



CERTIFICATE OF ANALYSIS

Product name	Tiotropium Bromide (CAS: 136310-93-5)		
Batch No.	20190303	Expiry date	2021-03-03
Report Date	2019-03-12	Quantity	5kg

Inspection Items	Accepted Standard	Results
Appearance	White or yellowish-white powder or crystals	Complies
Solubility	Sparingly soluble in water. Soluble in methanol. Practically insoluble in methylene chloride	Complies
Identification	A. Infrared absorption spectrophotometry. Comparison: tiotropium bromide monohydrate CRS.	Complies
	B. It gives reaction of bromides	Complies
Appearance of solution	The solution is clear and not more intensely colored than reference solution Y ₆	Complies
Impurities G and H	not more than 0.1%	Complies
Related substances	Impurity C: not more than 0.3%; Impurity F: not more than 0.15%; Impurity A, E: not more than 0.15%; Unspecified impurity: not more than 0.1%	Complies
	Total Impurities: Not more than 0.3%	0.06%
Heavy metals	not more than 10ppm	Complies
Residual Solvent	Methanol: not more than 3000ppm	Complies
Water	not more than 0.5%	0.28%
Sulfated ash	≤0.1%	0.03%
Assay	≥99.0%	99.91%
Conclusion : Conform to EP 8.0 standard		

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