



ICROM
S.p.A.

Certificate of Analysis

Product: Metoclopramide hydrochloride

Batch number: 003/10M

Batch size: Kg 500

Analysis number: PF023/10

Quality standard: Eur. Ph. 6th Ed.

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

L13030203

CAS number: 54143-57-6

ICROM code: PF-0010

Manufacturing date: March 2010

Retest date: March 2013

Director Técnico

PARAMETERS	RESULTS	SPECIFICATIONS
<i>Characters:</i>		
Appearance	Complies	White to almost white powder
Solubility in water	Complies	Very soluble
Solubility in ethanol	Complies	Freely soluble
Solubility in methylene chloride	Complies	Sparingly soluble
Melting point	183°C	182°C to 184°C
<i>Identification:</i>		
pH	4.8	4.5 to 6.0
IR	Positive	Positive
Chloride test	Positive	Positive
<i>Tests:</i>		
Solution 10% in water	Clear and colourless	Clear and colourless
Related substances, each one (TLC)	< 0.05%	≤ 0.5%
Heavy metals (Pb)	< 20 ppm	≤ 20 ppm
Impurity F (UV)	< 0.1%	≤ 0.1%
Water (KF)	4.8%	4.5% to 5.5%
Sulphated ash	0.02%	≤ 0.1%
Related substances (HPLC):		
any identified impurity	< 0.05%	≤ 0.2%
any unidentified impurity	< 0.05%	≤ 0.10%
total	< 0.05%	≤ 0.6%
Metanol (GC)	< 500 ppm	≤ 500 ppm
Isopropanol (GC)	< 1500 ppm	≤ 1500 ppm
<i>Assay:</i>		
Potentiometric (dried basis)	100.4%	99.0% to 101.0%

Conclusion: the test results meet with specifications.

Date: April 12, 2010

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Quality Assurance Revision: 13/4/10

Qualified Person Release: 13/4/2010