

26/05/2023

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METAPHARMACEUTICAL

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0340523



QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
FINISHED GOODS			
Product Name : METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE Ph. Eur.			
Batch No. :	22014M1RII	Batch Size :	586.20 Kg
Mfg Date :	Dec/2022	Retest Date :	NA
Expiry Date :	Nov/2027	A.R.No. :	IBDA-230944
Lims AR No.:	2102-51469	LIMS Specification ID.:	2102-14
Page No.:	1 of 2	Specification No.:	TS/API/M/COS/4.0

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)	184°C	It melts at about 183°C with decomposition.
Identification 1	4.69	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	0.05 %w/w	NMT 0.1% w/w.
Assay	100.3 %w/w	99.0% - 101.0% w/w of $C_{14}H_{23}Cl_2N_3O_2$ (on

Checked By (QC)	Amit Kumar Singh	Approved By (QA)	Himanshu Bhopte
Checked On	07/Apr/2023 16:44	Approved On	08/Apr/2023 17:46
Printed By : Anil M. Sharma	Printed on :	08/04/2023 17:47	Copy No. : 1
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Tests	Results	Specifications
		anhydrous basis).
Residual Solvents (By GC)	Not Detected	Methanol NMT 3000 ppm
	Less than 210 ppm	Isopropyl Alcohol NMT 3000 ppm
	BDL	Toluene NMT 50 ppm
REMARKS : The sample CONFORMS with respect to the above specifications		

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