SOLARA
Active Pharma Sciences

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METAPHARMACEUTICAL

N DE LOTE: 0280725

15/07/2025

CERTIFICATE OF ANALYSIS

Name of the Product: DISULFIRAM Ph. Eur.	Page No. 1 of 2
Batch No: MBFH25012A	Analytical Report No: 1101-FP-250337
Batch Quantity: 27.9 Kg	Manufacturing Date: June 2025
Retest Date: November 2027	
Storage Condition: Preserve in well closed containers. Protected from light.	

Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
1.	Description	White crystalline powder	White to off-white crystalline powder
2.	Solubility	Freely soluble in methylene chloride, soluble in acetone	Freely soluble in methylene chloride, soluble in acetone
3.	Identification by IR	Complies	The infrared absorption spectrum of sample matches with spectrum obtained from standard
4.	Melting Range	71.1°C to 72.3°C	70.0°C to 73.0°C
5.	Loss on drying	0.142%	Not more than 0.50%
6.	Sulphated ash	0.091%	Not more than 0.10%
7.	Diethyldithiocarbamate (Impurity B) by HPLC	BQL	Not more than 150 ppm
8.	Related substance by HPLC		
	Diethylthiocarbamic thioanhydride (Impurity A)	BDL	Not more than 0.15%
	Unspecified impurity	0.043%	Not more than 0.10%
	Total impurities	0.04%	Not more than 0.50%
9.	Assay by HPLC	100.0%	Not less than 98.5% and not more than 101.0% on dried basis
10.	Diethylamine content by GC Diethylamine	BDL	Not more than 1000 ppm

	Prepared By	Reviewed By	Approved By
Sign & Date	30/06/2025	30/06/2025	30/06/2025
Name	Renuka A	Sudhakar A Sapkal	Brijesh Kumar
Designation	Asst. Manager	Manager	Sr. Manager

A3/QC/076/F-01/R2

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Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
11.	Bulk density	0.37 g/ml	For information
12.	Tap density	0.68 g/ml	For information
13.	Particle size (By Malvern)		
	d90	98.0 µm	For information
	d50	36.1 µm	For information
	d10	8.8 µm	For information

BQL: Below quantifiable limit, **BDL:** Below detectable limit

LOD/LOQ values for Disulfiram Impurity B by HPLC

Impurity Name	LOD (in ppm)	LOQ (in ppm)
Impurity B (Diethylthiocarbamate)	7.40	44.75

LOD/LOQ values for Related substance by HPLC

Impurity Name	LOD	LOQ
Impurity A (Diethylthiocarbamic)	0.003%	0.008%

LOD/LOQ value for Diethylamine content by GC

Solvent name	LOD (in ppm)	LOQ (in ppm)
Diethylamine	10.1	101.0

REMARKS: The product complies as per Ph. Eur. Specification.

	Prepared By	Reviewed By	Approved By
Sign & Date	30/06/2025	30/06/2025	Brijesh Kumar 30/06/2025
Name	Renuka A	Sudhakar A Sapkal	Brijesh Kumar
Designation	Asst. Manager	Manager	Sr. Manager

A3/QC/076/F-01/R2