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KOPIJA
17.03.2020
GPN kravu noformētāja
A. Silineviča

Certificate of Analysis No. 11/3

Name of Product/ Chemical Name	**MELDONIUM DIHYDRATE**
CAS No.	86426-17-7
Order Number	2020 1546
Batch Number	110519
Batch Size	226.46 kg | Released from warehouse | 25.00 kg
Date of Manufacture	05-2019
Date of analysis	05.06.2019
Retest Date	05-2021
Destination country	Italy
Name and address of manufacturing site/quality control site	JSC Olainfarm 5 Rupniecu str., Olaine, LV-2114, Latvia
Number of Manufacturing Authorisation	AI-11032019; F00001
Number of GMP certificate	ZVA/LV/2015/011A

Tests	Requirements according to KQS8.619.046/5	Results
Description	White or almost white crystals or crystalline powder, deliquescent	Almost white crystalline powder, deliquescent
Solubility	Very soluble in water, freely soluble in methanol, practically insoluble in acetone	Conforms
Identification: A. IR spectrum (in 1 % KBr tablet) B. Qualitative reaction	Conforms to meldonium dihydrate CRS spectrum Positive	Conforms Positive
Particle size* - larger than 630 µm - smaller than 100 µm	Not more than 5 % Not more than 15 %	Not detected 9.0 %
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_2O)	Clear; comparing to reference suspension I	Clear, comparing to reference suspension I
Colour of solution (10.0 g; 50 mL H_2O)	Not more than reference solution B_9	Less than reference solution B_9
pH (10.0 g; 50 mL H_2O)	7.5 – 9.0	8.9
Water	19.7 % – 21.0 %	19.9 %
Sulfated ash (1 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-trimethylhydrazinium)propionate bromide - 1,1,1-trimethylhydrazinium salts on trimethylhydrazinium ion - each unknown impurity - total	Not more than 0.10 % Not more than 0.10 % Not more than 0.10 % Not more than 0.3 %	Less than 0.03 % Less than 0.03 % Less than 0.03 % Less than 0.03 %
Related substances:** - impurity A - impurity B - impurity C - impurity D - impurity E - impurity F - each unknown impurity - total	Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.15 % Not more than 0.10 % Not more than 0.3 %	Less than 0.05 % Less than 0.05 % Less than 0.05 % Less than 0.05 % Less than 0.05 % Less than 0.05 % Less than 0.05 % Less than 0.05 %
Residual solvents - ethyl alcohol	Not more than 3000 ppm	282 ppm
Assay, calculated to the anhydrous substance	99.0 % – 101.0 %	100.2 %
Microbiological quality: - total aerobic microbial count (TAMC) - total combined yeasts/moulds count (TAMC) - *Escherichia coli*	Not more than 10^3 CFU/1 g Not more than 10^2 CFU/1 g Absence in 1 g	Less than 10 CFU/1 g Less than 10 CFU/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 03.03.2020	Signature

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	Signature of Qualified Person certifying the batch
I.Svarinska	03.03.2020.	

*Recommended test. ** Impurities: impurity A – *N,N*-dimethylmethanaminium; impurity B – 1,1,1-trimethylhydrazinium-1-ium; impurity C – 2-(3-methoxy-3-oxopropyl)-1,1,1-trimethylhydrazin-1-ium; impurity D – 2-(3-ethoxy-3-oxopropyl)-1,1,1-trimethylhydrazin-1-ium; impurity E – 1,1,1-trimethyl-2-[3-(1-methylethoxy)-3-oxopropyl]hydrazin-1-ium; impurity F – 1,1-dimethyl-4,5-dihydro-1*H*-pyrazol-1-ium-3-olate