

**AKUMS HEALTHCARE LTD**Plot#-B-6,7,8 & 9 Sigaddi Growth Centre,SIDCUL
Kotdwar-246149,Uttarakhand,India**QUALITY CONTROL****CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name :	FAROSMART-200 TAB ALU 10X1X6		
Generic Name :	Faropenem Sodium Tablets JP 200 mg		
Mfg. Lic. No. :	13/UA/SC/P-2021	Market:	DOMESTIC
Batch No. :	JDUAA02	A. R. No.:	F20240831002
Mfg. Date :	08/2024	Pack Size:	1X6 Tablet
Expiry date:	07/2026	Pack Type:	Alu-Alu
Batch Size :	48000 Tablets	Sampled On:	31/08/24
Product Code :	40066498	Sample Quantity:	42 Tablets
Specification No,Ver No.:	STS/FP/40066498-00	Sampled By:	ANAND KUMAR MEHTO
Ref. STP No. , Ver No.:	STP/FP/0001-07	Analyzed By:	PRIYANSHU SINGH
Manufactured For :	HEALING PHARMA INDIA PVT.LTD.	Date of Analysis:	31/08/24
Manufactured By :	AKUMS HEALTHCARE LTD. PLANT-I, KOTDWAR	Analysis Completion Date:	07/09/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Brown coloured, elongated, biconvex, plain on both sides & film coated tablets. 6 tablets packed in a blister of printed Alu-Alu foil & plain Alu-Alu foil.	Brown coloured, elongated, biconvex, plain on both sides & film coated tablets. 6 tablets packed in a blister of printed Alu-Alu foil & plain Alu-Alu foil.
2	Identification (By UV)	Sample solution exhibits maxima between 254nm and 258nm and between 304nm and 308nm.	Sample solution exhibits maxima at 254.60nm and at 306.80nm.
3	Dimension	As below	As below
3.a	Length	17.7mm $\pm$ 0.2 mm	17.78 mm

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Name	SANJEEV KUMAR	BIKRAM SINGH RAWAT	VIDYUT VIMAL
Designation	ASST.EXECUTIVE	SR. EXECUTIVE	A.G.M.

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3.b	Width	7.6 mm $\pm$ 0.2 mm	7.68 mm
3.c	Thickness	6.0 mm $\pm$ 0.4 mm	6.06 mm
4	Average weight	775 mg $\pm$ 5.0 %	768.10 mg
5	Uniformity of weight	Within $\pm$ 5.0 % of average weight	+ve = +2.59% -ve = -1.33%
6	Disintegration Time	Not more than 30 Minutes	03 Minutes 45 Seconds
7	Water content (by KF)	For record purpose only	6.16%

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8	Dissolution	Not less than 85% of the stated amount of Faropenem is dissolved in 30 minutes.	1=93.78%, 2=94.78%, 3=93.58%, 4=96.17%, 5=96.76%, 6=93.98%, Min.93.58%, Max.96.76%, Mean 94.84%

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9	Uniformity of dosage units (By weight variation)	The acceptance value of the first 10 dosage units shall be less than or equal to L1%. If the acceptance value is greater then L1%, test the next 20 units, and calculate the acceptance value. The requirements shall met if the final acceptance value of the 30 dosage units less than or equal to L1%, and no individual content of any dosage unit shall be less than $[1 - (0.01)(L2)] M$ nor more than $[1 + (0.01)(L2)] M$ Where, L1 is 15.0 and	L1 = 2.63
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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
		L2 is 25.0.	
10	Related Substances	As below	As below
10.a	Faropenem derivative (RRT about 0.71)	Not more than 1.5%	Not detected
10.b	Total Impurities other than Faropenem	Not more than 2.5%	0.36 %
11	Microbial Testing	As below	As below
11.a	Total aerobic microbial count	Not more than 1000 cfu/g	Less than 10 cfu/g
11. b	Total Combined Yeasts & Molds Count	Not more than 100 cfu/g	Less than 10 cfu/g

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11.c	Test for specified Microorganisms	As below		As below
11.c. 1	Escherichia coli	Should be absent/g.		Absent/g.
12	Assay	Shelf Life Limit	Release Limit	

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12.a	Faropenem Sodium Hydrate JP Equivalent to Faropenem - 200 mg/Tab	NLT 188.00mg/Tab to NMT 212.00mg/Tab (NLT 94.00% to NMT106.00% of label claimed)	NLT 194.00mg/Tab to NMT 212.00mg/Tab (NLT 97.00% to NMT106.00% of label claimed)	201.73mg 100.87%

CONCLUSION : The Finished Product complies as per JP Specifications.

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