

CERTIFICATE OF ANALYSIS
TIOTROPIUM BROMIDE MONOHYDRATE

Material: 40D3TIMHN0

Batch: TIMHN0S003

Testing date: 20.07.2017

Test	Specification	Result
Description	White or yellowish-white powder or crystals	Complies
Identification		
a) by IR	IR absorption spectrum of the test sample complies with the spectrum of RS	Complies
b) by Bromides test	Positive	Complies
c) by HPLC	Positive	Complies
Color of solution	The 1% aqueous solution is not more intensely colored than reference solution Y6	Complies
Clarity of solution	1% aqueous solution is clear	Complies
Residue of ignition	Not more than 0.1%	0.0 %
Water content	2.5% - 4.0%	3.1 %
Assay by titration (calculated on anhydrous substance)	98.5 - 101.5%	100.1 %
Assay by HPLC (calculated on anhydrous substance)	98.0 - 102.0%	101.0 %
Related substances by TLC:		
Impurity G	Not more than 0.1%	<0.1 %
Impurity H	Not more than 0.1%	<0.1 %
Related substances by HPLC:		
Each impurity	Not more than 0.10%	<0.05 %
Total impurity	Not more than 0.2%	0.00 %
Acetic acid content by HPLC	Not more than 1000 ppm	<500 ppm

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Test	Specification	Result
Residual solvents by GC:		
Acetonitrile	Not more than 410 ppm	0 ppm
Dichloromethane	Not more than 600 ppm	2 ppm
Methanol	Not more than 1000 ppm	0 ppm
Toluene	Not more than 890 ppm	0 ppm
Acetone	Not more than 1000 ppm	0 ppm
Dimethylformamide	Not more than 880 ppm	0 ppm
X-Ray diffraction	XRD-gram corresponds to reference XRD-gram	Complies
Methyl Bromide content by GC	Not more than 100 ppm	0 ppm
PSD	D10 Not more than 1.0 µm D50 Not more than 2.5 µm D90 Not more than 5.0 µm	0.8 µm 1.8 µm 3.5 µm
Manufacturing date : June 2017 Retesting date : May 2022		

Conforms with current EP specification.

Legends of names:

<u>Wavelength API name</u>	<u>Ph. Eur. Name (Tiotropium Bromide monograph)</u>	<u>Chemical name</u>
Impurity G	Impurity G	(1R,2R,4S,5S,7s)-7-hydroxy-9,9-dimethyl-3-oxa-9-azoniatricyclo[3.3.1.0 ^{2,4}]nonane bromide
Impurity H	Impurity H	(1s,3RS,4RS,5RS,7SR)-4-hydroxy-6,6-dimethyl-2-oxa-6-azoniatricyclo[3.3.1.0 ^{3,7}]nonane bromide

Maya Kobin
 QA Engineer
 Date: 12 / 11 / 2019

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