

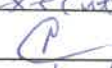
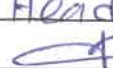
Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Carnotol-500	A.R. No.	FG/G/24A0153
Generic Name	Disulfiram Tablets IP 500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40249	Sample Received on	27/02/2024
Batch Size:	0.80 Lac	Analysis Date	27/02/2024
Mfg. Date.	02/2024	Release Date	04/03/2024
Exp. Date	01/2026	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 $\pm$ 3%	581.061 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 570.68 mg ; Max: 589.86 mg - 1.79% ; + 1.51%		
5.	Disintegration	Not more than 15 minutes.	05 minutes 10 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	8.4 Kg/cm ²		
7.	Friability	NMT 1.0 %w/w	0.32%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)	501.861 mg	100.37%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 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	Raveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	04/03/2024	04/03/2024	04/03/2024