

Como, 22-04-2010

Page 1 / 2

ANALISI N. F0089/10

Analysis

LOTTO N. 100210002

Batch

Manufacturing date: **March 2010**

Retest date: **March 2015**

Batch size **518 Kg**
PRODOTTO
MEIOCLOPRAMIDE HYDROCHLORIDE PH.EUR.

Product

Physical State Crystalline powder or crystals

Colour White or almost white

Odour Odourless

Solubility Very soluble in water, freely soluble in alcohol, sparingly soluble in methylene chloride

Molecular weight 354,28

Formula C14H22ClN3O2 HCl H2O

Method No 4101

DETERMINATIONS	RESULTS	V	LIMITS USP	LIMITS EP	LIMITS AMSA
IDENTIFICATION					
<i>I.R. Spectrum</i>	Conform			Positive	
<i>TLC</i>	Conform			Positive	
<i>Chlorides</i>	Conform			Positive	
<i>Primary aromatic amines</i>	Conform			Positive	
Melting point <i>on dried</i>	184 °C / 185 °C			About 183°C	
pH (10% in water)	5,39			min. 4.5 max. 6.0	
Appearance of the solution	Clear Colorless			Clear colourless (<B9)	
Related Substances TLC <i>Each</i> <i>N,N-diethylethylendiamine</i>	n.d. n.d.			n.m.t. 0.5% n.m.t. 0.5%	
Heavy Metals	Statistically			n.m.t. 20 ppm	
Water	4,74 %			min. 4.5% max. 5.5%	
Sulphated ash	0,07 %			n.m.t. 0.1%	
Assay <i>NaOH 0.1 N</i> <i>on anhydrous substance</i>	100,09 %			min. 99.0% max. 101.0%	
Impurities (TLC)					
<i>4-amino-5-chloro-2-methoxy benzoic acid</i>	1 t 0,025%				n.m.t. 0.2%
<i>4-acetyl metoclopramide</i>	1 t 0,025%				n.m.t. 0.2%
<i>Me, 4-acetamido-5-chloro-2-methoxy-benzoate</i>	1 t 0,05%				n.m.t. 0.2%
<i>N,N-diethylethylendiamine</i>	1 t 0,025%				n.m.t. 0.2%
<i>Unknown impurity</i>	1 t 0,025%				n.m.t. 0.1%
<i>Total impurities</i>	1 t 0,05%				n.m.t. 0.6%

Laura Ivaldi - (Qualified Person)

Barbara Angeli - (Q.C. Manager)