



JSC OlaFarm
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KOPIJA
06.04.2017
GPN mantzine

A. Silineviča

Certificate of Analysis No. 46/2

Name of Product/ Chemical Name	MEBICAR		
CAS No.	10095-06-4		
Order Number	2017 3900		
Batch Number	460417		
Batch Size	120.24 kg	Released from warehouse	25.00 kg
Date of Manufacture	04-2017		
Date of analysis	28.06.2017		
Retest Date	04-2022		
Destination country	Italy		
Name and address of manufacturing site/quality control site	JSC OlaFarm 5 Rupnleu str., Olaine, LV-2114, Latvia		
Number of Manufacturing Authorisation	AFV-01/	Number of certificate of ASMF	Version 03 29.04.2011
Number of GMP certificate	ZVA/LV/2015/011A		

Tests	Specifications according to KFS8.066.028/5	Results
Appearance	White crystalline powder, odourless	White crystalline powder, odourless
Solubility	Freely soluble in water, chloroform, soluble in ethyl alcohol	Conforms
Identification: A. IR spectrum (in 1 % KBr pellet) B., C. Qualitative reactions	Conforms to mebicar-WS spectrum Positives	Conforms Positives
Melting temperature	225.0 °C – 229.0 °C	226.4 °C – 227.3 °C
Clarity of solution (1 g; 10 mL of water)	Clear comparing with reference suspension I	Clear comparing with reference suspension I
Colour of solution (1 g; 10 mL of water)	Not more than reference solution B ₁	Less than reference solution B ₁
pH (10 % solution)	5.9 – 7.5	6.6
Chlorides	Not more than 100 ppm	Less than 100 ppm
Sulfates	Not more than 500 ppm	Less than 500 ppm
Sulfated ash (1.0 g)	Not more than 0.1 %	0.01 %
Loss on drying (0.5 g; 100 - 105 °C)	Not more than 0.5 %	0.28 %
Heavy metals (1.0 g)	Not more than 10 ppm	Less than 10 ppm
Related substances: - 1,3-dimethylurea - 1,3-dimethylhydantoin - each unknown impurity - total	Not more than 0.10 % Not more than 0.10 % Not more than 0.10 % Not more than 0.50 %	Less than 0.01 % Less than 0.01 % Less than 0.01 % Less than 0.01 %
Residual solvents: - isopropyl alcohol - n-butanol	Not more than 5000 ppm Not more than 500 ppm	4085 ppm Less than 20 ppm
Microbiological quality*: - Total aerobic microbial count (TAMC) - Total combined yeasts/moulds count (TYMC) - <i>Escherichia coli</i>	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
Assay, calculated on the dried substance	99.0 % – 101.5 %	100.4 %

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

Approved by N. Vershlovska Head of QC	Date of Signature 28.06.2017	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 and with the requirements of the ASMF.		
Name of the Qualified Person certifying the batch L. Kosmachova	Date of Signature 30.06.2017	Signature of Qualified Person certifying the batch

* Test is carried out for 1st and each 10th batch within a year