

CERTIFICATE OF ANALYSIS

Product : PYRANTEL EMBONATE (PAMOATE) Ph. Eur. 8 / USP 37

Code: 15701

Batch Nr: 276-MC

Manufacture: 01/2015

Re-test Date: 01/2020

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	0.03 p.cent
.1,2-Dimethyl-1,4,5,6-tetrahydr pyrimidine	Maximum 0.2 p.cent	0.05 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	0.08 p.cent
Pamoic acid content (ods)	63.4 to 67.3 p.cent	67.1 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	Maximum 0.5 p.cent	0.09 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	100.0 p.cent
.HPLC (on dried subs)	97.0 to 103.0 p.cent	101.9 p.cent
Thioacetamide (HPLC)	Maximum 60 ppm	< 60 ppm
ADDITIONAL TESTS		
Residual solvents	Ph.Eur. 5.4 & USP 467	Conforms
.Acetone	Maximum 1500 ppm	37 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.

FAGRON IBERICA, S.A.U
Corresponde al lote de Fagron:

LJ504006A

Director Técnico

Released by QA on 20/02/2015
CoA issued on 09/04/2015
Signed by Quality Control

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