



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Carnotol-250	A.R. No.	FG/G/24A1053
Generic Name	Disulfiram Tablets IP 250 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40768	Sample Received on	24/07/2024
Batch Size:	210 Lac	Analysis Date	24/07/2024
Mfg. Date.	07/2024	Release Date	31/07/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, flat scored mark on one side and other side plain, uncoated tablet.	White colour, round shaped, flat scored mark on one side and other side plain, uncoated tablet.		
2.	Identification:				
	A. By IR	The spectrum obtained due to active component in test preparation should correlate with that reference disulfiram chromatogram.	Complies		
	B. By HPLC	In the Assay, 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	600.00 mg $\pm$ 3%	607.24 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 599.18 mg ; Max: 615.62 mg - 1.33% ; + 1.38%		
5.	Disintegration	Not more than 15 minutes.	03 minutes 35 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	6.42 Kg/cm ²		
7.	Friability	NMT 1.0 %w/w	0.19% w/w		
8.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Disulfiram IP	250 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 225.0 mg to 275.0 mg)	242.955 mg	97.18%
9.	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

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	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	31/07/2024	31/07/2024	31/07/2024