

**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. :	JDUA01	A. R. No.:	F20240321002
Mfg. Date :	03/2024	Pack Size:	1X6 TAB
Expiry date:	02/2026	Pack Type:	Alu-Alu
Batch Size :	50000 Tablets	Sampled On:	21/03/24
Product Code :	40066498	Sample Quantity:	42 Tablets
Specification No,Ver No.:	STS/FP/40066498-00	Sampled By:	Hirdesh Kumar
Ref. STP No. , Ver No.:	STP/FP/0001-06	Analyzed By:	VIPUL KUMAR
Manufactured For :	HEALING PHARMA INDIA PVT.LTD.	Date of Analysis:	21/03/24
Manufactured By :	AKUMS HEALTHCARE LTD. PLANT-I, KOTDWAR	Analysis Completion Date:	28/03/24

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 between 256.20nm and between 306.80nm
3	Dimension	As below	As below
3.a	Length	17.7mm $\pm$ 0.2 mm	17.64 mm
3.b	Width	7.6 mm $\pm$ 0.2 mm	7.55 mm

	Prepared By QC	Reviewed By QC	Approved By QC
Date	28/03/24	28/03/24	28/03/24
Name	VIPUL KUMAR	JITENDRA KUMAR	VIDYUT VIMAL
Designation	ASST.EXECUTIVE	EXECUTIVE	A.G.M.

This is an electronically signed document, hence does not require any signatures

QA REVIEWED

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
3.c	Thickness	6.0 mm $\pm$ 0.4 mm	5.92 mm
4	Average weight	775 mg $\pm$ 5.0 %	772.00 mg
5	Uniformity of weight	Within $\pm$ 5.0 % of average weight	+ve= +1.95% -ve= -2.10%
6	Disintegration Time	Not more than 30 Minutes	4 Minute 56 second
7	Water content (by KF)	For record purpose only	7.34%
8	Dissolution	Not less than 85% of the stated amount of Faropenem is dissolved in 30 minutes.	1=95.24%, 2=95.64%, 3=91.27%, 4=100.99%, 5=97.02%, 6=97.02%, Min.91.27%, Max.100.99%, Mean 96.20%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
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 L2 is 25.0.	L1= 1.11

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
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%	0.43%
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)	202.46mg 101.23%

CONCLUSION : The Finished Product complies as per JP Specifications.

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