

CERTIFICATE No.: FP241058	ACME LIFE TECH-LLP Plot No.103,104,105-EPIP Phase-1,Jharmajri Baddi Tehsil Nalagarh,Dist.Solan.(H.P)
Quality Control Department.	

CERTIFICATE OF ANALYSIS

PRODUCT NAME : ATARISE-10 TABLET

GENERIC NAME: HYDROXYZINE TABLETS IP 10mg

BATCH No. : ALT240270	BATCH SIZE : 7.50 LACS
MFG. DATE : MAY 2024	EXP DATE : APR.2027
DATE OF SAMPLING : 10/05/2024	SAMPLE QTY : 140 TABLETS
DATE OF ANALYSIS : 10/05/2024	DATE OF RELEASE : 15/05/2024

REFERENCE SPECIFICATION No.: FP/PQ/003-01

SR.No.	TEST		RESULT	SPECIFICATION
1	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	Test (A) By HPLC	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.
		Test (B) By TLC	Complies	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a). The test is not valid unless the chromatogram obtained with reference solution (b) shows two clearly separated spots.
3	Average weight		0.1222 gm	0.1240 gm $\pm$ 3% (0.1200gm to 0.1280gm)
4	Uniformity of weight		0.1135 gm to 0.1269 gm	$\pm$ 7.5% of Avg. weight.
5	Uniformity of Length		10.19 mm to 10.27 mm	Bet. 10.00 mm & 10.60 mm
6	Uniformity of thickness		2.61 mm to 2.66 mm	Bet. 2.60 mm & 3.20 mm
7	Uniformity of Width		4.21 mm to 4.30 mm	Bet. 4.00 mm & 4.60 mm
8	Uniformity of Content		Min: 96.22% , Max : 104.60%	NLT 85.0% & NMT 115.0% of labeled amount.
9	Disintegration time		3 Minutes. 41 Seconds.	NMT 30 Minutes.
10	Dissolution		Min: 94.44% , Max : 98.89%	NLT 80 %
11	Related Substances		Ind. impurity : 0.069% Total. impurity : 0.111%	Ind. impurity : NMT 0.2% Total. impurity : NMT 0.5%
12	Assay : Each film coated tablet contains: Hydroxyzine Hydrochloride IP ----10 mg		9.798mg /tab i.e. 97.98%	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

[Signature]
15/05/2024

Checked By

[Signature]
15/05/2024

Approved By

[Signature]
15/05/2024

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