

ISOSORBIDI DINITRAS DILUTUS 5g

Lot No.: 24L05-F250081

Authorisation:	1890R05618	Date Of Analysis:	26/07/2024
Analytical Reference:	Ph.Eur. [01/2008:1117]	Production Number:	030325-G240115
CNK:	3833-548	Expiry Date:	04/2029

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Fine, white or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Spectrum complies with the spectrum obtained with isosorbide dinitrate CRS	Complies
Identification C	The chromatogram of the test solution complies with the chromatogram obtained with reference solution (a) for lactose or with reference solution (b) for mannitol	Complies
Identification D	69 °C to 72 °C	71°C
TESTS	SPECIFICATION	RESULT
Impurity A	≤ 0.5 %	Complies
Impurity B and C		
Impurity B	≤ 0.5 %	0.03 %
Impurity C	≤ 0.5 %	Not detected
ASSAY	SPECIFICATION	RESULT
Liquid chromatography	95.0 % to 105.0 %	99.6 %
Manufacturer identification code: S/GS/064		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: **Joran Smout** Digitally signed by Joran Smout (Signature)
(Signature) Date: 2025.03.28 13:32:36 +01'00'



DISTRIBUIDO POR
METAPHARMACEUTICAL
INDUSTRIAL SLU

28 OCT 2025

MAGIS PHARMA

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