

CERTIFICATE No.: FP241658	ACME LIFE TECH-LLP
Quality Control Department.	Plot No.103,104,105-EPIP Phase-I,Jharmajri Baddi Tehsil Nalagarh,Dist.Solan.(H.P)

CERTIFICATE OF ANALYSIS

PRODUCT NAME : ATARISE-10 TABLET			
GENERIC NAME: HYDROXYZINE TABLETS IP 10mg			
BATCH No.	: ALT240497	BATCH SIZE	: 7.50 LACS
MFG. DATE	: JUL.2024	EXP DATE	: JUN.2027
DATE OF SAMPLING	: 30/07/2024	SAMPLE QTY	: 140 TABLETS
DATE OF ANALYSIS	: 30/07/2024	DATE OF RELEASE	: 02/08/2024
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		0.1221 gm	0.1240 gm $\pm$ 3% (0.1200gm to 0.1280gm)
4	Uniformity of weight		0.1201 gm to 0.1255 gm	$\pm$ 7.5% of Avg. weight.
5	Uniformity of Length		10.23 mm to 10.31 mm	Bet. 10.00 mm & 10.60 mm
6	Uniformity of thickness		2.48 mm to 2.59 mm	Bet. 2.60 mm & 3.20 mm
7	Uniformity of Width		4.20 mm to 4.27 mm	Bet. 4.00 mm & 4.60 mm
8	Uniformity of Content		Min: 98.38% , Max : 102.68%	NLT 85.0% & NMT 115.0% of labeled amount.
9	Disintegration time		5 Minutes. 46 Seconds.	NMT 30 Minutes.
10	Dissolution		Min: 95.80% , Max : 100.22%	NLT 80 %
11	Related Substances		Ind. impurity : 0.1008% Total. impurity : 0.115%	Ind. impurity : NMT 0.2% Total. impurity : NMT 0.5%
12	Assay : Each film coated tablet contains: Hydroxyzine Hydrochloride IP ----10 mg		10.170 mg /tab i.e. 101.70%	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

30/08/2024

Checked By

02/08/2024

Approved By

02/08/2024

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