



CERTIFICATE OF ANALYSIS

PRODUCT NAME:	TOLTERODINE TARTRATE <i>2-[(1R)-3-[Bis(1-methylethyl)amino]-1-phenylpropyl]-4-methylphenol (2R,3R)-2,3-dihydroxybutanedioate (1:1)</i>		
FORMULA:	$C_{22}H_{31}NO \cdot C_4H_6O_6$		
MOLECULAR WEIGHT:	475.6		
BATCH No:	A181213002	QUANTITY:	5 Kg
MANUFACTURING DATE:	DECEMBER 2018	RETEST DATE:	DECEMBER 2022
ANALYSIS DATE:	DECEMBER 2018	RELEASE DATE:	DECEMBER 2018

PARAMETERS	METHODS	SPECIFICATIONS	RESULTS
Appearance	Visual inspection	White to off-white crystalline powder	Conform
Identification	A: Company (IR)	Conforms to structure	Conform
	B: Tartrate - USP <191>	A reddish-pink color is produced within 15 minutes	Conform
Water Content	Karl Fisher	NMT 0.5%	0.1%
Heavy Metals	EP 2.4.8 C	NMT 20 ppm	<20 ppm
Residue On Ignition	EP 2.4.14	NMT 0.1%	0.0%
Specific Optical Rotation	EP 2.2.7 ([α] _D 20°C, c=0.4%, MeOH)	+27.0° - +31.0°	+27.9°
Tartaric Acid Content	Potentiometric Titration	30.9% - 32.2%	31.6%
Assay	Potentiometric Titration	98.0% - 102.0%	101.9%
Related substances ¹	HPLC Company	Impurity A NMT 0.15%	<0.01%
		Impurity B NMT 0.15%	<0.01%
		Impurity C NMT 0.15%	<0.01%
		Single Unknown NMT 0.10%	0.08%
		Total Impurities NMT 0.5%	0.2%
Enantiomeric Purity	HPLC Company (Area %)	(S)-Tolterodine NMT 0.5%	<0.1%
Residual Solvents	GC Company	Ethanol NMT 1000 ppm	229 ppm
		Isopropanol NMT 1000 ppm	69 ppm
		Toluene NMT 500 ppm	<115 ppm
Particle Size Determination	Malvern (Company)	D ₉₀ 40 – 10 μm	31 μm
		D ₅₀ NMT 20 μm	12 μm

¹Legenda of Impurities:

Impurity A: *Diisopropyl-(3-phenyl-allyl)-amine*

Impurity B: *4-methyl-phenol*

Impurity C: *(Diisopropyl-(3-phenyl-3-p-toloxyl-propyl)-amine sulfate*

18 December 2018

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