

Como, 22-04-2010		Page 2 / 2	
ANALISI N. F0089/10 Analysis	LOTTO N. 100210002 Batch		
Manufacturing date: March 2010		Retest date: March 2015	
		Batch size 518 Kg	
PRODOTTO METOCLOPRAMIDE HYDROCHLORIDE PH. EUR.			
Product			
Physical State	Crystalline powder or crystals	Molecular weight	354,28
Colour	White or almost white	Formula	C ₁₄ H ₂₂ ClN ₃ O ₂ · HCl · H ₂ O
Odour	Odourless	Method No.	4101
Solubility	Very soluble in water, freely soluble in alcohol, sparingly soluble in methylene chloride		

DETERMINATIONS	RESULTS	V	LIMITS USP	LIMITS EP	LIMITS AMSA
Related Substances (HPLC)					
4-amino-5-chloro-2-methoxy benzoic acid	1 t 0,02%				n m t 0 2%
4-acetyl metoclopramide	1 t 0,02%				n m t 0 2%
Me, 4-acetamino-5-chloro-2-methoxy-benzoate	1 t 0,02%				n m t 0 2%
Unknown impurity	0,043 %				n m t. 0 10%
Total impurities	0,127 %				n m t. 0 6%
Residual Solvents GC					
Iso-butyl alcohol	186 ppm				n m t 1000 ppm

Class 1 solvent are absent according to ICHQ3C

We hereby certify that the material identified above has been analyzed and found in accordance with the specifications Ph. Eur. and A M S A S p A This batch was manufactured in compliance with detailed GMP and according to ICH Q7A

AMSA

Laura Ivaldi - (Qualified Person)

Barbara Anghin (Q.C. Manager)