



SOLARA
Active Pharma Sciences

METAPHARMACEUTICAL

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af 12/06/2023

Communication Address:
Solara Active Pharma Sciences Limited
Plot Nos.120A & B, 120P & 121,
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CERTIFICATE OF ANALYSIS

Name of the Product: DISULFIRAM Ph. Eur.	Page No. 1 of 2
Batch No: MBFH22024A	Analytical Report No: 1101-FP-220679
Batch Quantity: 109.3 Kg	Dispatch Quantity: 25 Kg
Manufacturing Date: AUGUST 2022	Retest /Expiry Date: JANUARY 2025
Storage Condition: Preserve in well closed containers. Protected from light.	
Customer Name: Vedans Laboratories.	

Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
1.	Description	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	70.9°C to 72.7°C	70.0°C to 73.0°C
6.	Loss on drying	0.195%	Not more than 0.50%
7.	Sulphated ash	0.031%	Not more than 0.10%
8.	Diethylthiocarbamate (Impurity B) by HPLC	BQL	Not more than 150 ppm
9.	Related substance by HPLC		
	Diethylthiocarbamic thioanhydride (Impurity A)	BQL	Not more than 0.15%
	Unspecified impurity	BQL	Not more than 0.10%
	Total impurities	Not detected	Not more than 0.50%
10.	Assay by titration	100.2%	Not less than 98.5% and not more than 101.0% on dried basis
11.	Residual Solvents by GC		
	Isopropyl alcohol	176 ppm	Not more than 5000 ppm
	Ethanol	BDL	Not more than 5000 ppm
	Benzene	BDL	Not more than 2 ppm

	Prepared By:	Approved By:
Sign & Date:	<i>af</i> 30/04/2023	<i>P</i> 30/04/2023
Name:	Srinivas M.	Brijesh Kumar
Designation:	Team Leader	Sr. Manager

A3/QC/076/F-01/R0

Solara Active Pharma Sciences Limited - CIN : L24230MH2017PLC291636

REGD. OFF : 201, Devavrata, Sector 17, Vashi Navi Mumbai - 400703, India / Tel : 91-22-2789 2924 / 2789 3199 / Fax: 91-22-2789 2942



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12.	Diethylamine content by GC Diethylamine	BQL	Not more than 1000 ppm
13.	Particle size (By Malvern)		
	d90	78.3 µm	Not more than 120 µm
	d50	32.5 µm	Not more than 50 µm
	d10	6.9 µm	Not more than 10 µm

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:	Approved By:
Sign & Date:	<i>30/04/2023</i>	<i>30/04/2023</i>
Name:	Srinivas M.	Brijesh Kumar
Designation:	Team Leader	Sr. Manager

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