



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	FAROPENEM SODIUM	CAS No:	122547-49-3.
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to yellowish colored crystalline powder with brownish tinge	yellowish colored crystalline powder
2	Solubility	Freely soluble in water and in methanol, Slightly soluble in ethanol (95), Practically in soluble in diethyl ether	Freely soluble in water and in methanol, slightly soluble in ethanol (95), Practically in soluble in diethyl ether
3	IDENTIFICATION - BY UV	The ultraviolet absorption spectrum of the sample solution exhibits maxima at the same wavelength as that of a similar solution of the Faropenem sodium working standard	The ultraviolet absorption spectrum of the sample solution exhibits maxima at the same wavelength as that of a similar solution of the Faropenem sodium working standard
4	IDENTIFICATION - By Chemical	A red brown to brown color must develop.	A red brown color develop.
5	IDENTIFICATION - By IR	The infrared absorption spectrum of the potassium bromide dispersion of the sample is concordant with that of a similar preparation of Faropenem Sodium working standard.	The infrared absorption spectrum of the potassium bromide dispersion of the sample is concordant with that of a similar preparation of Faropenem Sodium working standard.
6	WATER - By KF	12.6-13.1% w/w	12.90% w/w
7	SPECIFIC OPTICAL ROTATION	+145 to +150 (°) anhydrous basis	147°
8	HEAVY METALS	NMT 10 ppm	Less Than 10 ppm
9	ASSAY (By HPLC) (On anhydrous basis)	Not Less than 870 and not more than 943 µg/mg	Mean: 922 µg/mg
10	RELATED SUBSTANCES - (By HPLC) Epimer	NMT 0.3% w/w	0.15%
11	RELATED SUBSTANCES - (By HPLC) Total impurities	NMT 0.5% w/w	0.15%
12	RESIDUAL SOLVENTS (By GC) Method-I Methanol	NMT 3000 ppm	Not detected
13	RESIDUAL SOLVENTS (By GC) Method-I Acetone	NMT 5000 ppm	714 ppm

Sr No	Test	Acceptance Criteria	Results
14	RESIDUAL SOLVENTS (By GC) Method-I Dichloromethane	NMT 600 ppm	BQL (<70.207 ppm)
15	RESIDUAL SOLVENTS (By GC) Method-I Hexanes	NMT 290 ppm	Not detected
16	RESIDUAL SOLVENTS (By GC) Method-I Ethylacetate	NMT 5000 ppm	Not detected
17	RESIDUAL SOLVENTS (By GC) Method-I Tetrahydrofuran	NMT 720 ppm	Not detected
18	RESIDUAL SOLVENTS (By GC) Method-I Toluene	NMT 890 ppm	BQL (<12.613 ppm)
19	PARTICLE SIZE - (By Sieve analysis) Particles retained on BSS	30 mesh NMT 10	30 mesh - 0
20	PARTICLE SIZE - (By Sieve analysis) Particles retained on BSS	100 mesh NLT 60	100 mesh - 77

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

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