



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 225158**

|                   |                                                                 |
|-------------------|-----------------------------------------------------------------|
| Product:          | DAPSONE                                                         |
| Lot:              | 225158                                                          |
| Expiry date:      | 28/02/2027                                                      |
| Reference:        | Cumple PhEur10.8                                                |
| Synonyms:         |                                                                 |
| Formula:          | C <sub>12</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub> S |
| Molecular weight: | 248,30 g/mol                                                    |

| Assay                           | Result          | Specification  |   |
|---------------------------------|-----------------|----------------|---|
| Identification                  | Conform (A,B,C) | Test PhEur     |   |
| Organoleptic properties         | Conform         | PhEur          |   |
| Loss on drying                  | 0,03 %          | <= 1,5 %       |   |
| Sulphated ashes                 | 0,05 %          | <= 0,1 %       |   |
| Assay                           | 99,8 %          | 99,0 - 101,0 % |   |
| Related substances (HPLC)       | Conform         | Test PhEur     |   |
| Impurity A                      | 0,21 %          | <= 0,3 %       |   |
| Impurity C                      | 0,24 %          | <= 0,3 %       |   |
| Impurity B                      | 0,17 %          | <= 0,4 %       |   |
| Unspecified Impurities          | < 0,05 %        | <= 0,10 %      |   |
| Total impurities                | 0,3 %           | <= 1,0 %       |   |
| Elemental impurities            | Conform         | Test PhEur     | # |
| Residual solvent: Methanol      | < 3000 ppm      | <= 3000 ppm    | # |
| Residual solvent: chlorobenzene | <360 ppm        | <= 360 ppm     | # |
| Residual solvent: Benzene       | <2 ppm          | <= 2 ppm       | # |

Organoleptic characteristics: White or slightly yellowish-white, crystalline powder. Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in dilute mineral acids. It shows polymorphism.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/12/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00281 ATUL LIMITED

Manufacturer batch: 22-007

| Product | Name    | Capacity | Batch      |
|---------|---------|----------|------------|
| 1112020 | DAPSONA | 10 g     | 225158-F-1 |

1112022

DAPSONA

50 g

225158-I-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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