

QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
FINISHED GOODS			
Product Name : METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE Ph. Eur.			
Batch No. :	21007MR11	Batch Size :	426.30 Kg
Mfg Date :	Jan/2021	Retest Date :	NA
Expiry Date :	Dec/2025	A.R.No. :	IBD-210935
Lims AR No.:	2102-24216	LIMS Specification ID.:	2102-14
Page No.:	1 of 2	Specification No.:	TS/BPC/M/CS/COS/03

Tests	Results	Specifications
Characters (Appearance)	White crystalline powder	White or almost white, crystalline powder or crystals.
Characters (Solubility)	Conforms	Very soluble in water, freely soluble in ethanol (96%), sparingly soluble in methylene chloride.
Characters (Melting Point)	186°C	It melts at about 183°C with decomposition.
Identification 1	4.67	The pH of solution S is 4.5 to 6.0.
Identification 2	Conforms.	The infrared absorption spectrum of sample and standard are concordant.
Identification 3	Conforms.	The solution gives reaction (a) of chlorides.
Appearance of Solution	Conforms.	A 10% solution is clear and colourless.
Impurity E (By TLC)	< 0.5%	Impurity E : NMT 0.5%
Related Substances (By UPLC)	BQL	Any Unspecified Impurity NMT 0.10%
	BQL	Total Impurities NMT 0.20%
Water	5.09 %w/w	4.5% w/w to 5.5% w/w.
Sulphated Ash	0.07 %w/w	NMT 0.1% w/w.
Assay	100.2 %w/w	99.0% - 101.0% w/w of

Checked By (QC)	Amit Kumar Singh	Approved By (QA)	Rajendra Singh
Checked On	19/02/2021 15:43	Approved On	23/02/2021 09:59
Printed By : Rajendra Singh	Printed on :	23/02/2021 10:03	Copy No. : 1
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Tests	Results	Specifications
		C ₁₄ H ₂₃ Cl ₂ N ₃ O ₂ (on anhydrous basis).
Residual Solvents (By GC)	BDL	Methanol NMT 3000 ppm
	300ppm	Isopropyl Alcohol NMT 3000 ppm
	BDL	Toluene NMT 50 ppm
REMARKS : The sample CONFORMS with respect to the above specifications		

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