



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Chymofox Forte	A.R. No.	FG/G/24A1485
Generic Name	Trypsin - Chymotrypsin Tablets	Sample Quantity	120 Tablets
Batch No.:	AGT41086	Sample Received on	28/10/2024
Batch Size:	4.0 Lac	Analysis Date	28/10/2024
Mfg. Date.	10/2024	Release Date	06/11/2024
Exp. Date	09/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Red colour, round shaped, biconvex having both side plain, enteric coated tablet.	Red colour, round shaped, biconvex having both side plain, enteric coated tablet.
2.	Identification	Should be positive for Trypsin-Chymotrypsin.	Positive for Trypsin-Chymotrypsin.
3.	Average weight	150.00 mg $\pm$ 3.0%.	151.01 mg
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 146.84 mg ; Max: 154.04 mg -2.84% ; +2.01%
5.	Disintegration	Should not dissolve 2.0 hours in HCl	Complies
		NMT 60 minutes in Buffer.	14 minutes 12 seconds
6.	Hardness	Not less than 4.0 Kg/cm <sup>2</sup>	7.58 kg/cm <sup>2</sup>
7.	Assay : Each enteric coated tablet contains: 100000 Armour units of enzymatic activity supplied by a purified concentrate which has specific Trypsin and Chymotrypsin activity in a ratio of approximately six to one.		NLT 90000 AU NLT 90.00% 100976.00 AU 100.98 %
	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	Kuljeet Kaur	Ram Awadh yd
Designation	Executive	Head QC	Head-DA
Signature			
Date	06/11/2024	06/11/2024	11/11/2024