

CERTIFICATE No.: FP240029

Quality Control Department.

ACME LIFE TECH-LLP

Plot No.103,104,105-EPIP Phase-1,Jharmajri Baddi
Tehsil Nalagarh,Dist.Solan.(H.P)

CERTIFICATE OF ANALYSIS

PRODUCT NAME : ATARISE-25 TABLET

GENERIC NAME: HYDROXYZINE TABLETS IP 25 mg

BATCH No. : ALT230821

BATCH SIZE : 15.00 LACS

MFG. DATE : DEC.2023

EXP DATE : NOV.2026

DATE OF SAMPLING : 28/12/2023

SAMPLE QTY : 140 TABLETS

DATE OF ANALYSIS : 28/12/2023

DATE OF RELEASE : 05/01/2024

REFERENCE SPECIFICATION No.: IP

SR.No.	TEST	RESULT	SPECIFICATION
	Description	White coloured capsule shaped biconvex film coated tablets plain on one side & break line on the other side. Packed in blister packing.	White to off white coloured capsule shaped biconvex film coated tablets plain on one side & break line on the other side. Packed in blister packing.
2	Identification	Complies	The retention time of major peaks in the chromatogram of the sample preparation corresponds to that of the major peaks in the chromatogram of the standard preparation as obtained in the assay.
3	Average weight	0.1221 gm	0.1240 gm $\pm$ 3% (0.1200gm to 0.1280gm)
4	Uniformity of weight	0.1189 gm to 0.1248 gm	$\pm$ 7.5% of Avg. weight.
5	Uniformity of Length	10.34 mm to 10.37 mm	Bet. 10.00 mm & 10.60 mm
6	Uniformity of thickness	2.62 mm to 2.67 mm	Bet. 2.60 mm & 3.20 mm
7	Uniformity of Width	4.24 mm to 4.26 mm	Bet. 4.00 mm & 4.60 mm
8	Disintegration time	5 Minutes. 20 Seconds.	NMT 30 Minutes.
9	Dissolution	Min.: 96.54% . Max.: 99.98%	NLT 80 %
10	Related Substances	Ind. impurity : Not Detected Total. impurity : Not Detected	Ind. impurity : NMT 0.2% Total. impurity : NMT 0.5%
11	Assay : Each film coated tablet contains: Hydroxyzine Hydrochloride IP -----25 mg	25.102 mg /tab i.e. 100.41%	95.0% to 105.0%

Remarks : In the opinion of the undersigned the sample referred above complies / ~~Does not complies~~ as per finished product specification.

Analyzed By

05/01/2024

Checked By

05/01/2024

Approved By

05/01/2024

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