

CERTIFICATE OF ANALYSIS

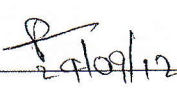
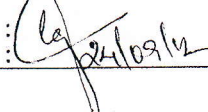
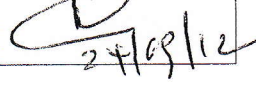
Commercial batch # : CTH/1209265	Dispatch Qty. : 40.00 Kg
In-house Batch # : 2CTH9/12245	Batch Qty. : 66.20 Kg
Mfg. Date : September- 2012	Retest. Date : August - 2016
Specification # : QCD/SP/FP/CTH/004-R ₃	Method # : QCD/MH/FP/CTH/004-R ₂

SI. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters - Appearance - Solubility	Almost white crystalline powder Meets the requirement	White or almost white crystalline powder Sparingly soluble in water and in anhydrous ethanol.
2	Identification - Optical rotation - IR absorption spectrophotometry - Test for Bromide	Meets the requirement Meets the requirement Positive	Should be positive. The IR absorption spectrum of sample should be concordant with that of working standard Should be positive
3	Loss on drying at 105°C for 4 hrs	0.20%	Not more than 0.5%
4	Optical rotation (5% solution in methanol at 20°C)	0.01°	Between -0.10° and + 0.10°
5	Sulphated ash	0.03%	Not more than 0.1%
6	Heavy metals	Less than 20 ppm	Not more than 20ppm
7	Related substances by HPLC Impurities at 230 nm - Impurity - B - Impurity - D - Maximum unspecified impurity - Sum of the impurities (Other than impurity-G) Impurities at 254 nm - Impurity -G	Not detected Not detected Below disregard limit (0.05%) Not found Below detection limit (0.0040%)	Not more than 0.15% Not more than 0.2% Not more than 0.10% Not more than 0.5% Not more than 0.15%
8	Assay by Potentiometry (on dried basis)	99.7%	99.0% - 101.5%
9	Additional tests a) Residual solvents - Methanol - Isopropyl Alcohol - Toluene	53ppm 93 ppm Below detection limit(0.5 ppm)	Not more than 500ppm Not more than 500ppm Not more than 100 ppm

Remark: The product complies with the above specification + Customer's specification (CSO# CSO/506-R₁/12).

Storage condition: Store in airtight containers below 25°C

Note: The values given in the parenthesis are of Below detection limit and disregard limit of residual solvents and HPLC

PREPARED BY : 	CHECKED BY : 	APPROVED BY : 
Date : 24/09/12	Date : 24/09/12	Date : 24/09/12

A Jubilant Bhartia Company

OUR VALUES



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