



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251986**

Product:	DAPSONE
Lot:	251986
Expiry date:	30/06/2029
Reference:	Cumple PhEur11.8
Synonyms:	Dapsone, 4,4'-diaminodifenilsulfona, DDS
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		
Organoleptic properties	Conform	PhEur	
Loss on drying	0,02 %	<= 1,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,8 %	99,0 - 101,0 %	
Related substances (HPLC)	Conform	Test PhEur	
Impurity A	< 0,05 %	<= 0,3 %	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity B	< 0,05 %	<= 0,4 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 1,0 %	
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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: 07/11/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00411 MEDILUX LABORATORIES PRIVATE LIMITED

Manufacturer batch: DAPS-24-25-003

Product	Name	Capacity	Batch
1112020	DAPSONA	10 g	251986-F-1
1112022	DAPSONA	50 g	251986-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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