



**SOLARA**  
Active Pharma Sciences

**METAPHARMACEUTICAL**

*M. G. Gowda*  
15/07/2025

N DE LOTE:

0270725

Communication Address :  
Solara Active Pharma Sciences Limited  
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**CERTIFICATE OF ANALYSIS**

Name of the Product: DISULFIRAM Ph.Eur	Page No. 1 of 2
Batch No: MBCQ25007A	Analytical Report No: 1101-FP-250289
Batch Quantity: 224.3 Kg	Manufacturing Date: June 2025
Retest Date: November 2027	
Storage Condition: Preserve in well closed containers. Protected from light.	

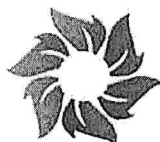
Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
1.	Description	White crystalline powder	White to off-white crystalline powder or pale yellow to greenish crystals (which appears off white when reduced to fine powder)
2.	Solubility	Freely soluble in methylene chloride, soluble in acetone	Freely soluble in methylene chloride, soluble in acetone
3.	Identification by IR	Complies	The infrared absorption spectrum of sample matches with spectrum obtained from standard
4.	Melting Range	71.5°C to 72.5°C	70.0°C to 73.0°C
5.	Loss on drying	0.392%	Not more than 0.50%
6.	Sulphated ash	0.031%	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	BDL	Not more than 0.10%
	Total impurities	Not detected	Not more than 0.50%
9.	Assay by HPLC	100.4%	Not less than 98.5% and not more than 101.0% on dried basis
10.	Diethylamine content by GC		
	Diethylamine	BQL	Not more than 1000 ppm

	Prepared By	Reviewed By	Approved By
Sign & Date	<i>Shridhara</i> 20/06/2025	<i>Renuka</i> 20/06/2025	<i>Brijesh Kumar</i> 20/06/2025
Name	Shridhara Gowda	Renuka A	Brijesh Kumar
Designation	Sr. Executive	Asst. Manager	Sr. Manager

A3/QC/076/F-01/R2

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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Sl. No.	TEST	RESULT	SPECIFICATION LIMIT
11.	Bulk density	0.78 g/ml	For information
12.	Tap density	0.87 g/ml	For information
13.	Particle size (By Malvern)		
	d90	689 µm	For information
	d50	308 µm	For information
	d10	116 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 (Diethyldithiocarbamate)	7.40	44.75

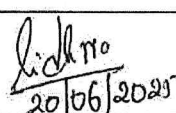
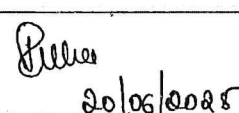
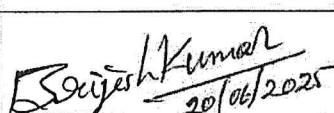
**LOD/LOQ values for Related substance by HPLC**

Impurity Name	LOD	LOQ
Disulfiram	0.010%	0.026%
Impurity A (Diethylthiocarbamic)	0.003%	0.008%

**LOD/LOQ values for Diethylamine content by GC**

Impurity Name	LOD (in ppm)	LOQ (in ppm)
Diethylamine	10.1	101.0

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

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Sign & Date	 20/06/2025	 20/06/2025	 20/06/2025
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Designation	Sr. Executive	Asst. Manager	Sr. Manager

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