

Laboratory **Central Drugs Testing Laboratory, CDSCO, Zonal FDA Bhawan, GMSD Compound, Belasis Road, Mumbai Central, Mumbai, Maharashtra**

Accreditation Standard **ISO/IEC 17025: 2017**

Certificate Number **TC-7327**

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Validity **03.06.2019 to 22.06.2020**

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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**BIOLOGICAL TESTING**

I.	DRUGS & PHARMACEUTICALS			
1.	<b>Parenteral Preparations (Injections)</b>			
a.	<b>Ceftriaxone Sodium Injection IP (250mg; 500mg; 1g and 2gm of Ceftriaxone)</b>	Bacterial Endotoxins (Gel clot method)	I.P. 2014 Pg. no - 1325, 28 to 33	Qualitative (Complies / Does not comply)
		Sterility (membrane filtration)	I.P. 2014 Pg. no-1324, 59 to 66	Qualitative (Complies / Does not comply)
b.	<b>Hydrocortisone Sodium Succinate Injection IP (100mg and 500mg of Hydrocortisone)</b>	Bacterial Endotoxins (Gel clot method)	I.P. 2014 Pg. no - 1911, 28 to 33	Qualitative (Complies / Does not comply)
		Sterility (membrane filtration)	I.P. 2014 Pg. no-1910, 59 to 66	Qualitative (Complies / Does not comply)
c.	<b>Streptomycin Injection IP ( 750mg and 1g of Streptomycin)</b>	Sterility (membrane filtration)	I.P. 2014 Pg. no-2799, 59 to 66	Qualitative (Complies / Does not comply)
		Assay (Method A)	I.P. 2014 Pg. no -2799, 50	Qualitative (Complies / Does not comply)
d.	<b>Amikacin Injection IP (100mg or 500mg of Amikacin in 2ml)</b>	Sterility (membrane filtration)	I.P. 2014 Pg. no -1029, 59 to 66	Qualitative (Complies / Does not comply)
e.	<b>Dextrose Injection IP (5,10,25 and 50 per cent w/v of Dextrose)</b>	Bacterial Endotoxins (Gel clot method)	I.P. 2014 Pg .no. 1543, 28 to 33	Qualitative (Complies / Does not comply)
		Sterility (membrane filtration)	I.P. 2014 Pg. no.- 1542, 59 to 66	Qualitative (Complies / Does not comply)

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f.	<b>Sodium Chloride Injection IP (0.9 per cent w/v of Sodium Chloride)</b>	Bacterial Endotoxins (Gel clot method)	I.P. 2014 Pg .no. 2744, 28 to 33	Qualitative (Complies / Does not comply)
		Sterility (membrane filtration)	I.P. 2014 Pg. no.- 2744, 59 to 66	Qualitative (Complies / Does not comply)
II.	<b>WATER</b>			
1.	<b>Sterile Water for Injections</b>	Bacterial Endotoxins (Gel clot method)	I.P. 2014 Pg .no. 2990, 28 to 33	Qualitative (Complies / Does not comply)
		Sterility (membrane filtration)	I.P. 2014 Pg. no.- 2990, 59 to 66	Qualitative (Complies / Does not comply)
III.	<b>MEDICAL ACCESSORIES &amp; SURGICAL PRODUCTS</b>			
1.	<b>Copper - T</b>	Sterility (Direct inoculation method)	I.P. 2014 Pg. no.- 59 to 66	Qualitative (Complies / Does not comply)
2.	<b>Tubal Ring</b>	Sterility (Direct inoculation method)	I.P. 2014 Pg. no.- 59 to 66	Qualitative (Complies / Does not comply)

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#### CHEMICAL TESTING

I. DRUGS & PHARMACEUTICALS				
1.	Tablets			
a.	Phenytoin Sodium Tablets IP (50mg; 100mg)	Identification (IR) Disintegration (DT)	I.P. 2014 Pg. no - 2487 I.P. 2014 Pg. no - 251, 252 (I), 960 (II)	Qualitative Qualitative
b.	Ethambutol Tablets IP (200mg; 400mg)	Identification (IR) Identification (Colour Test) Assay (HPLC)	I.P. 2014 Pg. no 1697 I.P. 2014 Pg. no 1697 I.P. 2014 Pg. no 1697, 1698	Qualitative Qualitative 50% to 120%
c.	Hydrochlorothiazide Tablets IP (25mg; 50mg)	Identification (TLC) Assay (UV)	I.P. 2014 Pg. no 1901 I.P. 2014 Pg. no 1902	Qualitative 50% to 120%
d.	Paracetamol Tablets IP (500mg; 650mg)	Identification (IR) Assay (UV)	I.P. 2014 Pg. no 2434	Qualitative 50% to 120%
f.	Albendazole Tablets IP (400mg)	Assay (UV)	I.P. 2014 Pg. No 1006	50% to 120%
2.	Drug Substances (API)			
a.	Metronidazole	Identification (IR)	I.P. 2014 Pg. no -2216	Qualitative
b.	Domperidone	Identification (IR)	I.P. 2014 Pg. no -1612	Qualitative
c.	Allopurinol	Identification (IR)	I.P. 2014 Pg. no -1012	Qualitative
d.	Atorvastatin Calcium	Identification (IR)	I.P. 2014 Pg. no -1099	Qualitative
f.	Paracetamol	Identification (IR)	I.P. 2014 Pg. no -2429	Qualitative
g.	Caffeine	Identification (IR)	I.P. 2014 Pg. no -1237	Qualitative