JSC Olainfarm
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KOPIJA
08.03.2018
GPN mantzinos
A. Silinevičs

Certificate of Analysis No. 62/2

Name of Product/ Chemical Name	**PHENIBUT**		
CAS No.	3060-41-1		
Order Number	2017 6842		
Batch Number	621217		
Batch Size	176.84 kg	Released from warehouse	50.0 kg
Date of Manufacture	12-2017		
Date of analysis	15.12.2017		
Retest Date	12-2022		
Destination country	Italy		
Name and address of manufacturing site/quality control site	JSC Olainfarm 5 Rupnicu str., Olaine, LV-2114, Latvia		
Number of Manufacturing Authorisation	AFV-01/,	Number of ASMF	DSDoss000125/1
Number of GMP certificate	ZVA/LV/2016/001A		

Tests	Requirements according to KFS8.011.029/6	Results
Appearance	White crystalline powder	White crystalline powder
Solubility	Freely soluble in water, soluble in ethyl alcohol, practically insoluble in acetone and ether	Conforms
Identification: A. IR spectrum in the range (2100-500) cm^{-1} in 1 % KBr tablet B. Qualitative reaction C. Reaction of chlorides	Conforms to phenibut WS spectrum Positive Positive	Conforms Positive Positive
Temperature of beginning of decomposition	194.0 °C – 202.0 °C	196.8 °C
Clarity of solution (1.0 g; 10 mL of water)	Clear	Clear
Colour of solution (1.0 g; 10 mL of water)	Colourless	Colourless
pH (2.5 % solution)	2.3 – 2.7	2.5
Related substances: - 4-Amino-3-phenylbutyric acid ethyl ester - 4-Phenylpyrrolidone-2 - each other unidentified impurity - total impurities	Not more than 0.15 % Not more than 0.15 % Not more than 0.10 % Not more than 0.50 %	**Less than 0.05 %** **Less than 0.03 %** **Less than 0.05 %** **Less than 0.05 %**
Loss on drying (1.0 g; 100 °C – 105 °C)	Not more than 0.5 %	0.03 %
Iron	Not more than 60 ppm	**Less than 60 ppm**
Heavy metals [1.0 g; 1 mL of lead standard solution (10 ppm Pb)]	Not more than 10 ppm	**Less than 10 ppm**
Sulfated ash (1.0 g)	Not more than 0.1 %	0.01 %
Residual solvents: - Acetone - Isopropyl alcohol	Not more than 500 ppm Not more than 500 ppm	**Less than 27 ppm** **Less than 53 ppm**
Assay, calculated on the dried substance	99.0 % – 101.0 %	100.2 %
Microbiological quality*: - Total aerobic microbial count (TAMC) - Total combined yeasts/moulds count (TYMC) - *Escherichia coli*	Not more than 10^3 CFU/1 g Not more than 10^2 CFU/1 g Absence in 1 g	- - -

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

Approved by	Date of Signature	Signature
N.Vershilovska Head of QC	07.03.2018	

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 of the destination country

Name of the Qualified Person certifying the batch	Date of Signature	Signature of Qualified Person certifying the batch
L.Kosmachova	08.03.2018	

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