

Certificate of Analysis

Product name: **Isosorbidi dinitras dilutus**

Batch number / Weight: **22D11-B05-224383 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22D11-B05 / INS-22-3961**

Reference Code / No.: **V01970 / 2203089**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Identification D	69 - 72	71,4	°C	
Impurity A	<=0,5	<0,5	%	
Impurities B and C	<=0,5% each	0,05 / 0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Isosorbide dinitrate	38,0 - 42,0	39,74	%m/m	
Assay	95,0-105,0 stated on label	99,11	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Acetone	<=5000	<5000	ppm	

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EISpol

Release:
 Ewelina Gadzinowska
 Qualified Person

28-10-2022

Expiration: 11-03-2027

Conclusion: APPROVED

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