

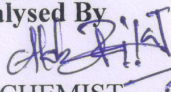
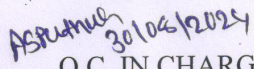
A/C OF HEALING PHARMA INDIA PVT LTD
QUALITY CONTROL DEPARTMENT

DRUG AND COSMETICS ACT 1940. THE RULES THERE UNDER FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : Azacan 50 mg Tablets		A.R. No. : FP/T/24/322	
Packing : 10 Tablets			
Generic Name : Azathioprine Tablets I.P. 50 mg		Rel. Dt. : 30/08/2024	
Batch No. : T2408322	Mfg. Dt: 08/2024	T.R. Slip No. : F322	
Actual Batch Size: 100000 Tablets	Exp. Dt.: 07/2026	T.R. Slip Dt. : 29/08/2024	
Packing Batch Size: 100000 Tablets	Mfg. Lic No. : G/25A/5312-A	Analysis Date : 29/08/2024	
Sample Size : 60 Tablets	Test As Per : IP	Remarks : Pass	
Released Qty : 99700 Tablets			

Sr. no.	Test	Result	Specification
1.	Description	Light yellow coloured, round shaped, biconvex uncoated tablets, having break line on one side.	Light yellow coloured, round shaped, biconvex uncoated tablets, having break line on one side.
2.	Identification	A. Complies B. Complies	A. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. B. A pale pink precipitate is produced.
3.	Weight of 20 tablets	3.7152 gm	4.0000 gm $\pm$ 7.5% (3.7000 gm to 4.3000 gm)
4.	Average Wt. of tablet	0.1857 gm	0.2000 gm $\pm$ 7.5% (0.1850 gm to 0.2150 gm)
5.	Uniformity of weights	+0.81% & -1.22%	$\pm$ 7.5% of the Av. Weight
6.	Disintegration Time (in water at 37°C)	04 min 20 sec	NMT 15 minutes
7.	Hardness	3.0 kg/cm ²	NLT 2.0 Kg/cm ²
8.	Diameter	8.00 mm	7.80 mm to 8.20 mm
9.	Thickness	3.64 mm	3.30 mm to 3.70 mm
10.	Dissolution	81.54%	NLT 75.0 %
11.	5-Chloro-l-methyl-4-nitroimidazole and 6-mercaptopurine	Complies	Complies as per I.P.
12.	Assay	98.13%	Each uncoated tablet contains: Azathioprine I.P.....50 mg (Limit: 92.5% to 107.5%)

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 there under for the result given above.

Analysed By  Q.C. CHEMIST 30/08/2024	Approved By  Q.C. IN CHARGE
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Format no. : QC/010/F03-01

Effective date: 17/10/2020