17% w/v
		c) pH	IP2014 Page 3142-43 Clause 2.4.24 Page 169-70 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		d) Volume	IP,2014 Page 956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150% of the label claim
23.	Diphtheria Antitoxin	a) Phenol	IP,2014 Page 3062-63 Clause 2.3.36 Page 109 SOP No CDL/WI/031 Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v

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	Diphtheria Antitoxin	b) Protein	IP2014 Page 3062-63 Clause 2.3.49 Page 120 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/028 Ed -03 Dt. 01-05-2013	1.0 % to 17% w/v
		c) pH	IP2014 Page 3062-63 Clause 2.4.24 Page 169-70 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 0.0
		d) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
24.	Anti Rabies Serum	a) Phenol	IP,2014Page 3133 & Clause 2.3.36 Page 109 SOP No CDL/WI/031Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v
		b) Protein	IP2014 Page 3133 Clause 2.3.49 Page 120 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/028 Ed -03 Dt. 01-05-2013	1.0 % to 17% w/v
		c) pH	IP2014 Page 3133 Clause 2.4.24 Page 169-70 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0

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Laboratory	Central Drugs Laboratory, C.R.I. Kasauli, Himachal Pradesh		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Chemical Testing	Issue Date	19.11.2014
Certificate Number	T-1789	Valid Until	18.11.2016
Last Amended on	-	Page	17 of 17

S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Anti Rabies Serum	d) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim
25.	Anti Snake Venom Serum (Freeze Dried))	a) Phenol	IP,201 Page 3142 Clause 2.3.36 Page 109 SOP No CDL/WI/031Ed -03 Dt. 01-05-2013	0.084 % to 0.50 % w/v
		b) Protein	IP2014 Page 3142 Clause 2.3.49 Page 120 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/028 Ed -03 Dt. 01-05-2013	1.0 % to 17% w/v
		c) Moisture	IP2014 Page 3142 Clause 2.4.43 Page 113-15 WHO TRS 904, 2002 P No.58-62 SOP No CDL/WI/033 Ed -03 Dt. 01-05-2013	0.5 % to 4.5 % w/w
		d) pH	IP2014 Page 3142 Clause 2.4.24 Page 169-70 WHO TRS 910 , 2002 P No. 54 SOP No CDL/WI/034 Ed -03 Dt. 01-05-2013	1.0 to 10.0
		e) Volume	IP,2014 Page No.956 Extractable volume should be more than label claim SOP No CDL/WI/035 Ed -03 Dt. 01-05-2013	50 % to 150 % of the label claim

-X-X-X-X-X-X-X-X-X-X-X-X-

Anuja Anand
Convenor

N. Venkateswaran
Program Manager