



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Feroheal-XT	A.R. No.	FG/G/24A0254
Generic Name	Ferrous Ascorbate & Folic Acid Tablets IP	Sample Quantity	60 Tablets
Batch No.:	AGT40398	Sample Received on	04/04/2024
Batch Size:	3.0 Lac	Analysis Date	04/04/2024
Mfg. Date.	03/2024	Release Date	10/04/2024
Exp. Date	02/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Dark pink colour, elongated shaped, biconvex, having both side plain, film coated tablet.	Dark pink colour, elongated shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification:				
	A) By Chemically (For Ferrous Ascorbate)	Should be positive for Ferrous Ascorbate.	Complies		
	B) By HPLC (For Folic Acid)	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	919.0 mg $\pm$ 3.0%.	914.765 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 881.58 mg ; Max: 946.63 mg -3.63% ; + 3.48%		
5.	Hardness	NLT 4.0 Kg/cm ²	16.6 Kg/cm ²		
6.	Disintegration	Not more than 30 minutes.	18 minutes 30 seconds.		
7.	Uniformity of content (For Folic Acid)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	3.81		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Ferrous Ascorbate IP Eq. to Elemental Iron	100 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 90.0 mg to 110.0 mg)	102.40 mg	102.40 %
	Folic Acid IP	1.5 mg	NLT 90.0% (NLT 1.35 mg)	1.9760 mg	131.73 %

Particulars	Prepared By	Checked By	Approved By
Name	Pravleen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	10/04/2024	10/04/2024	10/04/2024



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9.	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	DURGESH KUMAR	Gaurtarn Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	10/04/2024	10/04/2024	10/04/2024