



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 225158

Product:	DAPSONE
Lot:	225158
Expiry date:	28/02/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formule:	C ₁₂ H ₁₂ N ₂ O ₂ S
Poids moléculaire:	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

Produit	Nom	Capacité	Lot
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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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