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-500	**A.R. No.**	FG/G/24A0321
Generic Name	Disulfiram Tablets IP 500 mg	**Sample Quantity**	60 Tablets
Batch No.:	AGT40470	**Sample Received on**	25/04/2024
Batch Size:	2.0 Lac	**Analysis Date**	25/04/2024
Mfg. Date.	04/2024	**Release Date**	01/05/2024
Exp. Date	03/2026	**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 of 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**	580.00 mg ± 3%	583.255 mg
4.	**Uniformity of weight**	± 5% of its average weight.	Min: 572.59 mg ; Max: 589.05 mg - 1.83% ; + 0.99%
5.	**Disintegration**	Not more than 15 minutes.	06 minutes 24 seconds.
6.	**Hardness**	NLT 4.0 Kg/cm^2	7.5 Kg/cm^2
7.	**Friability**	NMT 1.0 %w/w	0.30%w/w
8.	**Assay:**		

Each uncoated tablet contains:	Claim	Limit	mg	%
Disulfiram IP	**500 mg**	Between 90.0 % to 110.0 % of labeled amount. (Between 450.0 mg to 550.0 mg)	489.720 mg	97.94%

9.	**Microbial Limit Tests:**		
i.	**Total aerobic microbial count**	NMT 1000 cfu/g	45 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	01/05/2024	01/05/2024	01/05/2024