

Laboratory **Quality Control Laboratory, Theon Pharmaceuticals Limited, Village Saini Majra, Nalagarh, Himachal Pradesh**

Accreditation Standard **ISO/IEC 17025: 2005**

Discipline **Biological Testing** **Issue Date** **05.06.2014**

Certificate Number **T-2985** **Valid Until** **04.06.2016**

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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. Dry Powder Injection (Raw Materials)				
1	Ceftriaxone Sodium	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
2	Cefepime HCl	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
3	Ceftazidime Pentahydrate	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
4	Cloxacillin sodium	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
5	Cefotaxime Sodium	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative

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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
B. Oral Solid Dose Product (Raw Materials)				
1.	Croscarmellose Sodium	a) Total microbial count b) <i>E.coli</i>	IP 2014 (Page No-1470, Vol.2)	10-10000cfu/g Absent/Present per gm
2.	Hard Gelatin Capsule shells	a) Total microbial count b) <i>E.coli</i> c) Salmonella	IP 2014 (Page No-1848, Vol.2)	10-10000 cfu /g Absent/Present per gm Absent/Present per gm
3.	Lactose	a) Total Microbial Count b) <i>E.coli</i> c) Salmonella	IP 2014 (Page No-2050, Vol.2)	10-10000 cfu/g Absent/Present per gm Absent/Present per gm
4.	Serratiapeptidasae	a) Total viable aerobic count b) <i>E.coli</i>	IP 2014 (Page No-2719, Vol.3)	10-10000 cfu/ml Absent/Present per ml
5.	Xanthan gum	a) Total bacterial count b) Total Fungal Count c) <i>E.coli</i>	IP 2014 (Page No-2996, Vol.3)	10-10000 cfu/g 10-100 cfu/g Absent/Present per gm
C. Dry Powder Injection (Finished Product)				
1.	Imipenem and Cilastatin	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
2.	Meropenem injection	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative

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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.	Ceftriaxone Sulbactam injection	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol II	Qualitative Qualitative
4.	Ceftriaxone Tazobactam injection	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
5.	Cefepime and Tazobactam injection	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
6.	Sterile Water For Injection	Sterility Bacterial Endotoxin Test	USP 37 Chapter<71> Page No.71, Vol I USP 37 Chapter<85> Page No.92, Vol I	Qualitative Qualitative
D. Oral Solid Dose Product (Finished Product)				
1.	Flemiklox LBX (Amoxicillin, dicloxacillin & lactic acid bacillus)	a) Total viable aerobic count b) <i>E.coli</i>	IP 2014 (Page No.49, Table No.5, Vol I)	10-1000 cfu/g Absent/Present per gm
2.	Theoclave Amoxicillin & clavulanate potassium	a) Total viable aerobic count b) <i>E.coli</i>	IP 2014 (Page No.49, Table No.5, Vol I)	10-1000 cfu/g 10-100 cfu/g Absent/Present per gm

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3.	Monti-FX Montelukast & Fexofenadine	a) Total viable aerobic count b) <i>E.coli</i>	IP 2014 (Page No.49, Table No.5, Vol I)	10-1000 cfu/g 10-100 cfu/g Absent/Present per gm
4.	Glemont-F Montelukast & Fexofenadine	a) Total viable aerobic count b) <i>E.coli</i>	IP 2014 (Page No.49, Table No.5, Vol I)	10-1000 cfu/g 10-100 cfu/g Absent/Present per gm

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