



OlainFarm
Meldonium dihydrate
(for non-sterile products preparation)

Chemical name: 3-(2,2,2-trimethylhydrazinium)propionate dihydrate

Molecule formula: $C_6H_{14}N_2O_2 \cdot 2H_2O$

Structure formula:

$$\begin{array}{c} \text{CH}_3 \diagup \\ \text{CH}_3 - \text{N}^+ - \text{NH} - \text{CH}_2 - \text{CH}_2 - \text{C} \begin{array}{l} \diagup \text{O} \\ \diagdown \text{O}^- \end{array} \\ \text{CH}_3 \diagdown \end{array} \cdot 2 \text{H}_2\text{O}$$

Molecule mass: 182.22

CAS No.: 86426-17-7

No.	Test	Specification	Method
1.	Description	White or almost white crystalline powder	Visual
2.	Solubility	Very soluble in water, freely soluble in methanol, practically insoluble in acetone	Ph.Eur., 5.11
3.	Identity A. IR spectrum (1 % KBr disc) B. Quality reaction	Conforms to meldonium dihydrate CRS spectrum Positive	Ph.Eur., 2.2.24 Ph.Eur.
4.	Particle size* Greater than 630 µm Smaller than 100 µm	Not more than 5 % Not more than 15 %	Ph.Eur., 2.9.12
5.	Chlorides	Not more than 100 ppm	Ph.Eur., 2.4.4
6.	Sulfates	Not more than 100 ppm	Ph.Eur., 2.4.13
7.	Clarity of solution (10.0 g; 50 mL H ₂ O)	Clear in compare with reference solution I	Ph.Eur., 2.2.1, visual method
8.	Colour of solution (10.0 g; 50 mL H ₂ O)	Not more intensely coloured than reference solution B ₉	Ph.Eur., 2.2.2, method II
9.	pH (10.0 g; 50 mL H ₂ O)	7.5 – 9.0	Ph.Eur., 2.2.3
10.	Water (0.120 g, methanol)	19.7 % - 21.0 %	KF titration
11.	Sulphated ash (1.0 g)	Not more than 0.1 %	Ph.Eur., 2.4.14
12.	Heavy metals [(10 % m/V solution); lead standard solution (1 ppm Pb)]	Not more than 10 ppm	Ph.Eur., 2.4.8, Method A
13.	Related substances: - 3-methyl-(2,2,2-trimethylhydrazinium) propionate bromide - 1,1,1-trimethylhydrazinium salts on the trimethylhydrazinium ion - each unknown impurity	Not more than 0.10 % Not more than 0.10 % Not more than 0.10 %	Ph.Eur., 2.2.29

	- total	Not more than 0.3 %	
14.	Residual solvents - ethanol	Not more than 3000 ppm	Ph.Eur., 2.2.28
15.	Assay calculated on the dried substance	99.0 % – 101.0 %	Ph.Eur., visual titration
16.	Microbiological quality: - Total aerobic microbial count (TAMC) - Total combined yeasts/moulds count (TYMC) - <i>Escherichia coli</i>	Not more than 10^3 CFU/g Not more than 10^2 CFU/g Absence in 1 g	Ph.Eur., 2.6.12, 2.6.13

Notes: * Recommended test