



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Chymoforce Forte	A.R. No.	FG/G/24A0330
Generic Name	Trypsin - Chymotrypsin Tablets	Sample Quantity	120 Tablets
Batch No.:	AGT40417	Sample Received on	27/04/2024
Batch Size:	3.50 Lac	Analysis Date	27/04/2024
Mfg. Date.	04/2024	Release Date	27/04/2024
Exp. Date	03/2026	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 filled weight	150.00 mg $\pm$ 3.0%.	150.063 mg
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 147.71 mg ; Max: 153.87 mg -1.57% ; +2.54%
5.	Disintegration	Should not dissolve 2.0 hours in HCl and NMT 1 hour in Buffer.	19 minutes 39 seconds
6.	Hardness	Not less than 4.0 Kg/cm ²	9.92 kg/cm ²
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%	108504.4 AU 108.50 %
8.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	35 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	Pravleen Kumar	DURGESH KOMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	27/04/2024	27/04/2024	27/04/2024