



SOLARA
Active Pharma Sciences

METAPHARMACEUTICAL

N DE LOTE:

0030324

Communication Address:

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Signature

02/03/2024

CERTIFICATE OF ANALYSIS

Name of the Product: DISULFIRAM Ph. Eur.	Page No. 1 of 2
Batch No: MBFH24004A	Analytical Report No: 1101-FP-240053
Batch Quantity: 50.2 Kg	Manufacturing Date: January 2024
Retest Date: June 2026	
Storage Condition: Preserve in well closed containers. Protected from light.	

Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
1.	Description	Off -white powder	White to off-white 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.	Appearance of solution	Solution is less intense than most appropriate color reference solution GY6	Solution should be less intense than most appropriate color reference solution Y6, GY6 and BY6
5.	Melting Range	71.0°C to 72.6°C	70.0°C to 73.0°C
6.	Loss on drying	0.056%	Not more than 0.50%
7.	Sulphated ash	0.037%	Not more than 0.10%
8.	Diethyldithiocarbamate (Impurity B) by HPLC	BQL	Not more than 150 ppm
9.	Related substance by HPLC		
	Diethylthiocarbamic thioanhydride (Impurity A)	BDL	Not more than 0.15%
	Unspecified impurity	BDL	Not more than 0.10%
	Total impurities	Not detected	Not more than 0.50%
10.	Assay by HPLC	99.7%	Not less than 98.5% and not more than 101.0% on dried basis
11.	Residual Solvents by GC		
	Isopropyl alcohol	455 ppm	Not more than 5000 ppm
	Ethanol	BDL	Not more than 5000 ppm
	Benzene	BDL	Not more than 2 ppm

	Prepared By	Reviewed By	Approved By
Sign & Date	<i>Shridhara Gowda</i> 02/02/2024	<i>Sandesh H K</i> 02/02/2024	<i>Thirumoorthi D</i> 02/02/2024
Name	Shridhara Gowda	Sandesh H K	Thirumoorthi D
Designation	Sr. Executive	Team Leader	Group Leader

A3/QC/076/F-01/R1

Solara Active Pharma Sciences Limited - CIN : L24230MH2017PLC291636

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Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
12.	Diethylamine content by GC Diethylamine	BQL	Not more than 1000 ppm
13.	Bulk density	0.81 g/ml	For information
14.	Tap density	0.90 g/ml	For information
15.	Particle size (By Malvern)		For information
	d90	385.0 µm	For information
	d50	170.0 µm	For information
	d10	65.8 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

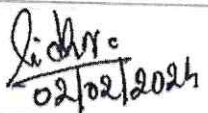
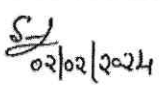
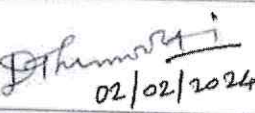
LOD/LOQ values for Related substance by HPLC

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

LOD/LOQ values for residual solvents by GC

Solvent name	LOD (in ppm)	LOQ (in ppm)
Isopropyl Alcohol	50.1	100.3
Ethanol	50.1	100.1
Benzene	0.22	0.61
Diethylamine	10.1	101.0

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

	Prepared By	Reviewed By	Approved By
Sign & Date	 02/02/2024	 02/02/2024	 02/02/2024
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