



JSC OleinFarm
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Lot: 0161116

QUALITY CERTIFICATE No. 15/2

Name of Product/ Chemical Name	MELDONIUM DIHYDRATE		
CAS No.	86426-17-7		
Order number	2016 6514		
Batch Number	150816		
Batch Size/kg	214.48 kg	Released from warehouse/kg	25.00 kg
Date of Manufacture	08-2016		
Retest date	08-2018		
Importing country/Destination	Italy		
Name and address of manufacturing site/quality control site	JSC OleinFarm 5 Rupniec str., Olaine, LV-2114, Latvia		
Number of manufacturing Authorisation	AFV-01/		
Number of GMP certificate	ZVA/LV/2015/011A		

Results of Analysis

Tests	Specifications according to KQSB.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) 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 %	1 % 1 %
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 ₂	Less than reference solution B ₂
pH (10.0 g; 50 mL H ₂ O)	7.5 – 9.0	8.9
Water	19.7 % – 21.0 %	20.5 %
Sulfated ash (1.0 g)	Not more than 0.1 %	0.04 %
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-trimethylhydrazin- ium)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 0.01 % Less than 0.01 % Less than 0.01 % Less than 0.01 %
Residual solvents - ethyl alcohol	Not more than 3000 ppm	280 ppm
Assay, calculated to anhydrous substance	99.0 % – 101.0 %	100.2 %
Microbiological quality: - total aerobic microbial count (TAMC) - total combined yeasts/moulds count (TAMC) - <i>Escherichia coli</i>	Not more than 10 ³ CFU/1 g Not more than 10 ² CFU/1 g Absent in 1 g	Less than 10 CFU/1 g Less than 10 CFU/1 g Absent in 1 g
Approved by N.Vershilovska Acting Head of QC	Date	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.Borova Qualified Person	Date	Signature of person authorising the batch release

*Recommended test