

MOEHS CATALANA, S.L.

Polígono Rubí Sur

César Martinell i Brunet, 12A - 08191 Rubí (Barcelona - SPAIN)

Tel. (34) 93 586 05 20

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CERTIFICATE OF ANALYSIS

Product: PYRANTEL EMBONATE (PAMOATE) Ph. Eur. 8

Code: 76770

Batch Nr: 333-MC

Manufacture: 11/2016

Re-test Date: 11/2021

Customer: FAGRON IBERICA, S.A.U.

Shipment (Kg): 40,00

Packs: 2

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS		
Appearance	Powder	Conforms
Colour	Pale yellow to yellow	Conforms
Solubility	Conforms to Ph. Eur. & USP	Conforms
IDENTIFICATION		
IR Spectrum	Conforms to Std.	Conforms
SPECIFIC TESTS		
LoD(acetone, eth. acetate, formic a., methyl formate)	Maximum 0,5%	0,03 %
ORGANIC IMPURITIES		
Related Substances (HPLC)		
Impurity C	Maximum 0,10%	0,04 %
Impurity D	Maximum 0,2%	0,08 %
Unspecified impurities (biggest)	Maximum 0,10%	< 0,05 %
Sum of impurities other than D	Maximum 0,3%	< 0,05 %
INORGANIC IMPURITIES		
Sulfated ash	Maximum 0,1%	0,01 %
Chloride	Maximum 360 ppm	< 360 ppm
Iron	Maximum 75 ppm	< 75 ppm
Heavy Metals	Maximum 20 ppm	< 20 ppm
Sulfates	Maximum 0,1%	< 0,1%
ASSAY		
Assay (Potent.) (on dried subst.)	98,0% to 102,0%	101,2 %

We hereby certify that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control, in the above mentioned site in full compliance with the GMP requirements. The batch processing, packaging and analysis records were reviewed and found to be in compliance with ICH Q7, EU GMP Part II and 21 CFR Parts 210 & 211.

Released by QA on 10/01/2017
CoA issued on 17/03/2017
Signed by Quality Control

Pilar Gallego
QC Manager

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TESTS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS IDENTIFICATION UV spectrum HPLC	Conforms to Std. Conforms to Std.	Conforms Conforms
ADDITIONAL TESTS Pamoic acid content (ods) Thioacetamide (HPLC) Assay (HPLC) on dried subst.	63,4% to 67,3% Maximum 60 ppm 97,0% to 103,0%	65,7 % Conforms 99,0 %
ADDITIONAL TESTS RESIDUAL SOLVENTS Acetone Toluene	Ph.Eur. 5.4 & USP 467 Maximum 1500 ppm Maximum 890 ppm	Conforms 88 ppm 35 ppm

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