



JSC Olainfarm

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Olainfarm

Certificate of Analysis No. 11/2

KOPĪJA

20.06.2018

GPN mēntzings

A. Silina

MELDONIUM DIHYDRATE			
Name of Product/ Chemical Name			
CAS No.	86426-17-7		
Order Number	2018 3940		
Batch Number	110518		
Batch Size	219.66 kg	Released from warehouse	25.00 kg
Date of manufacture	05-2018		
Date of analysis	28.05.2018		
Retest Date	05-2020		
Destination country	Italy		
Name and address of manufacturing site/quality control site	JSC Olainfarm 5 Rupniecīu str., Olaine, LV-2114, Latvia		
Number of Manufacturing Authorisation	A1 – 22012018; AFV-01/4		
Number of GMP certificate	ZV/LV/2015/0011A		

Tests	Requirements according to	Results
Description	KQS8.619.046/4	
	White or almost white crystals or crystalline powder. Is soluble absorbing atmospheric humidity	Almost white crystalline powder, is soluble absorbing atmospheric humidity
Solubility	Very soluble in water, freely soluble in methanol, practically insoluble in acetone	Conforms
Identification	Conforms to meldonium dihydrate CRS spectrum	Conforms
A. IR spectrum (in 1 % KBr tablet)	Positive	Positive
B. Qualitative reaction		
Particle size*	Not more than 5 %	Not detected
- larger than 610 µm	Not more than 15 %	14.5 %
- smaller than 100 µm	Not more than 100 ppm	Less than 100 ppm
Chlorides	Not more than 100 ppm	Less than 100 ppm
Sulfates	Not more than 100 ppm	Less than 100 ppm
Clarity of solution (10.0 g; 50 mL H₂O)	Clear, comparing to reference suspension I	Clear, comparing to reference suspension I
Colour of solution (10.0 g; 50 mL H₂O)	Not more than reference solution B ₂	Less than reference solution B ₂
pH (10.0 g; 50 mL H₂O)	7.5 - 9.0	8.7
Water	19.7 % - 21.0 %	20.3 %
Sulfated ash (1.0 g)	Not more than 0.1 %	0.02 %
Heavy metals (10 % m/v solution; lead standard solution (1 ppm Pb))	Not more than 10 ppm	Less than 10 ppm
Related substances:		
- 3-methyl-(2,2,2-trimethylhydrazine)propionate bromide	Not more than 0.10 %	Less than 0.01 %
- 1,1,1-trimethylhydrazinium salts on trimethylhydrazinium ion	Not more than 0.10 %	Less than 0.01 %
- each unknown impurity	Not more than 0.3 %	Less than 0.01 %
Residual solvents		
- Ethyl alcohol	Not more than 3000 ppm	622 ppm
Assay (calculated to anhydrous substance)	99.0 % - 101.0 %	100.7 %
Microbiological quality:		
- total aerobic microbial count (TAMC)	Not more than 10 ⁶ CFU/1 g	Less than 10 CFU/1 g
- total combined yeasts/moulds count (TAMC)	Not more than 10 ⁶ CFU/1 g	Less than 10 CFU/1 g
- <i>Escherichia coli</i>	Absence in 1 g	Absent in 1 g

I hereby certify that the analytical results are authentic and accurate, comply with the specifications

Approved by N.Vershilovska Head of QC	Date of Signature 15.06.2018	Signature
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Certification Statement

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU

Name of the Qualified Person certifying the batch	Date of Signature 15.06.2018	Signature of Qualified Person certifying the batch
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I.Svirinskis

*Recommended test