

Certificate of Analysis

Productname: Isosorbidi dinitras dilutus
Number of analysis/Inspection Code: 2 / KEUR-180295B
Batchnumber: 18J18-B01-366233
Reference code / No.: 2292 / 195293
Analysed according to: PH.EUR 9.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		TLC
Identification D	69 - 72	71	°C	
Impurity A	<=0,5	Conform	%	TLC
Impurities B and C	<=0,5% each	Conform	%	HPLC
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Isosorbide dinitrate	38,0 - 42,0	40,5	%m/m	HPLC
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/10/20

Expiration: 02-2023

Conclusion: APPROVED

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