



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/24A1219
Generic Name	Disulfiram Tablets IP 250 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40853	Sample Received on	30/08/2024
Batch Size:	3.0 Lac	Analysis Date	30/08/2024
Mfg. Date.	08/2024	Release Date	06/09/2024
Exp. Date	07/2026	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%	607.76 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 598.24 mg ; Max: 615.46 mg - 1.57% ; + 1.27%		
5.	Disintegration	Not more than 15 minutes.	03 minutes 45 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	7.25 Kg/cm ²		
7.	Friability	NMT 1.0 %w/w	0.25% 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)	246.924 mg	98.77%
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	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	06/09/2024	06/09/2024	06/09/2024