

Laboratory **Quality Control Laboratory, Theon Pharmaceuticals Ltd., Vill. Saini Majra, Nalagarh, Baddi, Himachal Pradesh**

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

Certificate Number **TC-6504**

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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.	<b>DRUGS &amp; PHARMACEUTICALS</b>			
1.	<b>Amoxicillin &amp; Clavulanate Potassium Tablets</b>	Total Bacterial count (TBC) Total Fungal count (TFC) Pathogen: E.coli Salmonella abony P.aeruginosa S.aureus	USP 39, NF 34 2016 Vol.2 p2526-2527	10 cfu/g to 1000 cfu/g 10 cfu/g to 100 cfu/g Absent / ml Absent / 10 gm Absent / ml Absent / ml
2.	<b>Montelukast Tablets</b>	Total Bacterial count (TBC) Total Fungal count (TFC) Pathogen: E.coli Salmonella abony P.aeruginosa S.aureus	IH GTP No. GTP/008, Issue No. 03, Issue dt. 05/07/16	10 cfu/g to 1000 cfu/g 10 cfu/g to 100 cfu/g Absent / ml Absent / 10 gm Absent / ml Absent / ml
3.	<b>Cefixime Tablets</b>	Total Bacterial count (TBC) Total Fungal count (TFC) Pathogen: E.coli Salmonella abony P.aeruginosa S.aureus	IH GTP No. GTP/008, Issue No. 03, Issue dt. 05/07/16	10 cfu/g to 1000 cfu/g 10 cfu/g to 100 cfu/g Absent / ml Absent / 10gm Absent / ml Absent / ml
4.	<b>Erythromycin Tablets</b>	Assay	USP39,NF34 2016 Vol.2p3751	50.0 % to 120.0 % of label claim

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5.	<b>Amoxicillin Capsules</b>	Total Bacterial count (TBC) Total Fungal count (TFC) Pathogen: E.coli Salmonella abony P.aeruginosa S.aureus	USP 39, NF 34 2016 Vol.2 p2521	10 cfu/g to 1000 cfu/g 10 cfu/g to 100 cfu/g  Absent / ml Absent /10gm Absent / ml Absent / ml
6.	<b>Thiocolchicoside capsules</b>	Total Bacterial count (TBC) Total Fungal count (TFC) Pathogen: E.coli Salmonella abony P.aeruginosa S.aureus	GTP No.- GTP/008, Issue No. 03 Issue dt. 05/07/16	10 cfu/g to 1000 cfu/g 10 cfu/g to 100 cfu/g  Absent / ml Absent / 10gm Absent / ml Absent /ml
7.	<b>Ceftriaxone Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IP 2014 Vol. 2 p1325	Qualitative Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
8.	<b>Cefotaxime Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IP 2014 Vol. 2 p1325	Qualitative Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
9.	<b>Cefuroxime Sodium Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IP 2014 Vol. 2 p1329-1330	Qualitative Qualitative  10 µm: 1- 6000 particle 25 µm: 1- 600 particle

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10.	<b>Ceftriaxone for Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39 NF 34 2016 Vol. 2 p3044	Qualitative Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
11.	<b>Imipenem &amp; Cilastatin Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IP 2014 Vol. 2 p1953	Qualitative Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
12.	<b>Meropenem Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IP 2014 Vol. 2 p2180	Qualitative Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
13.	<b>Ceftriaxone &amp; Sulbactam Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
14.	<b>Cefotaxime &amp; Sulbactam Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle

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15.	<b>Cefotaxime for Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39, NF 34 2016 Vol.2 p3015-3016	Qualitative Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
16.	<b>Ceftidime for injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39, NF 34 2016 Vol.2 p3040-3041	Qualitative Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
17.	<b>Ceftidime &amp; Sulbactam Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
18.	<b>Cefoperazone Sodium &amp; Sulbactam</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative  10µm: 1 to 6000 particle 25µm: 1 to 600 particle
19.	<b>Cefuroxime for Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39, NF 34 2016 Vol.2 p3048	Qualitative Qualitative  10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle

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20.	<b>Cefepime &amp; Sulbactam</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
21.	<b>Cefepime &amp; Tazobactam</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	IH Sterility GTP No.- GTP/005 Issue No. 03 Issue dt. 06/07/16 BET GTP No. – GTP/006 Issue No. 03 Issue dt. 06/07/16 LBPC GTP No. – GTP/007 Issue No. 01 Issue dt. 26/08/16	Qualitative  Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
22.	<b>Cefepime for Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39, NF 34 2016 Vol.2 p2997-2998	Qualitative Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle
23.	<b>Meropenem for Injection</b>	Sterility Bacterial Endotoxin Test (BET) Liquid borne particle count (LBPC)	USP 39, NF 34 2016 Vol.3 p4742-4743	Qualitative Qualitative 10 µm: 1 to 6000 particle 25 µm: 1 to 600 particle

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**CHEMICAL TESTING**

I.	<b>DRUGS AND PHARMACEUTICALS</b>			
1.	<b>Amlodipine Tablets</b>	Related Substance (By HPLC) Amlodipine Impurity B Total impurities	IP 2014 Vo.2 p-1047	0.05 % to 5.0 % 0.05 % to 5.0 %
		Assay ( By HPLC)	IP 2014 Vo.2 p-1047	60.0 % to 120.0 % of Label Claim
2.	<b>Amoxicillin &amp; Potassium Clavulanate Tablets</b>	Assay ( By HPLC)	IP 2014 Vo.2 p-1060	50.0% to 120.0% of Label Claim
3.	<b>Atorvastatin Tablets</b>	Assay (By HPLC)	IP 2014 Vo.2 p-1101-1102	70.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Individual impurity Total impurities	IP 2014 Vo.2 p-1101	0.05 % to 5.0 % 0.05 % to 5.0 %
4.	<b>Betahistine Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 2 p-1167	60.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Individual impurity Total impurities	IP 2014 Vol. 2 p-1167	0.05 % to 5.0 % 0.05 % to 5.0 %
5.	<b>Cefixime Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 2 p-1308	60.0 % to 120.0 % of Label Claim
6.	<b>Cefpodoxime Proxetil Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 2 p-1318	60.0 % to 120.0 % of Label Claim
7.	<b>Clopidogrel Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 2 p-1441-1442	50.0 % to 120.0 % of Label Claim
		Related Substance (By HPLC)	IP 2014 Vol. 2 p-1441	0.05 % to 5.0 % 0.05 % to 5.0 %

**Anand Deep Gupta**  
Convenor

**N. Venkateswaran**  
Program Director

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		Clopidogrel Impurity A Clopidogrel Impurity C Other Impurity Total Impurities		0.05 % to 5.0 % 0.05 % to 5.0 %
8.	<b>Doxophylline Tablets</b>	Assay(By HPLC)	IP 2014 Vo.2 p-1627	55.0 % to 120.0 % of Label Claim
		Related substances Individual impurity Total impurities	IP 2014 Vo.2 p-1626	0.05 % to 5.0 % 0.05 % to 5.0 %
9.	<b>Fexofenadine HCL Tablets</b>	Assay(By HPLC)	IP 2014 Vol. 2 p-1759	60.0 % to 120.0 % of Label Claim
		Related Substance (By HPLC) Fexofenadine Impurity A Individual Impurity Decarboxilateddegradant Total impurities	IP 2014 Vol. 2 p-1758-1759	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
10.	<b>Levofloxacin Tablets</b>	Assay (By HPLC )	IP 2014 Vol. 2 p-2088-2089	60.0 % to 120.0 % of Label Claim
		Related substances Individual impurity Total impurities	IP 2014 Vol. 2 p-2088	0.05 % to 5.0 % 0.05 % to 5.0 %
11.	<b>Linezolid Tablets</b>	Assay (By HPLC)	IP 2014 Vo.2 p-2103-2104	80.0 % to 120.0 % of Label Claim
		Related substances (By HPLC) Individual impurity Total impurities	IP 2014 Vo.2 p-2103	0.05 % to 5.0 % 0.05 % to 5.0 %
12.	<b>Losartan Tablets</b>	Assay (By HPLC)	IP 2014 Vo.2 p-2123-2124	60.0 % to 120.0 % of Label Claim
		Related substances (By HPLC) Individual	IP 2014 Vo.2 p2123	0.05 % to 5.0 % 0.05% to 5.0%

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		impurity Total impurities		
13.	<b>Losartan Potassium and Hydrochlorothiazide Tablets</b>	Assay (By HPLC)	IP 2014 Vo.2 p-2126	60.0 % to 120.0 % of Label Claim
14.	<b>Metformin Tablets</b>	Assay (By UV)	IP 2014 Vol. 2 p-2187	55.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Dicyandiamide Impurity Other Impurity	IP 2014 Vol. 2 p-2187	0.05 % to 5.0 % 0.05 % to 5.0 %
15.	<b>Mifepristone tablets</b>	Assay (By HPLC)	IP 2014 Vol.2 p-2235-2236	50.0 % to 120.0 % of Label Claim
		Related substances (By HPLC) Individual impurity Total impurities	IP 2014 Vol.2 p-2235-2236	0.05 % to 5.0 % 0.05 % to 5.0 %
16.	<b>Misoprostol Tablets</b>	Assay (By HPLC)	IP 2014 Vol.2 p-2239-2240	60.0 % to 120.0 % of Label Claim
17.	<b>Montelukast Tablets</b>	Assay (By HPLC)	IP 2014 Vol.2 p-2249	55.0 % to 120.0 % of Label Claim
		Sulphoxide Impurity Styrene Impurity Individual impurity Total impurities	IP 2014 Vol.2 p-2248-2249	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
18.	<b>Rosuvastatin Tablets</b>	Assay (By HPLC)	IP 2014 Vol.3 p-2685	50.0 % to 120.0 % of Label Claim
		Related substances Individual impurity Total impurities	IP 2014 Vol. 3 p-2685	0.05 % to 5.0 % 0.05 % to 5.0 %
19.	<b>Telmisartan Tablets</b>	Assay (By HPLC)	IP 2014 Vol.3 p-2832-2833	60.0 % to 120.0 % of Label Claim



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		Related substance (By HPLC) Any Individual impurity Total Impurities	IP 2014 Vol.3	0.05 % to 5.0 % 0.05 % to 5.0 %
20.	<b>Ursodeoxycholic Acid Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 3 p-2945	60.0 % to 120.0 % of Label Claim
21.	<b>Voglibose Tablets</b>	Assay (By HPLC)	IP 2014 Vol. 3 p-2981-2982	60.0 % to 120.0 % of Label Claim
22.	<b>Levofloxacin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3 p-4549	70.0 % to 120.0 % of Label Claim
23.	<b>Acetaminophen &amp; Tramadol Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p2323	55.0 % to 120.0 % of Label Claim
24.	<b>Fexofenadine Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p3899	60.0 % to 120.0 % of Label Claim
25.	<b>Levofloxacin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3 p-4549	60.0 % to 120.0 % of Label Claim
26.	<b>Ofloxacin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3 p5124-5125	70.0 % to 120.0 % of Label Claim
27.	<b>Metformin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3 p4765	60.0 % to 120.0 %
		Related Substances (By HPLC) Any Individual Impurity Total Impurities	USP39, NF 34 2016 Vol.3 p4766	0.05 % to 5.0 % 0.05 % to 5.0 %
28.	<b>Azithromycin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p2662	60.0 % to 120.0 % of Label Claim
29.	<b>Ciprofloxacin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p3165	60.0 % to 120.0 % of Label Claim
30.	<b>Clopidogrel Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p3250-3251	60.0 % to 120.0 % of Label Claim
31.	<b>Clarithromycin Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2 p3195-3196	55.0 % to 120.0 % of Label Claim
32.	<b>Losartan Tablets</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3	70.0 % to 120.0 % of

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			p4625-4626	Label Claim
33.	Ranitidine Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.3p5673	80.0 % to 120.0 % of Label Claim
34.	Ibuprofen Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p4270	65.0 % to 120.0 % of Label Claim
35.	Amoxicillin & Clavulanate Potassium Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p2526-2527	50.0 % to 120.0 % of Label Claim
36.	Cefixime Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3003-3004	60.0 % to 120.0 % of Label Claim
37.	Cefpodoxime Proxetil Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3031	60.0 % to 120.0 % Of Label Claim of Label Claim
38.	Cefuroxime Axetil Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3050	60.0 % to 120.0 % of Label Claim
39.	Ursodiol Tablets	Assay (By HPLC)	USP39, NF 34 2016 Vol.3p6305	70.0 % to 120.0 % of Label Claim
40.	Betahistine Tablets	Assay (By HPLC)	BP 2016 Vol-3 p189-189	55.0 % to 120.0 % of Label Claim of Label Claim
41.	Paracetamol Tablets	Assay (By HPLC)	BP 2016 Vol-3 p972-973	50.0 %to 120.0 % of Label Claim
42.	Cefixime & Ofloxacin Tablets	Assay (By HPLC)	IH – STP NO./OSDC008 Revision- 03 Effective 01/2017	60.0 % to 120.0 % of Label Claim
43.	Cefixime & Potassium Clavulanate Tablets	Assay (By HPLC)	IH – STP NO./OSDC007 Revision- 04 Effective 05/2015	60.0 % to 120.0 % of Label Claim
44.	Cefpodoxime & Potassium Clavulanate Tablets	Assay (By HPLC)	IH – STP NO./ OSDCO32 Revision- 02 Effective 05/2015	55.0 % to 120.0 % of Label Claim
45.	Febuxostat Tablets	Assay (By HPLC)	IH – STP NO./OSDG007 Revision- 09	70.0 % to 120.0 % of Label Claim

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			Effective 07/2016	
		Related substances (By HPLC) Individual impurity Total impurities	IH – STP NO./OSDG007 Revision- 09 Effective 07/2016	0.05 % to 5.0 % 0.05 % to 5.0 %
46.	<b>Glimepiride &amp; Metformin Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG158 Revision- 02 Effective 10/2015	60.0 % to 120.0 % of Label Claim
47.	<b>Levosulpiride Tablets</b>	Assay (By HPLC)	IH – STP NO./ OSDG086 Revision- 02 Effective 09/2014	70.0 % to 120.0 % of Label Claim
48.	<b>Montelukast &amp; Levocetirizine Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG085 Revision- 01 Effective 04/2014	70.0 % to 120.0 % of Label Claim
49.	<b>Olmisartan Medoxomil Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG062 Revision- 02 Effective 09/2014	60.0 % to 120.0 % of Label Claim
50.	<b>Moxifloxacin Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG243 Revision- 01 Effective 02/2016	60.0 % to 120.0 % of Label Claim
51.	<b>Ofloxacin &amp; Ornidazole Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG072 Revision- 02 Effective 04/2015	55.0 % to 120.0 % of Label Claim
52.	<b>Voglibose &amp; Metformin Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG242 Revision- 03 Effective 01/2015	60.0 % to 120.0 % of Label Claim
53.	<b>Tranexamic Acid &amp; Ethmysylate Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG206 Revision- 03 Effective 01/2016	60.0 % to 120.0 % Of Label Claim
54.	<b>Rosuvastatin &amp; Fenofibrate Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG062 Revision- 01 Effective 09/2014	70.0 % to 120.0 % of Label Claim
55.	<b>Montelukast &amp; Fexofenadine</b>	Assay (By HPLC)	IH – STP NO./OSDG072 Revision- 01	60.0 % to 120.0 % of Label Claim

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	<b>Tablets</b>		Effective 09/2014	
56.	<b>Desloratadine Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG090 Revision- 01 Effective 09/2015	65.0 % to 120.0 % Of Label Claim
57.	<b>Desloratadine &amp; Montelukast Tablets</b>	Assay (By HPLC)	IH – STP NO./ OSDG017 Revision- 02 Effective 08/2015	70.0 % to 120.0 % of Label Claim
58.	<b>Dapoxetine Tablets</b>	Assay (By UV)	IH – STP NO./ OSDG059 Revision- 01 Effective 01/2017	55.0 % to 120.0 % of Label Claim
59.	<b>Sitagliptin Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG035 Revision- 02 Effective 01/2016	60.0 % to 120.0 % of Label Claim
60.	<b>Sitagliptin &amp; Metformin HCl Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG037 Revision- 01 Effective 08/2014	70.0 % to 120.0 % of Label Claim
61.	<b>Rabeprazole Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG301 Revision- 02 Effective 10/2015	70.0 % to 120.0 % of Label Claim
62.	<b>Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate &amp; Caffeine Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG024 Revision- 03 Effective 07/2014	70.0 % to 120.0 % of Label Claim
63.	<b>Sildenafil Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG036 Revision- 03 Effective 08/2014	70.0 % to 120.0 % of Label Claim
64.	<b>Acarbose Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG134 Revision- 01 Effective 08/2015	60.0 % to 120.0 % of Label Claim
65.	<b>Citicoline Tablets</b>	Assay (By HPLC)	IH – STP NO./OSDG111 Revision- 03 Effective 09/2015	60.0 % to 120.0 % of Label Claim

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66.	Etoricoxib Tablets	Assay (By HPLC)	IH – STP NO./OSDG211 Revision- 02 Effective 10/2015	70.0 % to 120.0 % of Label Claim
67.	Aceclofenac & Paracetamol Tablets	Assay (By HPLC)	IH – STP NO./ OSDG119 Revision- 01 Effective 04/2015	55.0 % to 120.0 % of Label Claim
68.	Atorvastatin & Amlodipine Tablets	Assay (By HPLC)	IH – STP NO./ OSDG177 Revision- 01 Effective 09/2015	50.0 % to 120.0 % of Label Claim
69.	Atorvastatin & Ezetimibe Tablets	Assay (By HPLC)	IH – STP NO./ OSDG237 Revision- 01 Effective 09/2015	55.0 % to 120.0 % of Label Claim
70.	Rosuvastatin Tablets	Assay (By HPLC)	IH – STP NO./ OSDG011 Revision- 02 Effective 01/2017	60.0 % to 120.0 % Of Label Claim
71.	Roxithromycin Tablets	Assay (By HPLC)	IH – STP NO./OSDG099 Revision- 01 Effective 02/2014	60.0 % to 120.0 % of Label Claim
72.	Artemether & Lumefantrine Tablets	Assay (By HPLC)	IH – STP NO./ OSDG118 Revision- 01 Effective 04/2015	55.0 % to 120.0 % Of Label Claim
73.	Lornoxim & Paracetamol Tablets	Assay (By HPLC)	IH – STP NO./OSDG014 Revision- 00 Effective 05/2014	65.0 % to 120.0 % of Label Claim
74.	Aceclofenac Tablets	Assay (By HPLC)	IH – STP NO./OSDG057 Revision- 01 Effective 11/2014	55.0 % to 120.0 % of Label Claim
75.	Deflazacort Tablets	Assay (By HPLC)	IH – STP NO./ OSDG125 Revision- 02 Effective 03/2015	60.0 % to 120.0 % of Label Claim
76.	Cefuroxime & Potassium Clavulanate	Assay (By HPLC)	IH – STP NO./OSDC023 Revision- 01 Effective 12/2015	70.0 % to 120.0 % of Label Claim

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	<b>Tablets</b>			
77.	<b>Amoxicillin Capsules</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1056	70.0 % to 120.0 % of Label Claim
78.	<b>Ampicillin Capsules</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1064	60.0 % to 120.0 % of Label Claim
79.	<b>Cephalexin Capsules</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1337	60.0 % to 120.0 % of Label Claim
		Related Substances (By TLC) 7-aminodesacetoxy cephalosporanic acid DL-phenylglycine Secondary Impurities	IP 2014 Vol. 2 p1336-1337	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
80.	<b>Pregabalin Capsules</b>	Assay (By HPLC)	IP 2014 Vol. 3 p2550	55.0 % to 120.0 % of Label Claim
		Related Substances (By HPLC) Lactam Lactose Conjugate Impurity Any Individual impurity Total Impurities	IP 2014 Vol. 3 p2550	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
81.	<b>Thiocolchicoside Capsules</b>	Assay (By HPLC)	IP 2014 Vol. 3 p2862	50.0 % to 120.0 % of Label Claim
		Related Substances (By HPLC) N-Deacetyl-N-formyl thiocolchicoside and colchicoside Total Impurities	IP 2014 Vol. 3 p2862	0.05 % to 5.0 % 0.05 % to 5.0 %
82.	<b>Amoxicillin Capsules</b>	Assay (By HPLC)	USP 39, NF34 2016 Vol. 2 p-2521	80.0 % to 120.0 % of Label Claim
83.	<b>Ampicillin Capsules</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p2540	70.0 % to 120.0 % of Label Claim

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84.	<b>Doxycycline Capsules</b>	Assay (By HPLC)	BP 2016 Vol-3 p508	55.0 % to 120.0 % of Label Claim
85.	<b>Gastro-resistant Omeprazole Capsules</b>	Assay (By HPLC)	BP 2016 Vol-3 p972-973	60.0 % to 120.0 % of Label Claim
86.	<b>Flucloxacillin Capsules</b>	Assay (By HPLC)	BP 2016 Vol-3 p573	60.0 % to 120.0 % of Label Claim
87.	<b>Amoxicillin &amp; Cloxacillin Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDB026 Revision- 01 Effective 06/2015	55.0 % to 120.0 % of Label Claim
88.	<b>Pantoprazole &amp; Domperidone Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDG081 Revision- 03 Effective 04/2015	55.0 % to 120.0 % of Label Claim
89.	<b>Pantoprazole &amp; Levosulpiride Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDG102 Revision- 07 Effective 01/2016	60.0 % to 120.0 % of Label Claim
90.	<b>Pregabalin, Methylcobalmin, Alphalipoic Acid Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDG208 Revision- 01 Effective 11/2015	60.0 % to 120.0 % of Label Claim
91.	<b>Celecoxib Capsules</b>	Assay (By HPLC)	IH – STP NO./ OSDG174 Revision- 01 Effective 08/2015	55.0 % to 120.0 % of Label Claim
92.	<b>Duloxetine Delayed Release Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDG097 Revision- 01 Effective 12/2014	60.0 % to 120.0 % of Label Claim
93.	<b>Ampicillin &amp; Cloxacillin Capsules</b>	Assay (By HPLC)	IH – STP NO./OSDB026 Revision- 01 Effective 06/2015	55.0 % to 120.0 % of Label Claim
94.	<b>Cefixime for oral Suspension</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1307	55.0 % to 120.0 % of Label Claim

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95.	<b>Amoxicillin &amp; Potassium Clavulanate for Oral Suspension</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p2526	60.0 % to 120.0 % of Label Claim
96.	<b>Amoxicillin for Oral Suspension</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p2523	60.0 % to 120.0 % of Label Claim
97.	<b>Cefixime for Oral Suspension</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3002-3003	50.0 % to 120.0 % of Label Claim
98.	<b>Artemether &amp; Lumefantrine for Oral Suspension</b>	Assay (By HPLC)	IH – STP NO./OSDG215 Revision- 01 Effective 11/2015	55.0 % to 120.0 % of Label Claim
99.	<b>Ceftriaxone injection</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1325	70.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Individual Impurity Total Impurities	IP 2014 Vol. 2 p1325	0.05 % to 5.0 % 0.05 % to 5.0 %
100.	<b>Cefotaxime injection</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1312	60.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Individual Impurity Total Impurities	IP 2014 Vol. 2 p1312	0.05 % to 5.0 % 0.05 % to 5.0 %
101.	<b>Cefuroxime Sodium Injection</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1329-1330	60.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Descarbamoyl-cefuroxime Any other Individual impurity Total Impurities	IP 2014 Vol. 2 p1329	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
102.	<b>Imipenem &amp; Cilastatin</b>	Assay (By HPLC)	IP 2014 Vol. 2 p1953	55.0 % to 120.0 % of Label Claim



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	<b>Injection</b>			
<b>103.</b>	<b>Meropenam Injection</b>	Assay (By HPLC)	IP 2014 Vol. 2 p2180	70.0 % to 120.0 % of Label Claim
		Related Substances (By HPLC) Any Individual impurity Total Impurities	IP 2014 Vol. 2 p2179-2180	0.05 % to 5.0 % 0.05 % to 5.0 %
<b>104.</b>	<b>Ceftriaxone for Injection</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3044	55.0 % to 120.0 % of Label Claim
		Related substance (By HPLC) Deacetylcefotaxime lactone Ceftriaxone triazineanalog Ceftriaxone benothiazolyl oxime Deacyl ceftriaxone Ceftriaxone-3-eneisomer Ceftriaxine E-Isomer Individual Impurity Total Impurities	USP39, NF 34 2016 Vol.2 p3044-3045	0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 % 0.05 % to 5.0 %
<b>105.</b>	<b>Cefotaxime for Injection</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3015-3016	60.0 % to 120.0 % of Label Claim
		Related Substances (By HPLC)Individual impurity Total Impurities	USP39, NF 34 2016 Vol.2p3016	0.05 % to 10.0 % 0.05 % to 10.0 %
<b>106.</b>	<b>Ceftazidime for injection</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3040-3041	60.0 % to 120.0 % of Label Claim
<b>107.</b>	<b>Cefuroxime for Injection</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.2p3048	70.0 % to 120.0 % of Label Claim
<b>108.</b>	<b>Cefepime for</b>	Assay (By HPLC)	USP39, NF 34 2016	55.0 % to 120.0 % of

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	<b>injection</b>		Vol.2p2997-2998	Label Claim
<b>109.</b>	<b>Meropenem for Injection</b>	Assay (By HPLC)	USP39, NF 34 2016 Vol.3 p4741-4742	50.0 % to 120.0 % of Label Claim
		Related Substances (By HPLC) Meropenem Impurity I Meropenem Impurity II	USP39, NF 34 2016 Vol.3 p4742-4743	0.05 % to 5.0 % 0.05 % to 5.0 %
<b>110.</b>	<b>Ceftriaxone &amp; Sulbactam injection</b>	Assay (By HPLC)	IH – STP NO./INJC0012 Revision- 02 Effective 04/2015	70.0 % to 120.0 % of Label Claim
<b>111.</b>	<b>Ceftazidime &amp; Sulbactam injection</b>	Assay (By HPLC)	IH – STP NO./INJC0015 Revision- 02 Effective 04/2015	60.0 % to 120.0 % of Label Claim
<b>112.</b>	<b>Cefoperazone &amp; Sulbactam injection</b>	Assay (By HPLC)	IH – STP NO./INJC0018 Revision- 02 Effective 04/2015	70.0 % to 120.0 % of Label Claim