Area, Phase-2, Panchkula, Haryana

Accreditation Standard ISO/IEC 17025: 2005

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Validity 29.06.2018 to 28.06.2020 Last Amended on --

SI.	Product / Material	Specific Test	Test Method Specification	Range of Testing /
!	of Test	Performed	against which tests are	Limits of Detection
1	İ	•	performed	

BIOLOGICALTESTING

I.	DRUGS AND PHARMACEUTICALS		 	
1.	Pharmaceutical	: Microbial Limit Test		
	Raw Material	Total Aerobic Microbial Count.	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	1cfu/g to 1000 cfu/g
		Total Fungal Count	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	1cfu/g to 100 cfu/g
· · · · · · · · · · · · · ·	 	Specified Micro Organisms		
		Staphylococcus aureus	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		Pseudomonas aeruginosa	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		E.coli	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
r · : : : : :	T	Salmonella	Indian Pharmacopoeia British Pharmacopoeia	Qualitative (Absent/Present per g)

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SI.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			United States Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	
		Clostridia	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		Shigella	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		Candida albicans	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
II.	FINISHED PRODUC	TS		
1.	Cream	Microbial Limit Test		
		Total Aerobic Microbial Count	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	1 to 1000 cfu/g
		Total Fungal Count	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	1 to 100 cfu/g
! ! ! !		Specified Micro organisms		
		Staphylococcus aureus	Indian Pharmacopoeia	Qualitative

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SI.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			British Pharmacopoeia United States Pharmacopoeia	(Absent/Present per g)
I I I I I I I I		Pseudomonas aeruginosa	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		E.coli	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		Salmonella	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
		Clostridia	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
 	†	Shigella	Indian Pharmacopoeia	Qualitative (Absent/Present per g)
		Candida albicans	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative (Absent/Present per g)
II.	WATER			
1.	Potable water	Coliform count / MPN	IS 1622 IS 1622	1 to500 cfu/mL <2MPN to 1161/100 mL
I I I I	1 1 1 1	E.coli	IS 1622	Qualitative (Present / Absent)

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SI.	Product / Material	Specific Test	Test Method Specification	Range of Testing /
!	of Test	Performed	against which tests are	Limits of Detection
1	İ	•	performed	

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SI.	Product / Material	Specific Test	Test Method Specification	Range of Testing /	1
į	of Test	Performed	against which tests are	Limits of Detection	i
i !			performed	i !	į

r	CHEMICAL TESTING				
ī.	DRUGS & PHARM	ACEUTICALS	T		
1.	Pharmaceutical Raw Material	Identification	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative	
			Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative	
		-by Chemical	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative	
 	 	Arsenic	Indian Pharmacopoeia British Pharmacopoeia	Qualitative	
		Iron	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative	
		Chloride	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative	
 	†	Sulphate	Indian Pharmacopoeia British Pharmacopoeia	Qualitative	

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SI.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			United States Pharmacopoeia	
		Lead	Indian Pharmacopoeia United States Pharmacopoeia	Qualitative
		Crystallinity	Indian Pharmacopoeia United States Pharmacopoeia	Qualitative
		Heavy Metals	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative
		Clarity &colour of Solution	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative
		Acidity or Alkalinity	Indian Pharmacopoeia	Qualitative
		Unsaponifiable matter	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopoeia	Qualitative
		Light Absorption	Indian Pharmacopoeia United States Pharmacopoeia	Qualitative
r 1 1 1 1 1		Solubility	Indian Pharmacopoeia	Qualitative
В.	Raw Material (API)			
1.	Aciclovir	Assay (by Chemical) Water (by Chemical)	Indian Pharmacopoeia	80% to 110% 80% to 110%

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SI.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Sulphated Ash		80% to 110%
2.	Amoxycillin Trihydrate	Assay (by HPLC) Water (by Chemical) Specific Optical Rotation	Indian Pharmacopoeia	80% to 110% 80% to 110% 80% to 110%
3.	Atorvastatin Calcium	Assay (by HPLC) Water (by Chemical)	Indian Pharmacopoeia	80% to 110% 80% to 110%
4.	Cephalexin	Assay (by HPLC) Water (by Chemical)	Indian Pharmacopoeia	80% to 110% 80% to 110%
5.	Paracetamol	Assay (by Titration) LOD (by Chemical) Sulphated Ash	Indian Pharmacopoeia	80% to 110% 80% to 110% 80% to 110%
6.	Riboflavine	Assay (by UV) LOD (by Chemical)	Indian Pharmacopoeia	80% to 110% 80% to 110%
C.	Tablet			
1.	Amoxycillin TrihydrateTablet	Assay (by HPLC)	Indian Pharmacopoeia	70% to 150%
3.	Atorvastatin Calcium Tablet	Assay (by HPLC)	Indian Pharmacopoeia	70% to 150%
4.	Cephalexin Tablet	Assay (by HPLC)	Indian Pharmacopoeia	70% to 150%
D.	Capsule			
1.	Cephalexin Capsule	Assay (by HPLC) Dissolution (By UV)	Indian Pharmacopoeia	70% to 150% 70% to 150%
2.	Amoxycillin Trihydrate Capsule	Assay (by HPLC) Dissolution (By UV)	Indian Pharmacopoeia	70% to 150% 70% to 150%