



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233765

Product:	FUROSEMIDE
Lot:	233765
Expiry date:	30/03/2028
Reference:	Cumple PhEur11.2
Synonyms:	Frusemida.
Formula:	C ₁₂ H ₁₁ ClN ₂ O ₅ S
Molecular weight:	330,74 g/mol

Assay	Result	Specification	
Appearance of solution	Conform	Test PhEur	
Assay	100,2 %	98,5-101,0%	
Sulphated ashes	0,00 %	<= 0,1 %	
Residual solvent: methyl acetate	< 5000 ppm	<= 5000 ppm	#
Loss on drying	0,02 %	<= 0,5 %	
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform		
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 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	
Nitrosamine impurities	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Organoleptic properties	Conform	PhEur	
Identification	Conform (B)	Test PhEur (B)	
Total impurities	0,20 %	<= 0,5 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Impurity D	012 %	<= 0,15 %	
Impurity C	0,08 %	<= 0,2 %	

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: 15/11/2023

Responsible: M. Mesa

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00397 MANGALAM DRUGS AND ORGANICS LTD. (Unit 1)

Manufacturer batch: FUR-1A-232007

Product	Name	Capacity	Batch
1145602	FUROSEMIDA	5 g	233765-E-1
1145602	FUROSEMIDA	5 g	233765-E-2
1145604	FUROSEMIDA	25 g	233765-G-2
1145604	FUROSEMIDA	25 g	233765-G-3
1145604	FUROSEMIDA	25 g	233765-G-4
1145606	FUROSEMIDA	100 g	233765-J-2
1145606	FUROSEMIDA	100 g	233765-J-4
1145606	FUROSEMIDA	100 g	233765-J-5
1145606	FUROSEMIDA	100 g	233765-J-6
1145609	FUROSEMIDA	1 kg	233765-P-2
1145609	FUROSEMIDA	1 kg	233765-P-3
1145609	FUROSEMIDA	1 kg	233765-P-4
1370182	FUROSEMIDA (FLB)	100 g	233765-J-1
1370182	FUROSEMIDA (FLB)	100 g	233765-J-3

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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