

ZEE LABORATORIES
47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. : 242523064

Document No. : 242534539

Ref. STS No.	APNT-151	Product Code	FG04863
Product Name	TAB. BETATINE-16		
Generic Name	BETAHISTINE HYDROCHLORIDE TABETS I.P		
Batch No.	425-472	Date Of Sampling	25/03/2025
Batch Size	200000.000 Tab	Sample Quantity	100.000 Tab
Mfg. Date	03/2025	Exp. Date	02/2028
A. R. No.	ZL25FG01591	Date Of Release	29/03/2025

S NO.	Tests	Specification	Results
1	Description	A white colour, rounded, biconvex and uncoated tablet.	Complies
2	Identification	Positive for Betahistine Hydrochloride	Complies
3	Av. Weight	120 mg \pm 7.5%	118.53 mg
4	Disintegration Time	NMT 15 Min	3 min
5	Friability	NMT 1.0% w/w	0.48%
6	Uniformity of weight	With in Limits	Complies
7	Uniformity of content	With in Limits	Complies
8	Dissolution Test	NLT D + 80.0%	88.52 %
9	Assay: Each uncoated tablet contains: Betahistine hydrochloride I.P. 16 mg	NLT 95.0% and NMT 105.0% of labeled amount	99.63 %

Remarks The above sample complies/does not comply with prescribed standards of **IP/BP/USP/In house specification.** Quality with respect to above tests as per

Particulars	Prepared / Analysed by	Reviewed By	Approved / Authorized By
Signature:	(N)	(S)	
Name:	Neeraj Maurya	Sunit Patel	
Designation:	QC Executive	Asst. QCM	
Date	29/03/2025	29/03/2025	