



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260550

Product:	Diazepam
Lot:	260550
Expiry date:	30/01/2031
Reference:	Cumple PhEur12.2
Synonyms:	
Formula:	C ₁₆ H ₁₃ CIN ₂ O
Molecular weight:	284.7 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Impurity A	< 0,05 %	<= 0,1 %	
Impurity B	< 0,05 %	<= 0,1 %	
Impurity E	< 0,05 %	<= 0,1 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,2 %	<= 0,2 %	
Loss on drying	0,07 %	<= 0,5 %	
Sulphated ashes	0,02 %	<= 0,1 %	
Assay	100,4 %	99,0 - 101,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white crystalline powder, hygroscopic, very soluble in water without carbon dioxide (a small fraction may be insoluble), soluble in ethanol (96%), practically insoluble in methylene chloride.

Conservation: In tightly closed containers. PROTECT FROM LIGHT AND HUMIDITY.

Date of analysis: 14/05/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01050 LAKE CHEMICALS PVT. LTD.

Manufacturer batch: 867026001A

Product	Name	Capacity	Batch
1125461	DIAZEPAM	10 g	260550-F-1
1125462	DIAZEPAM	5 g	260550-E-1
1125463	DIAZEPAM	100 g	260550-J-1
1125464	DIAZEPAM	50 g	260550-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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Date of edition: 08/06/2026

