

A/C OF HEALING PHARMA INDIA PVT LTD
QUALITY CONTROL DEPARTMENT
THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : COLCHIHEAL 0.5	A.R. No. : F/0334/2425
Packing : 10x10 TAB	Rel. Dt. : 10-05-2024
Generic Name : COLCHICINE TABLETS IP 0.5 MG	T.R. Slip No. : CHPAP24041
Product Code : TC-151HEAL	T.R. Slip Dt. : 10-05-2024
Batch No. : TC-1510010	Analysis Date : 10-05-2024
Actual Batch Size : 202000 TAB	Specification No. : CRFS/TC-151HEAL/23
Mfg. Dt. : MAR-2024	Specification Dt. : 14-06-2023
Exp. Dt. : FEB-2027	STP No. : STP/TC-151HEAL/AS PER IP
Test Packing : 10X10 TABS	Location : GORWA01
Mfg. Lic No. : G/25A/5141-A	Make : HEALING
Sample Size : 50.000 TAB	
Released Qty : 202000.000 TAB (2020 CAR)	
Test As Per : IP	
Remarks : pass	

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 BY IR	IR spectrume obtain from the test solution is concurrent with the working standard spectrum.	IR spectrume obtain from the test solution should concurrent with the working standard spectrum.
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	76.43 mg	75.01 mg $\pm$ 10.00 % of avg. weight
4	UNIFORMITY OF WEIGHT	H.L.: + 2.45 % L.L.: - 1.74 %	Within $\pm$ 10.00 % of avg. weight
5	THICKNESS	2.91 mm	2.90 mm $\pm$ 0.2 mm
6	DIAMETER	5.52 mm	5.50 mm $\pm$ 0.2 mm
7	DISINTEGRATION TIME	02 Minutes 52 Seconds in Water Medium at 37 °C	NMT 15 Minutes in Water Medium at 37 °C
8	HARDNESS	5.1 kg/cm2	NLT 3.0 kg/cm2
9	FRIABILITY	0.55 %	NMT 1.00 %
10	DISSOLUTION	94.95 %	NLT 75.00 % (Q)
11	RELATED SUBSTANCES	Complies	Must complies as per IP
12	UNIFORMITY OF CONTENT	MAX=100.24 % MIN=105.00 % AVG= 103.12 %	85.00 % TO 115.00 %
13	ASSAY		Each uncoated tablet contains:

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

f *RPB*

YASHPAL JAMADAR
TRAINEE OFFICER

Checked By

MANISHA
MANISHA
EXECUTIVE

Approved By

ASMITA
ASMITA
QUALITY HEAD

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Actual Batch Size : 202000 TAB

Mfg. Dt. : MAR-2024
Exp. Dt. : FEB-2027
Test Packing : 10X10 TABS

Mfg. Lic No. : G/25A/5141-A

Sample Size : 50.000 TAB
Released Qty : 202000.000 TAB (2020 CAR)

Test As Per : IP

Remarks : pass

A.R. No. : F/0334/2425

Rel. Dt. : 10-05-2024

T.R. Slip No. : CHPAP24041

T.R. Slip Dt. : 10-05-2024

Analysis Date : 10-05-2024

Specification No. : CRFS/TC-151HEAL/23

Specification Dt : 14-06-2023

STP No. : STP/TC-151HEAL/AS
PER IP

Location : GORWA01

Make : HEALING

Sr.	Test	Result	Specification
		104.37 %	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"

Prepared By

Checked By

Approved By


YASHPAL JAMADAR
TRAINEE OFFICER


MANISHA
EXECUTIVE


ASMITA
QUALITY HEAD

SURBHI 25-05-24 10:40 AM

FGANLCERTQA