



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240623

Product:	ACETAZOLAMIDE
Lot:	240623
Expiry date:	30/08/2028
Reference:	Cumple PhEur11.4
Synonyms:	
Formula:	C ₄ H ₆ N ₄ O ₃ S ₂
Molecular weight:	222,24 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test RFE/Ph. Eur.	=
Sulphates	< 500 ppm	<= 500 ppm	=
Heavy metals	< 20 ppm	<= 20 ppm	=
Related substances (HPLC)	Conform	Test RFE/Ph. Eur.	=
Loss on drying (105°C)	0,13 %	<= 0,5%	
Sulphated ashes	0,00 %	<= 0,1%	=
Assay (acid-base PFP)	99,8 %	98,5-101,0%	
Impurity A	< 0,05 %	<= 0,15 %	=
Impurity B	0,09 %	<= 0,15 %	=
Impurity C	< 0,05 %	<= 0,15 %	=
Impurity D	0,11 %	<= 0,15 %	=
Impurity E	< 0,05 %	<= 0,15 %	=
Impurity F	< 0,05 %	<= 0,15 %	=
Unspecified Impurities	< 0,05 %	<= 0,10 %	=
Total impurities	0,20 %	<= 0,6 %	=
Residual solvent: Acetic acid	< 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 05/06/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00362 NAKODA CHEMICALS LIMITED

Manufacturer batch: ACT-2309147C

Product	Name	Capacity	Batch
1100902	ACETAZOLAMIDA (INACTIVO)	5 g	240623-E-1
1100905	ACETAZOLAMIDA	100 g	240623-J-1
1100905	ACETAZOLAMIDA	100 g	240623-J-2
1100907	ACETAZOLAMIDA (INACTIVO)	1 kg	240623-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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