

METAPHARMACEUTICAL

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SOLARA
Active Pharma Sciences

[Signature]
31/10/2025

Communication Address :
Solara Active Pharma Sciences Limited
Plot Nos.120 A&B, 120P & 121, Plot No 36
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CERTIFICATE OF ANALYSIS

Name of the Product: Disulfiram Ph. Eur.	
Batch No: MBCQ25008A	Page No. 1 of 2
Analytical Report No: 1101-FP-250490	Batch Quantity: 236.3 Kg
Manufacturing Date: October 2025	Retest Date: March 2028
Storage Condition: Preserve in well closed containers. Protected from light.	

Sl. No.	TESTS	SPECIFICATIONS	RESULTS	METHOD REFERENCE
1.	Description	White to off-white crystalline powder or pale yellow to greenish crystals (which appears off white when reduced to fine powder)	Off-white crystalline powder	Inhouse
2.	Solubility	Freely soluble in methylene chloride, soluble in acetone	Freely soluble in methylene chloride, soluble in acetone	Inhouse
3.	Identification by IR	The infrared absorption spectrum of sample matches with spectrum obtained from standard	Complies	Ph.Eur
4.	Melting Range	70.0°C to 73.0°C	70.6°C to 71.7°C	Ph.Eur
5.	Loss on drying	Not more than 0.50%	0.342%	Ph.Eur
6.	Sulphated ash	Not more than 0.10%	0.031%	Ph.Eur
7.	Diethyldithiocarbamate (Impurity B) by HPLC	Not more than 150 ppm	BQL	Inhouse
8.	Related substance by HPLC			Inhouse
	Diethylthiocarbamic thioanhydride (Impurity A)	Not more than 0.15%	BQL	
	Unspecified impurity	Not more than 0.10%	BQL	
	Total impurities	Not more than 0.50%	Not detected	
9.	Assay by HPLC	Not less than 98.5% and not more than 101.0% on dried basis	99.4%	Inhouse

	Prepared By	Reviewed By	Approved By
Sign & Date	<i>[Signature]</i> 11/10/2025	<i>[Signature]</i> 11/10/2025	<i>[Signature]</i> 11/10/2025
Name	Shridhara Gowda	Renuka A	Sudhakar A Sapkal
Designation	Sr. Executive	Asst. Manager	Sr. Manager

A3/QC/076/F-01/R3

Solara Active Pharma Sciences Limited - CIN : L24230MH2017PLC291636

Registered Office : 9th Floor, 'Cyber One', Unit No. 902, Plot No. 4 & 6, Sector 30A, Vashi, Navi Mumbai - 400 703. India, Tel : 91-22-2789 2924

Corporate Office : TICEL BIO PARK LTD., 6th floor, Module No. 601, 602, 603, Phase II-CSIR Road, Tharamani, Chennai, Tamil Nadu - 600113. India



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10.	Diethylamine content by GC Diethylamine	Not more than 1000 ppm	BQL	Inhouse
11.	Particle size (By Malvern)			Inhouse
	d90	For information	667 µm	
	d50	For information	342 µm	
	d10	For information	125 µm	
12	Bulk density	For information	0.79 g/ml	Inhouse
13	Tap density	For information	0.85 g/ml	Inhouse

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

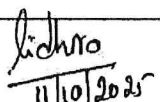
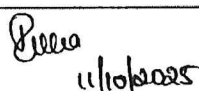
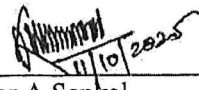
LOD/LOQ values for Related substance by HPLC

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	 11/10/2025	 11/10/2025	 11/10/2025
Name	Shridhara Gowda	Renuka A	Sudhakar A Sapkal
Designation	Sr. Executive	Asst. Manager	Sr. Manager

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