



JSC OlaFarm
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KOPIJA
 13.06.2016
 GPN krāvu nolikuma
 J. Staņukeviča

QUALITY CERTIFICATE No. 3/2

Name of Product/ Chemical Name	MELDONIUM DIHYDRATE		
CAS No.	86426-17-7		
Order number	2016 2901		
Batch Number	30216		
Batch Size/kg	101.31 kg	Released from warehouse/kg	5.00 kg
Date of Manufacture	02-2016		
Retest date	02-2018		
Importing country/Destination	Italy		
Name and address of manufacturing site/quality control site	JSC OlaFarm 5 Rupnieu str., Olaine, LV-2114, Latvia		
Number of manufacturing Authorisation	AFV-01/3		
Number of GMP certificate	ZVA/LV/2015/011A		

Results of Analysis		
Tests	Specifications according to KQS8.619.046/3	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Solubility	Very soluble in water, freely soluble in methanol, practically insoluble in acetone	Conforms
Identification		
A. IR spectrum (in 1 % KBr tablet)	Conforms to meldonium dihydrate CRS spectrum	Conforms
B. Qualitative reaction	Positive	Positive
Particle size*		
- larger than 630 µm	Not more than 5 %	Not detected
- smaller than 100 µm	Not more than 15 %	6 %
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. H ₂ O)	Clear, comparing to reference suspension I	Clear, comparing to reference suspension I
Colour of solution (10.0 g; 50 ml. H ₂ O)	Not more than reference solution B ₉	Less than reference solution B ₉
pH (10.0 g; 50 ml. H ₂ O)	7.5 – 9.0	8.6
Water	19.7 % – 21.0 %	19.9 %
Sulfated ash (1.0 g)	Not more than 0.1 %	0.08 %
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-trimethylhydrazini- um)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 0.10 %	Less than 0.01 %
- total	Not more than 0.3 %	Less than 0.01 %
Residual solvents		
- ethyl alcohol	Not more than 3000 ppm	1442 ppm
Assay, calculated to anhydrous substance	99.0 % – 101.0 %	99.7 %
Microbiological quality:		
- total aerobic microbial count (TAMC)	Not more than 10 ³ CFU/1 g	Less than 10 CFU/1 g
- total combined yeasts/moulds count (TAMC)	Not more than 10 ² CFU/1 g	Less than 10 CFU/1 g
- <i>Escherichia coli</i>	Absence in 1 g	Absent in 1 g
Approved by A. Zemcova Head of QC	Head of IPCD N. Vershilovska Date 13.06.2016	Signature
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.		
Released by J. Borcova Qualified Person	Date 14/06/2016	Signature of person authorising the batch release

*Recommended test