

CERTIFICATE OF ANALYSIS

Product Name	doxazosin mesylate	Batch NO.	RY190606
Production date	2019.06.06	Expired Date	2021.06.05
CAS NO.	77883-43-3	Standard	Enterprise standard
Tests	Limits	Test results	
Appearance	White or of white crystalline powder, odourless tasteless, lightly soluble in water, methanol solution, soluble in mixed solution of 15 volume water and 35 volume furanidine,almost unsoluble in acetone.	Conform	
Identification	The retention time of the main peak of the supplier should be consistent with the retention time of the control peak of Doxazosin mesylate.	Conform	
	The infrared absorption spectra of this product should be consistent with the control map(spectral set 733)	Conform	
PH	2.5~4.5	3.8	
CI	≤0.06%	Conform	
Related substance	Each impurity ≤0.10%	0.045%	
	The total impurities ≤0.30%	0.06%	
Organic solvent residue	Methanol ≤0.3%	N.D.	
	Ethyl acetate ≤0.5%	N.D.	
	N-butanol ≤0.5%	N.D.	
	Toluene≤0.089%	N.D.	
	Dichloromethane≤0.06%	N.D.	
Heavy metals	≤20ppm	Conform	
Loss on drying	≤1.0%	0.48%	
Methyl methanesulfonate	≤1900ppm(0.19%)	N.D.	
Residue on ignition	≤0.1%	0.1%	
Assay	98.0%~102.0%	100.9%	
Microbial limit	Should be met the requirement	Conform	
Conclusion: This batch meets enterprise standard			

Tested by: Esther

Checked by: Alice

Approved by: Mich