



武汉福鑫化工有限公司

Wuhan Fortuna Chemical Co.,Ltd

地址：武汉市金桥大道107号凯信大厦2号楼2015-2016室
Address: Room 2015-2016, No.2 Building, Kaixin Mansion, No.107 Jinqiao Avenue, Wuhan, China.
Tel: +86-27-85767163, 59207850 Fax: +86-27-59524646 Zip code: 430013
Website: www.fortunachem.com E-mail: sales@fortunachem.com info@fortunachem.com

Certificate of Analysis

Name of product : Tamsulosin Hydrochloride Date of manufacturing: 2020/08/01
Packing: 1KG/drum Date of check: 2020.08.03
Batch weight: 3.2kg Batch No: 20080110
Date of expiry: 2022.07.31

ITEMS	SPECIFICATIONS	RESULTS
Characters	White or almost white powder	Complies
Solubility	Slightly soluble in water, slightly soluble in anhydrous ethanol, freely soluble in formic acid	Complies
Melting point	About 230 °C	Complies
Identification	1. IR: corresponds to IR spectrum of the reference substance	Complies
	2. Specific optical rotation: -17° to -20.5°	-19.2°
	3. Enantiomeric purity: dextroisomer meets the requirement	Complies
	4. UV: compare the spectrum with the reference spectrum, both spectra exhibits similar intensities of absorption at the same wavelengths.	Complies
	5. Chemical reaction: it gives the reaction of Chlorides	Complies
Related substances	Unspecified impurities $\leq 0.10\%$	0.04%
	Total impurities $\leq 0.2\%$	0.08%
Enantiomeric purity	Impurity G $\leq 0.1\%$	Not detected
Loss on drying	$\leq 0.5\%$	0.06%
Sulphated ash	$\leq 0.1\%$	$< 0.05\%$
Heavy Metals (Pb)	≤ 20 ppm	< 20 ppm
Residual solvents	Methanol $\leq 0.1\%$	Not detected
	Ethanol $\leq 0.3\%$	0.02%
	Acetone $\leq 0.5\%$	$< 0.01\%$



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	Acetonitrile $\leq 0.01\%$	Not detected
	Methylene chloride $\leq 0.06\%$	Not detected
Microbial Limits	Total Aerobic Microbial count $\leq 500\text{cfu/g}$	$< 10\text{cfu/g}$
	Total Yeasts and Moulds count $\leq 50\text{cfu/g}$	$< 10\text{cfu/g}$
	Escherichia Coli : Absent	Not detected
Assay	99.0% – 101.0% (Dried substances)	100.05%
Conclusion:	The product complies with EP specification.	

Director: Luo Xiaofeng

Re-tester: AT02

Tester: AT03