



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Noristop-TZ	A.R. No.	FG/G/24A0993
Generic Name	Norfloxacin and Tinidazole Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT406122	Sample Received on	08/07/2024
Batch Size:	2.90 Lac	Analysis Date	08/07/2024
Mfg. Date.	06/2024	Release Date	21/07/2024
Exp. Date	05/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, elongated, biconvex, scored mark on one side and other side plain, film coated tablet.	Yellow colour, elongated, biconvex, scored mark on one side and other side plain, film coated tablet.		
2.	Identification	In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	1224.0 mg $\pm$ 3%	1236.60 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 1228.2 mg ; Max: 1245.7 mg -0.68% ; +0.74%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 42 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	10.25 Kg/cm ²		
7.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Norfloxacin IP	200 mg	Between 90.00 % to 110.00 % of stated amount (Between 180.00 mg to 220.0 mg)	208.03 mg	104.01%
	Tinidazole IP	300 mg	Between 90.00 % to 110.00 % of stated amount (Between 270.0 mg to 330.0 mg)	300.08 mg	100.03%
8.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	21/07/2024	21/07/2024	21/07/2024