

CERTIFICATE No.: FP242163	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. : ALT240597		BATCH SIZE : 7.50 LACS		
MFG. DATE : SEP.2024		EXP DATE : AUG.2027		
DATE OF SAMPLING : 24/09/2024		SAMPLE QTY : 140 TABLETS		
DATE OF ANALYSIS : 24/09/2024		DATE OF RELEASE : 04/10/2024		
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		0.1232 gm	0.1240 gm $\pm$ 3% (0.1200gm to 0.1280gm)
4	Uniformity of weight		0.1195 gm to 0.1255 gm	$\pm$ 7.5% of Avg. weight.
5	Uniformity of Length		10.16 mm to 10.19 mm	Bet. 10.00 mm & 10.60 mm
6	Uniformity of thickness		2.64 mm to 2.66 mm	Bet. 2.60 mm & 3.20 mm
7	Uniformity of Width		4.12mm to 4.14 mm	Bet. 4.00 mm & 4.60 mm
8	Uniformity of Content		Min: 97.05% , Max : 102.29%	NLT 85.0% & NMT 115.0% of labeled amount.
9	Disintegration time		3 Minutes. 30 Seconds.	NMT 30 Minutes.
10	Dissolution		Min: 96.03% , Max : 98.39%	NLT 80 %
11	Related Substances		0.027%	Ind. impurity : NMT 0.2%
			0.141%	Total. impurity : NMT 0.5%
12	Assay : Each film coated tablet contains: Hydroxyzine Hydrochloride IP ----10 mg		10.285 mg /tab i.e. 102.85%	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 04/10/2024

Checked By 04/10/2024

Approved By 04/10/2024

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