



**SOLARA**  
Active Pharma Sciences

**METAPHARMACEUTICAL**

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27/11/2023

Communication Address :  
Solara Active Pharma Sciences Limited  
Plot Nos.120A & B, 120P & 121,  
Industrial Area, Baikampady  
New Mangalore-575011, Karnataka, India  
Tel : +91 824 2402100  
E-mail : info@solara.com  
www.solara.co.in

**CERTIFICATE OF ANALYSIS**

|                                                                              |                                      |
|------------------------------------------------------------------------------|--------------------------------------|
| Name of the Product: DISULFIRAM Ph. Eur.                                     | Page No. 1 of 3                      |
| Batch No: MBCQ23026A                                                         | Analytical Report No: 1101-FP-230693 |
| Batch Quantity: 222.8 Kg                                                     | Dispatch Quantity: 50 Kg             |
| Manufacturing Date: November 2023                                            | Retest Date: April 2026              |
| Storage Condition: Preserve in well closed containers. Protected from light. |                                      |
| Customer Name:                                                               |                                      |

| Sl. No. | TEST                                           | RESULT                                                                     | SPECIFICATION LIMIT                                                                            |
|---------|------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| 1.      | Description                                    | Off-white crystalline 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 Y6 | Solution should be less intense than most appropriate color reference solution Y6, GY6 and BY6 |
| 5.      | Melting Range                                  | 71.4°C to 72.5°C                                                           | 70.0°C to 73.0°C                                                                               |
| 6.      | Loss on drying                                 | 0.144%                                                                     | Not more than 0.50%                                                                            |
| 7.      | Sulphated ash                                  | 0.022%                                                                     | Not more than 0.10%                                                                            |
| 8.      | Diethyldithiocarbamate (Impurity B) by HPLC    | BDL                                                                        | Not more than 150 ppm                                                                          |
| 9.      | Related substance by HPLC                      |                                                                            |                                                                                                |
|         | Diethylthiocarbamic thioanhydride (Impurity A) | BDL                                                                        | Not more than 0.15%                                                                            |
|         | Unspecified impurity                           | 0.031%                                                                     | Not more than 0.10%                                                                            |
|         | Total impurities                               | 0.03%                                                                      | Not more than 0.50%                                                                            |
| 10.     | Assay by titration                             | 100.1%                                                                     | Not less than 98.5% and not more than 101.0% on dried basis                                    |
| 11.     | Residual Solvents by GC                        |                                                                            |                                                                                                |
|         | Isopropyl alcohol                              | 1034 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>Renuka</i> 27/11/2023 | <i>Shridhara</i> 27/11/2023 | <i>Sudhakar</i> 27/11/2023 |
| Name        | Renuka A                 | Shridhara Gowda             | Sudhakar Sapkal            |
| Designation | Sr. Executive            | Sr. Executive               | Manager                    |

A3/QC/076/F-01/R1

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    |
|---------|--------------------------------------------|-----------|------------------------|
| 12.     | Diethylamine content by GC<br>Diethylamine | BDL       | Not more than 1000 ppm |
| 13.     | Bulk density                               | 0.79 g/ml | For information        |
| 14.     | Tap density                                | 0.89 g/ml | For information        |
| 15.     | Particle size (By Malvern)                 |           |                        |
|         | d90                                        | 605.0 µm  | For information        |
|         | d50                                        | 331.0 µm  | For information        |
|         | d10                                        | 94.9 µm   | For information        |

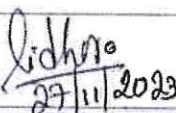
**BQL:** Below quantifiable limit, **BDL:** Below detectable limit

#### 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% |

|             | Prepared By                                                                                    | Reviewed By                                                                                     | Approved By                                                                                      |
|-------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Sign & Date |  27/11/2023 |  27/11/2023 |  27/11/2023 |
| Name        | Renuka A                                                                                       | Shridhara Gowda                                                                                 | Sudhakar Sapkal                                                                                  |
| Designation | Sr. Executive                                                                                  | Sr. Executive                                                                                   | Manager                                                                                          |

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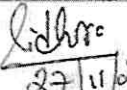
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| Customer Name:                                                               |                                      |

**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 |  27/11/2023 |  27/11/2023 |  27/11/2023 |
| Name        | Renuka A                                                                                       | Shridhara Gowda                                                                                | Sudhakar Sapkal                                                                                  |
| Designation | Sr. Executive                                                                                  | Sr. Executive                                                                                  | Manager                                                                                          |

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