

**MALIK LIFESCIENCES PVT. LTD.**Plot No.-16, Vardhman Industrial Estate, N.H. 58, Haridwar-247667
(Uttarakhand)**QUALITY CONTROL****CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name :	AMOXYHEAL-CV 375 TABLETS		
Generic Name :	Amoxycillin and Potassium Clavulanate Tablets IP 375 mg		
Mfg. Lic. No. :	48/UA/SC/P-2013	Market:	DOMESTIC
Batch No. :	MA2AF12	A. R. No.:	F20240317016
Mfg. Date :	Mar. 2024	Pack Size:	1 x 10 Tablets
Expiry date:	Feb. 2026	Pack Type:	Strip
Batch Size :	100000 Tablets	Sampled On:	17/03/24
Product Code :	40047777	Sample Quantity:	10 Tablets
Specification No, Ver No.:	STS/FP/40047777-00	Sampled By:	SUMIT KUMAR
Ref. STP No. , Ver No.:	STP/FP/0002-02	Analyzed By:	Deepak Kumar Deshwal
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	19/03/24
Manufactured By :	Malik Lifesciences Pvt. Ltd.	Analysis Completion Date:	20/03/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	White to off white coloured, capsule shaped, biconvex, plain on both side & film coated tablets. 10 tablets packed in a strip of printed aluminium foil & base aluminium foil.	Off white coloured, capsule shaped, biconvex, plain on both side & film coated tablets. 10 tablets packed in a strip of printed aluminium foil & base aluminium foil.
2	Identification	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution. (One peak due to Amoxycillin & other due to Potassium Clavulanate).	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution. (One peak due to Amoxycillin & other due to Potassium Clavulanate).

	Prepared By QC	Reviewed By QC	Approved By QC
Date	20/03/24	20/03/24	20/03/24
Name	Sandeep Rawat	Jai Prakash Singh	Sudhir Sharma
Designation	ASST.EXECUTIVE	MANAGER	SR. MANAGER

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QA REVIEWED

Name : Shivam Chauhan ; Date : 20/03/2024

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
3	Dimension	As below	As below
3.a	Length	19.0 mm $\pm$ 0.2 mm	19.01 mm
3.b	Width	8.9 mm $\pm$ 0.2 mm	8.98 mm
3.c	Thickness	6.0 mm $\pm$ 0.4 mm	6.26 mm
4	Average weight	837.0 mg $\pm$ 5.0 %	817.51 mg
5	Uniformity of weight	Within $\pm$ 5.0 % of average weight.	-1.8% to +2.6%
6	Disintegration Time	Not more than 30 minutes	Passes (05 Minutes 36 Seconds)
7	Water	Not more than 7.5% w/w	3.43 %w/w
8	Dissolution(By HPLC)	As below	As below

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
8.a	For Amoxycillin	S1- Each tablet is not less than 90% of the labeled amount dissolved in 30 minutes. If the results do not conform to the requirements at the stage S1, continue testing with additional tablets through stages S2 and S3 unless the result conforms at stage S2. S2- Average of 12 tablets (S1+S2) is equal to or greater than 85%, and no tablet is less than 70%. S3- Average of 24 tablets (S1+S2+S3) is equal to or greater than 85%, not more than 2 tablets are less than 70%, and no tablet is less than 60%.	1=98.91%, 2=100.15%, 3=101.75%, 4=101.70%, 5=102.47%, 6=102.26%, Min.98.91%, Max.102.47%, Mean 101.21%

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S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
8.b	For Clavulanic Acid	S1- Each tablet is not less than 85% of the labeled amount dissolved in 30 minutes. If the results do not conform to the requirements at the stage S1, continue testing with additional tablets through stages S2 and S3 unless the result conforms at stage S2. S2- Average of 12 tablets (S1+S2) is equal to or greater than 80%, and no tablet is less than 65%. S3- Average of 24 tablets (S1+S2+S3) is equal to or greater than 80%, not more than 2 tablets are less than 65%, and no tablet is less than 55%.	1=110.46%, 2=109.72%, 3=109.78%, 4=109.14%, 5=108.10%, 6=107.21%, Min.107.21%, Max.110.46%, Mean 109.07%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
9	Uniformity Content of Clavulanic Acid	85% to 115% of Average value		1=100.40%, 2=100.50%, 3=99.64%, 4=100.85%, 5=100.50%, 6=100.45%, 7=100.50%, 8=100.55%, 9=100.20%, 10=100.32%, Min.99.25%, Max.100.46%, Mean 100.39%
10	Assay - Each film coated tablet contains:	Shelf Life Limit	Release Limit	

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
10.a	Amoxycillin Trihydrate IP eq. to Amoxycillin - 250 mg/Tab	NLT 225.00mg/Tab to NMT 300.00mg/Tab (NLT 90.00% to NMT120.00% of label claimed)	NLT 237.50mg/Tab to NMT 300.00mg/Tab (NLT 95.00% to NMT120.00% of label claimed)	250.76mg 100.30%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
10.b	Potassium Clavulanate Diluted IP eq. to Clavulanic Acid - 125 mg/Tab	NLT 112.50mg/Tab to NMT 150.00mg/Tab (NLT 90.00% to NMT120.00% of label claimed)	NLT 118.75mg/Tab to NMT 150.00mg/Tab (NLT 95.00% to NMT120.00% of label claimed)	124.78mg 99.82%

CONCLUSION : The Finished Product complies as per IP/IH Specifications.

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