

A/C OF HEALING PHARMA INDIA PVT LTD

QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: COLCHIHEAL 0.5	A.R. No.	: F/1220/2425
Packing	: 10x10 TAB	Rel. Dt.	: 02-09-2024
Generic Name	: COLCHICINE TABLETS IP 0.5 MG	T.R. Slip No.	: CHPAP24137
Product Code	: TC-151HEAL	T.R. Slip Dt.	: 31-08-2024
Batch No.	: TC-1510011	Analysis Date	: 31-08-2024
Actual Batch Size	: 202000 TAB	Specification No.:	CRFS/TC-151HEAL/2425
		Specification Dt.	: 31-08-2024
Sample Size	: 50.000 TAB	STP No.	: STP/TC-151HEAL/AS PER IP
Released Qty	: 202000.000 TAB (2020 CAR)	Location	: GORWA01
Remarks	: PASS	Make	: HEALING
	Mfg. Dt. : 16/07/2024		
	Exp. Dt. : 30/06/2027		
	Test Packing: 10X10 TAB		
	Mfg. Lic No. : G/25A/5141-A		
	Test As Per : IP		

Sr.	Test	Result	Specification
1	DESCRIPTION	A white coloured , Round shaped ,Biconvex, Uncoated Tablet, plain on Both Sides.	A white coloured , Round shaped ,Biconvex, Uncoated Tablet, plain on Both Sides.
2	IDENTIFICATION	Complies	Must Complies as per IP
1	IDENTIFICATION A	At 246 nm : 0.3846 At 352 nm : 0.0013	When examined the solution in the range 220 nm to 400 nm shows absorption maxima at about 246 nm and 352 nm.
2	IDENTIFICATION B	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the Assay, the principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution.
3	AVERAGE WEIGHT OF TABLETS	76.64 mg	75.01 mg $\pm$ 10.00 % of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.: + 4.77 % L.L.: - 4.10 %	Within $\pm$ 10.00 % of avg. weight
5	THICKNESS	2.84 mm	2.90 mm $\pm$ 0.2 mm
6	DIAMETER	5.47 mm	5.50 mm $\pm$ 0.2 mm
7	HARDNESS	4.54 kg/cm ²	NLT 3.0 kg/cm ²
8	DISINTEGRATION TIME	05 Minutes 38 Seconds in Water Medium at 37 °C	NMT 15 Minutes in Water Medium at 37 °C
9	FRIABILITY	0.11 %	NMT 1.00 %
10	DISSOLUTION	93.90 %	NLT 75.00 % (Q)
11	UNIFORMITY OF CONTENT	MAX= 113.77 % MIN= 97.89 % AVG= 105.97 %	85.00 % TO 115.00 %
12	RELATED SUBSTANCES	Complies	Must complies as per IP
13	ASSAY		

Conclusion : The above sample complies as per IP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
 NIKITA B PRAJAPATI QC OFFICER	 MAYUR BHOYA EXECUTIVE	 ASMITA QUALITY HEAD

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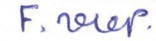
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	Test Packing : 10X10 TAB		
	Mfg. Lic No. : G/25A/5141-A		
	Test As Per : IP		

Sr.	Test	Result	Specification
		98.23 %	Each uncoated tablet contains: Colchicine IP0.5 mg [Limit: 95.00 % to 105.00 %]

Conclusion : The above sample complies as per IP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

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