

CERTIFICATE OF ANALYSIS

Code: 15701

Product : PYRANTEL EMBONATE (PAMOATE) Ph. Eur. 8 / USP 38

Batch Nr: 291-MC

Manufacture: 12/2015

Re-test Date: 12/2020

Client : FAGRON IBERICA, S.A.U.

Shipment (Kg): 40.00

Packs: 1

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS / DESCRIPTION	Powder	Conforms
SOLUBILITY	Pale yellow to yellow	
IDENTIFICATION	Conforms to Ph.Eur. & USP	Conforms
.IR spectrum	Conforms to St	Conforms
.UV spectrum	Conforms to St	Conforms
.HPLC	Conforms to St	Conforms
Related substances (HPLC)		
.Impurity A	Maximum 0.5 p.cent	< 0.05 p.cent
.Impurity B	Maximum 0.2 p.cent	< 0.05 p.cent
.2-Thiophenecarboxaldehyde	Maximum 0.10 p.cent	< 0.02 p.cent
.1,2-Dimethyl-1,4,5,6tetrahydr pyrimidine	Maximum 0.2 p.cent	0.04 p.cent
.Any other unknown impurity	Maximum 0.10 p.cent	< 0.05 p.cent
.Sum of impur other than A & B	Maximum 0.3 p.cent	0.04 p.cent
Pamoic acid content (ods)	63.4 to 67.3 p.cent	65.9 p.cent
Chloride	Maximum 360 ppm <0.036%)	< 360 ppm
Sulfate	Maximum 0.1 p.cent	< 0.1 p.cent
Iron	Maximum 75 ppm <0.0075%)	< 75 ppm
Heavy metals	Maximum 20 ppm (0.002%)	< 20 ppm
Loss on drying (acetone, ethyl acetate, formic ac., methyl formate)	Maximum 0.5 p.cent	0.03 p.cent
Sulfated ash	Maximum 0.1 p.cent	< 0.01 p.cent
ASSAY		
.Potentiom. (on dried subs.)	98.0 to 102.0 p.cent	99.7 p.cent
.HPLC (on dried subs)	97.0 to 103.0 p.cent	99.1 p.cent
Thioacetamide (HPLC)	Maximum 60 ppm	< 60 ppm
ADDITIONAL TESTS		
Residual solvents	Ph.Eur. 5.4 & USP 467	Conforms
.Acetone	Maximum 1500 ppm	50 ppm
.Toluene	Maximum 890 ppm	15 ppm

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 17/12/2015
CoA issued on 13/01/2016
Signed by Quality Control

Pag.: 1/1