

瑾 岚 医 药 技 术 开 发 有 限 公 司

JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED Hangzhou ROYAL Import & Export Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product Name	(3R)-N-methyl-3-(2-methylphe noxy)-3-phenylpropan-1-amine hydrochloride (technical)		Batch NO.	RY190707
Production date	2019.07.07		Expired Date	2021.07.06
CAS NO.	82248-59-7		standard	Enterprise standard
Tests		Limits		Test results
Appearance		White or off-white powder, odourless		Conforms
Solubility		It is easy to soluble in absolute ethanol, slightly soluble in water, and almost insoluble in heptane		Conforms
Melting point		166℃~169℃		167.5℃~168℃
Specific rotation		-34.0°~-38.0°		Conforms
Identification		Retention time of the main peak of the test product and the main peak of the reference product are the same		Conforms
		The infrared light absorption spectrum should be consistent with the reference spectrum		Conforms
		Identification of chlorides in aqueous solution of this product		Positive
		O-cresol≤0.10%		Conforms
		Amphetamine≤0.10%		N.D.
		Phenylpropanolamine≤0.10%		N.D.
Related substances		Dimethyl tomoxetine≤0.10%		N.D.
		Desmethoxetine≤0.3%		0.03%
		The single impurity ≤0.10%		0.04%
		The total	0.14%	
Enantiomer		≤0.15%		0.001%
M-tomoxetine		≤0.10%		N.D.
P-tomoxetine		≤0.10%		N.D.

	Methanol≤0.30%	0.18%
	Dichloromethane≤0.06%	N.D.
D. H. L. L.	N-hexane≤0.029%	N.D.
Residual solvents	Ethyl acetate≤0.50%	N.D.
	Cyclohexane≤0.388%	N.D.
	Toluene≤0.089%	N.D.
Loss on drying	≤0.50%	0.09%
Residue on ignition	≤0.10%	0.04%
Heavy metal	≤10ppm	NORUCE JANForms
Assay (drying)	98.0%~102.0%	是有数数数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据数据
Conclu	sion: This batch meets enterprise standa	ard. 质检专用章

Tested by:

Esther

Checked by: Alice

Approved by: Mich