

Laboratory **Food & Drugs Administrations Laboratory, FDA Maharashtra State, 341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra**

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

Certificate Number **TC-6678** Page 1 of 12

Validity **10.10.2018 to 25.12.2019** 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
-----	----------------------------	-------------------------	---	--

BIOLOGICAL TESTING

I. DRUGS & PHARMACEUTICALS				
1.	Amikacin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1028 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
2.	Ampicillin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1068, Vol. IV, Page no. 3483 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
3.	Benzyl Penicillin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1164, Vol. IV, Page no. 3489 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 2 of 12

Validity 10.10.2018 to 25.12.2019

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
4.	Calcium Gluconate Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1254 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
5.	Cefazolin Sodium Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1300 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
6.	Cefotaxime Sodium Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 ,Vol. II, Page no. 1311, Add. 2015 Page no. 3823 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
7.	Cefpirome Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1314 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 3 of 12

Validity 10.10.2018 to 25.12.2019

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
8.	Ceftazidime for Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no.1320 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
9.	Ceftriaxone Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1324, Vol. IV, Page no. 3497 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
10.	Cefuroxime Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1329, Add. 2016 Page no. 4169 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
11.	Chlorpheniramine Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1376, Vol. IV, Page no., 3498, Add. 2015 Page no. 3826 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 4 of 12

Validity 10.10.2018 to 25.12.2019

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
			Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	
12.	Ciprofloxacin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1400, Vol. IV, Page no. 3501, Add. 2016 Page no. 4170 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
13.	Compound Sodium Lactate injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2757 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
14.	Dexamethasone Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II , Page no. 1526, Vol. IV, Page no. 3509, Add. 2015, Page no. 3840, Add. 2016 ,Page no. 4173 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 5 of 12

Validity 10.10.2018 to 25.12.2019

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
15.	Dextrose Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1542 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
16.	Diazepam Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1547, Vol. IV, Page no. 3510 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
17.	Fruosemide Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014, Vol. II, Page no. 1834, Vol. IV, Page no. 3528, Add. 2016 ,Page no. 4331 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
18.	Gentamicin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014, Vol. II, Page no. 1859, Vol. IV, Page no. 3529, Add. 2015 Page no. 3867 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 6 of 12

Validity 10.10.2018 to 25.12.2019

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
			Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	
19.	Heparin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 1888 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
20.	Ketamine hydrochloride Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 2033 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
21.	Mannitol injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 2153 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
22.	Meropenem Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 2179, Add. 2015 Page no. 3891 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 7 of 12

Validity 10.10.2018 to 25.12.2019

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
			Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	
23.	Metoclopramide Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 2211, Add. 2015 Page no. 3898 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
24.	Metronidazole Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. II, Page no. 2218 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
25.	Ondansetron Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2376, Add. 2016 Page no. 4231 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory **Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra**

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

Certificate Number **TC-6678**

Page 8 of 12

Validity **10.10.2018 to 25.12.2019**

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
26.	Oxytetracycline Hydrochloride Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2407, Vol. IV, Page no. 3557 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
27.	Oxytocin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2410, Add. 2015 Page no. 3915 I.P. 2014, Vol. I, Page no. 28, Addendum 2015, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
28.	Sodium Chloride & Dextrose Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2741 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
29.	Sodium Chloride Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2744, Add. 2015, Page no. 3929 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 9 of 12

Validity 10.10.2018 to 25.12.2019

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
30.	Sterile Water for Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2989 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
31.	Streptomycin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 , Vol. III, Page no. 2799 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)
32.	Tobramycin Injection I.P.	Bacterial Endotoxin Test (BET)	IP 2014 ,Vol. III, Page no. 2881, Add. 2015 Page no. 3942, Add. 2016 Page no. 4253 I.P. 2014, Vol. I, Page no. 28, Appendix 2.2.3. under Bacterial Endotoxins Method A.-Gel-Clot Limit Test Method	Complies / Does not Comply (Qualitative)

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678

Page 10 of 12

Validity 10.10.2018 to 25.12.2019

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
<u>CHEMICAL TESTING</u>				
I. DRUGS & PHARMACEUTICALS				
1.	Albendazole tablets IP	Identification – A & B Uniformity of weight Disintegration Assay	IP 2014, Page no. 1006	Qualitative 5 % to 10 % of average weight 10 sec. to 3 Hrs. 80% to 120% of label claim
2.	Amoxicillin trihydrate Dispersible tablets IP	Identification Disintegration Uniformity of Weight Uniformity of dispersion Assay	IP 2014 , Page no. 1056 Addendum 2016, Page no. 4155	Qualitative 10 sec. to 3 Hrs. 5 % to 10 % of average weight Qualitative 80% to 120% of label claim
3.	Ascorbic acid tablets IP	Identification – A, B & C Uniformity of weight Disintegration Assay	IP 2014 , Page no. 1087	Qualitative 5 % to 10 % of average weight 10 sec. to 3 Hrs. 80% to 120% of label claim
4.	Cefadroxil tablets IP	Identification Dissolution Uniformity of Weight Water Assay	IP 2014 , Page no. 1295	Qualitative 50% to 150% of label claim 5 % to 10 % of average weight 0.1 % to 17.0 % 80% to 120% of label claim

Laboratory **Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra**

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

Certificate Number **TC-6678**

Page 11 of 12

Validity **10.10.2018 to 25.12.2019**

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
5.	Cefadroxil Oral suspension IP	Identification pH Water Assay Stability of suspension Uniformity of weight/volume	IP 2014 , Page no. 1294	Qualitative 1 to 14 0.1 % to 17.0 % 80% to 120% of label claim 80% to 120% of label claim 80% to 120% of average volume
6.	Chloramphenicol capsules IP	Identification – A & B Specific Optical Rotation Dissolution Uniformity of Weight Assay	IP 2014 , Page no. 1349 Addendum 2015, Page no. 3825	Qualitative - 340° to + 340° 50% to 150% of label claim 5 % to 10 % of average weight 80% to 120% of label claim
7.	Furazolidone oral suspension IP	Identification pH Assay Uniformity of weight / volume	IP 2014 , Page no. 1837	Qualitative 1 to 14 80% to 120% of label claim 80% to 120% of average volume
8.	Furazolidone tablets IP	Identification Uniformity of weight Disintegration Assay	IP 2014 , Page no. 1837	Qualitative 5 % to 10 % of average weight 10 sec. to 3 Hrs. 80% to 120% of label claim
9.	Paracetamol syrup IP	Identification – A , B 4-Aminophenol Assay Uniformity of weight / volume	IP 2014 , Page no. 2433 Addendum 2015, Page no. 3915	Qualitative Qualitative 80% to 120% of label claim 80% to 120% of average volume

Laboratory Food & Drugs Administrations Laboratory, FDA Maharashtra State,
341, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-6678 **Page 12 of 12**

Validity 10.10.2018 to 25.12.2019 **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
10.	Pyrazinamide tablets IP	Identification – A,B & C Uniformity of weight Related substances Disintegration Assay	IP 2014 , Page no. 2597	Qualitative 5 % to 10 % of average weight Qualitative 10 sec. to 3 Hrs. 80% to 120% of label claim
11.	Trimethoprim and Sulphame-thoxazole oral suspension IP	Identification pH Assay Uniformity of weight / volume	IP 2014 , Page no. 2923	Qualitative 1 to 14 Trimethoprim - 80% to 120% of label claim Sulphamethoxazole - 80% to 120% of label claim 80% to 120% of average volume