



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,
Aurangabad-431154, Maharashtra, India.

Call/ WhatsApp: +91-8767062101 Email: enquiry@sdp.org.in
website: www.sdp.org.in

CERTIFICATE OF ANALYSIS

Product Name	Argatroban	CAS No:	74863-84-6
Batch No:	2605001	Manufactured by	-
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Date of Retest	APR2031

Sr. No	Test	Acceptance Criteria	Results
1.	Description	White to off-white crystals or crystalline powder.	White crystalline powder
2.	Solubility	Freely soluble in glacial acetic acid. Slightly soluble in ethanol and insoluble in acetone, ethyl acetate and ether.	Freely soluble in glacial acetic acid. Slightly soluble in ethanol and insoluble in acetone, ethyl acetate and ether.
3.	Identification		
	By FTIR	The IR absorption spectrum of sample exhibits maxima only at the same wavelength as that of a similar preparation of the standard.	The IR absorption spectrum of sample exhibits maxima only at the same wavelength as that of a similar preparation of the standard.
	By HPLC	In the assay test, the retention time of the major peak obtained with the sample should correspond to that of the standard chromatogram	In the assay test, the retention time of the major peak obtained with the sample should correspond to that of the standard chromatogram
4.	Water determination by KF (With 0.5 g of Sample in Methanol)	Between 3.0% w/w and 6.0% w/w	3.5% w/w
5.	Residue on ignition (With 1.0 g of Sample)	Not more than 0.15% w/w	0.05%
6.	Organic impurities by HPLC		
	Related compound-A	Not more than 0.15% w/w	Not Detected



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	Related compound-B	Not more than 0.15% w/w	Not Detected
	Any unspecified impurity	Not more than 0.10% w/w	0.08% w/w
	Total impurities (Including Related compound-C)	Not more than 0.5% w/w	0.19% w/w
7.	Content of stereoisomers by HPLC		
	(R)-Argatroban	Not less than 63% and not more than 67%	65%
	(S)-Argatroban	Not less than 33% and not more than 37%	36%
8.	Assay by HPLC	Argatroban contains Not less than 98.0% and not more than 102.0% of Argatroban (C ₂₃ H ₃₆ N ₆ O ₅ S) calculated on the anhydrous and solvent-free basis.	100.4% of Argatroban(C ₂₃ H ₃₆ N ₆ O ₅ S) calculated on the anhydrous and solvent-free basis.
9.	Residual solvents by GCHS		
	Methanol	Not more than 3000 ppm	Not Detected
	Ethanol	Not more than 5000 ppm	Not Detected
	Dichloromethane	Not more than 600 ppm	Not Detected
	Acetone	Not more than 5000 ppm	Not Detected
	Ethyl acetate	Not more than 5000 ppm	Not Detected
	Tetrahydrofuran	Not more than 720 ppm	Not Detected
	Toluene	Not more than 890 ppm	Not Detected
10.	Additional test: Bacterial Endotoxin Test (Clot gel method)	Not more than 2.0 EU/mg	Less than 1.0 EU/mg



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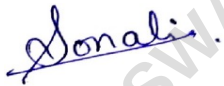
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11.	Additional test: Microbial Enumeration Tests		
	Total combined molds and yeast count	Not more than 10^2 cfu/gm	Less than 10 cfu/gm
	Total aerobic microbial count	Not more than 10cfu/gm	cfu/gm
12.	Test for specified microorganisms		
	Escherichia coli	Should be absent/g	Absent/g
	Salmonella species	Should be absent/g	Absent/g
	Pseudomonas aeruginosa	Should be absent/g	Absent/g
	Staphylococcus aureus	Should be absent/g	Absent/g

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
Sonali Nirmal 	Dadarao kakde 	Nayna Nehete 
Date: 23/05/2026	Date: 23/05/2026	Date: 23/05/2026

