

CERTIFICATE No.: FP242679	ACME LIFE TECH-LLP Plot No.103,104,105-EPID 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. : ALT240799			BATCH SIZE : 9.00 LACS	
MFG. DATE : NOV.2024			EXP DATE : OCT.2027	
DATE OF SAMPLING : 30/11/2024			SAMPLE QTY : 140 TABLETS	
DATE OF ANALYSIS : 30/11/2024			DATE OF RELEASE : 06/12/2024	
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		0.1263 gm	0.1240 gm ± 3% (0.1200gm to 0.1280gm)
4	Uniformity of weight		0.1209 gm to 0.1239 gm	± 7.5% of Avg. weight.
5	Uniformity of Length		10.31 mm to 10.36 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		4.22mm to 4.31 mm	Bet. 4.00 mm & 4.60 mm
8	Uniformity of Content		Min: 98.23% , Max : 102.17%	NLT 85.0% & NMT 115.0% of labeled amount.
9	Disintegration time		4 Minutes. 05 Seconds.	NMT 30 Minutes.
10	Dissolution		Min: 95.33% , Max : 104.25%	NLT 80 %
11	Related Substances		Not detected	Ind. impurity : NMT 0.2%
			Not detected	Total. impurity : NMT 0.5%
12	Assay : Each film coated tablet contains: Hydroxyzine Hydrochloride IP ----10 mg		10.135mg /tab i.e. 101.35%	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.

Vijay
Analyzed By

Anand Parkash
Checked By

Shashi Kumar
Approved By

Format No: SOP/QC/017/F05-00