

Quality And Accreditation Institute Centre for International Accreditation

(formerly Centre for Laboratory Accreditation)



Certificate of Accreditation

Eurofins Biopharma Product Testing India Pvt. Ltd.

Plot No.-21 & 22, Phase II, Peenya Industrial Area,
Bengaluru-560058, Karnataka, India

has been assessed and accredited in accordance with the Standard
ISO/IEC 17025:2017

“General Requirements for the Competence of Testing and Calibration Laboratories”
In the field of
Testing

This certificate remains valid for the Scope of Accreditation as specified
in the annexure subject to continued compliance to the above standard &
any other requirements specified by QAI.



QAI/CIA/TL/2025/0103

Valid from: 18 February 2025

Valid until: 17 February 2027

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. Vikram Kumar
Chair, CIA

User is advised to verify the current scope of accreditation by visiting our website: www.qai.org.in



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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Drugs and Pharmaceuticals		
1.	Atorvastatin Calcium Tablets	Identification by HPLC (High Performance Liquid Chromatography)	IP (2.4.14):2022 Page No. 1537
2.	Atorvastatin Calcium Tablets	Assay content by HPLC as C33H35FN05	IP (2.4.14):2022 Page No. 1537
3.	Atorvastatin Calcium Tablets	Dissolution by HPLC as C33H35FN2O5	IP (2.5.2):2022 Page No. 1536
4.	Polypropylene bags for injection (packing material for drug product or pharmaceutical packing /delivery system)	Qualitative assessment of extractable impurities	
5.		i) Non-volatile impurities:	USP [1663 & 1664], Ed. (USP 47 NF 42)
6.		MEHP (Phthalate)	Inhouse methods: EBPT/SOP/AS/068
7.		Irganox1010 (Phenolic antioxidant)	EBPT/ELS/24/SP/010
8.		ii) Volatile impurities	USP [1663 & 1664], Ed. (USP 47 NF 42)
9.		1-Propanol	Inhouse methods: EBPT/SOP/AS/068
10.		Toluene d8	EBPT/ELS/24/SP/010
11.		iii) Semi volatile impurities	USP [1663 & 1664], Ed. (USP 47 NF 42) ; Inhouse methods:
12.		2 FBP (PAH)	EBPT/SOP/AS/068
13.		Dimethyl phthalate	EBPT/ELS/24/SP/010

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1 of 7

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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
Drugs and Pharmaceuticals			
14.	Polypropylene bags for injection (packing material for drug product or pharmaceutical packing/delivery system)	iv) Elemental Impurities	USP [1663 & 1664], Ed. (USP 47 NF 42) Inhouse methods: EBPT/SOP/AS/068 EBPT/ELS/24/SP/010
15.		Class – 1	
16.		Cadmium	
17.		Lead	
18.		Arsenic	
19.		Mercury	
20.		Class – 2A	
21.		Cobalt	
22.		Vanadium	
23.		Nickel	
24.		Class – 2B	
25.		Thallium	
26.		Gold	
27.		Palladium	
28.		Iridium	
29.		Osmium	
30.		Rhodium	
31.		Ruthenium	
32.		Selenium	
33.		Silver	
34.		Platinum	

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2 of 7

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Chemical Testing				
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method	
Drugs and Pharmaceuticals				
35.	Polypropylene bags for injection (packing material for drug product or pharmaceutical packing/delivery system)	Class – 3	USP [1663 & 1664], Ed. (USP 47 NF 42) Inhouse methods EBPT/SOP/AS/068 EBPT/ELS/24/SP/010	
36.		Lithium		
37.		Antimony		
38.		Barium		
39.		Molybdenum		
40.		Copper		
41.		Tin		
42.		Chromium		
43.		Qualitative assessment of Leachable impurities		USP [1663 & 1664], Ed. (USP 47 NF 42) Inhouse methods EBPT/SOP/AS/068 EBPT/ELS/24/SP/010
44.		Non-volatile impurities		
45.		MEHP (Phthalate)		
46.		Irganox1010 (Phenolic antioxidant)		
47.		Volatile impurities		
48.		1-Propanol		
49.	Toluene d8			
50.	Semi volatile impurities			
51.	2 FBP			
52.	Dimethyl phthalate			

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3 of 7

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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
Drugs and Pharmaceuticals			
53.	Polypropylene bags for injection (packing material for drug product or pharmaceutical packing/delivery system)	Elemental Impurities	USP [1663 & 1664], Ed. (USP 47 NF 42) Inhouse methods EBPT/SOP/AS/068 EBPT/ELS/24/SP/010
54.		Class – 1	
55.		Cadmium	
56.		Arsenic	
57.		Mercury	
58.		Class – 2A	
59.		Cobalt	
60.		Vanadium	
61.		Nickel	
62.		Class – 2B	
63.		Thallium	
64.		Gold	
65.		Palladium	
66.		Indium	
67.		Osmium	
68.		Rhodium	
69.		Ruthenium	
70.		Selenium	
71.		Silver	

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4 of 7

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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
Drugs and Pharmaceuticals			
72.	Polypropylene bags for injection (pharmaceutical packing/delivery system)	Class – 3	USP [1663 & 1664], Ed. (USP 47 NF 42) Inhouse methods EBPT/SOP/AS/068 EBPT/ELS/24/SP/010
73.		Lithium	
74.		Antimony	
75.		Barium	
76.		Molybdenum	
77.		Copper	
78.		Tin	
79.		Chromium	
80.		FRF Tip-100 (Medical device)	
81.	Non-volatile impurities		
82.	MEHP (Phthalate)		
83.	Irganox 1010 (Phenolic antioxidant)		
84.	Volatile impurities		
85.	1-Propanol		
86.	Toluene d8		
87.	Semi volatile impurities		
88.	2 FBP		
89.	Dimethyl phthalate		

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5 of 7

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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Drugs and Pharmaceuticals		
90.	FRF Tip-100 (Medical device)	Elemental Impurities	ISO 10993:18 & 12 In-house: EBPT/SOP/AS/068 EBPT/ELS/24/SP/009
91.		Class – 1	
92.		Cadmium	
93.		Lead	
94.		Arsenic	
95.		Mercury	
96.		Class – 2A	
97.		Cobalt	
98.		Vanadium	
99.		Nickel	
100.		Class – 2B	
101.		Thallium	
102.		Gold	
103.		Palladium	
104.		Iridium	
105.		Osmium	
106.		Rhodium	
107.		Ruthenium	
108.		Selenium	
109.		Silver	
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6 of 7

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Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Drugs and Pharmaceuticals		
111.	FRF Tip-100 (Medical device)	Class – 3	ISO 10993:18 &12 In-house: EBPT/SOP/AS/068 EBPT/ELS/24/SP/009
112.		Lithium	
113.		Antimony	
114.		Barium	
115.		Molybdenum	
116.		Copper	
117.		Tin	
118.		Chromium	
119.		Anions –	
120.		Chloride	
121.		Fluoride	
122.		Bromide	
123.		Nitrite	

