



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 217206

Product:	FUROSEMIDE
Lot:	217206
Expiry date:	01/08/2026
Reference:	Cumple PhEur10.5
Synonyms:	Frusemida.
Formula:	C ₁₂ H ₁₁ CIN ₂ O ₅ S
Molecular weight:	330,74 g/mol

Assay	Result	Specification	
Impurity C	<= 0,05 %	<= 0,2 %	
Organoleptic properties	Conform	PhEur	
Identification	Conform (B)	Test PhEur (B)	
Total impurities	<= 0,5 %	<= 0,5 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Impurity D	<= 0,05 %	<= 0,15 %	
Related substances (HPLC)	Conform		
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Heavy metals	Conform	<= 20 ppm	#
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Sulphates	<= 300 ppm	<= 300 ppm	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Chlorides	<= 200 ppm	<= 200 ppm	
Appearance of solution	Conform	Test PhEur	
Assay	99,2 %	98,5-101,0%	
Sulphated ashes	0,00 %	<= 0,1 %	
Residual solvent: methyl acetate	<= 5000 ppm	<= 5000 ppm	#
Loss on drying (1 g, 105°C)	0,11 %	<= 0,5%	
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Pract. insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 %), pract. insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 05/01/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00426 MANGALAM DRUGS AND ORGANICS LTD. (UNIT 2)

Manufacturer batch: FRM-2C-212015

Product	Name	Capacity	Batch
1145602	FUROSEMIDA	5 g	217206-E-1
1145602	FUROSEMIDA	5 g	217206-E-3
1145604	FUROSEMIDA	25 g	217206-G-1
1145604	FUROSEMIDA	25 g	217206-G-3
1145606	FUROSEMIDA	100 g	217206-J-1
1145606	FUROSEMIDA	100 g	217206-J-2
1145606	FUROSEMIDA	100 g	217206-J-4
1145609	FUROSEMIDA	1 kg	217206-P-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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