

ANALYSIS REPORT

PRODUCT		
ISOSORBIDE DINITRATE 40 % WITH LACTOSE		
Product code: 500425 "NOT FOR PARENTERAL AND OPHTHALMIC USE"		
LOT NO. 2405300	QUANTITY 10 Kg	Package (total number) 1
CUSTOMER : MAGIS-PHARMA NV		Order No. PO06627
DATE OF MANUFACTURE May 04, 2024	RE-TEST DATE May 04, 2029	

RAW MATERIALS

Isosorbide Dinitrate			
Test	Limit	Test Method	Result
Description	White crystalline powder	visual examination	Complies
Identification	Melting point	USP	Complies
Melting Point	69,0 + 72,0°C	USP <741>	70,4 °C
Water	≤ 0,3%	USP <921>	0,03%
Related substances	One spot on 800 µg	TLC	Complies
Acidity	None	MIL-P-387C	Complies
Alkalinity	≤ 0,015% Na ₂ CO ₃	MIL-P-387C	0,001 %
Stability at 80°C	≥ 60 minutes	Abel	Complies
Inorganic nitrates	≤ 0,5%	TLC	Complies
Sulphates	≤ 100 µg/g	USP <221>	Complies
Assay	97 + 103 %	UV	100,8 + 101,5 %
Residual Solvents	Acetone: ≤ 300 ppm	GC-Company	max 158 ppm
Granulation through 200 ASTM	≥ 75 %	Wet sieving	88 %
Lactose: Pharmaceutical grade USP-NF/EP;			

EXAMINATION OF FINISHED PRODUCT

Description	Fine, white, crystalline powder	visual examination	Complies
Identification	ISDN: positive	EP – test B (TLC)	Complies
	ISDN: positive	EP –test D - melting point	Complies
	Lactose: positive	EP – test C (TLC)	Complies
Loss on drying	≤ 0,2%	USP <731>	0,05 %
Impurity A	≤ 0,5% (Inorganic nitrates)	EP	Complies
Related substances	Impurity C ≤ 0,5% (IS5MN)	EP	Complies
	Impurity B ≤ 0,5% (IS2MN)	EP	Complies
Assay	39,2 + 40,8%	EP	39,9 %

Elemental impurities: none of the elemental impurity reported in ICHQ3D is likely to be present

Analysis report n. 40000067618

Date June 03, 2024

[Signature]
Quality Control

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Quality Assurance