

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/24/120
Packing : 10 Tablets	
Generic Name : Azathioprine Tablets I.P. 50 mg	Rel. Dt. : 15/04/2024
Batch No. : T2404120	Mfg. Dt: 04/2024
Actual Batch Size: 100000 Tablets	Exp. Dt.: 03/2026
Packing Batch Size: 100000 Tablets	Mfg. Lic No. : G/25A/5312-A
	T.R. Slip No. : F120
	T.R. Slip Dt. : 13/04/2024
	Analysis Date : 15/04/2024
Sample Size : 60 Tablets	Test As Per : IP
Released Qty : 100000 Tablets	Remarks : Pass

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	3.7096 gm	4.0000 gm $\pm$ 7.5% (3.7000 gm to 4.3000 gm)
4.	Average Wt. of tablet	0.1855 gm	0.2000 gm $\pm$ 7.5% (0.1850 gm to 0.2150 gm)
5.	Uniformity of weights	+0.65% & -1.67%	$\pm$ 7.5% of the Av. Weight
6.	Disintegration Time (in water at 37°C)	5 min 20 sec	NMT 15 minutes
7.	Hardness	3.0 kg/cm ²	NLT 2.0 Kg/cm ²
8.	Diameter	8.01 mm	7.80 mm to 8.20 mm
9.	Thickness	3.62 mm	3.30 mm to 3.70 mm
10.	Dissolution	80.23%	NLT 75.0 %
11.	5-Chloro-1-methyl-4-nitroimidazole and 6-mercaptopurine	Complies	Complies as per I.P.
12.	Assay	97.45%	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.

<i>Paul</i> 15/04/2024 Analysed By Q.C. CHEMIST	<i>Paul</i> 15/04/2024 Approved By Q.C. IN CHARGE
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