



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233784

Product:	DAPSONE
Lot:	233784
Expiry date:	30/04/2028
Reference:	Cumple PhEur11.2
Synonyms:	
Formula:	C ₁₂ H ₁₂ N ₂ O ₂ S
Molecular weight:	248,30 g/mol

Assay	Result	Specification	
Identification	Conform(A,B,C)	Test PhEur	
Organoleptic properties	Conform	PhEur	
Loss on drying	0,01 %	<= 1,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,9 %	99,0 - 101,0 %	
Related substances (HPLC)	Conform	Test PhEur	
Impurity A	0,15 %	<= 0,3 %	
Impurity C	0,12 %	<= 0,3 %	
Impurity B	0,24 %	<= 0,4 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,51 %	<= 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	#
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: 05/12/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00281 ATUL LIMITED

Manufacturer batch: 23-009

Product	Name	Capacity	Batch
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1112020	DAPSONA	10 g	233784-F-1
1112020	DAPSONA	10 g	233784-F-2
1112020	DAPSONA	10 g	233784-F-3
1112022	DAPSONA	50 g	233784-I-2
1112022	DAPSONA	50 g	233784-I-3
1112022	DAPSONA	50 g	233784-I-4
1370130	DAPSONA (FLB)	50 g	233784-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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