



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Cortibrook-6	A.R. No.	FG/G/24A1059
Generic Name	Deflazacort Tablets 6 mg	Sample Quantity	120 Tablets
Batch No.:	AGT40761C	Sample Received on	24/07/2024
Batch Size:	2.0 Lac	Analysis Date	24/07/2024
Mfg. Date.	07/2024	Release Date	03/08/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex, having both side plain, uncoated tablet.	White colour, round shaped, biconvex, having both side plain, uncoated tablet.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	170.00 mg ± 3%	170.22 mg		
4.	Uniformity of weight	±7.5% of its average weight.	Min: 167.85 mg ; Max: 173.14 mg -1.39% ; + 1.72%		
5.	Disintegration	Not more than 15 minutes.	02 minutes 35 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	6.5 Kg/cm ²		
7.	Friability	NMT 1.0 %w/w	0.17 %w/w		
8.	Dissolution	Not less than 75.0%	Minimum = 91.14% Maximum = 94.77% Average = 92.21%		
9.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	3.19		
10.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Deflazacort	6 mg	Between 90.0 % to 110.0 % of stated amount (Between 5.4 mg to 6.6 mg)	5.8902 mg	98.17%
11.	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	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	03/08/2024	03/08/2024	03/08/2024