

CERTIFICATE OF ANALYSIS

Product Name	Tolterodine tartrate	Batch NO.	RY180906
Production date	2018.09.06	Expired Date	2021.09.05
CAS NO.	124937-52-6	Standard	Enterprise standard
Tests	Limits	Test results	
Appearance	White crystalline powder odourless	Conforms	
Solubility	Light soluble in methanol and water almost insoluble in chloroform	Conforms	
EE	≤99.0%	99.5%	
Identification	Positive	Conforms	
	λ max282	Conforms	
	Positive	Conforms	
	Positive	Conforms	
PH	3.0~4.5	3.7	
Chloride	Positive	Positive	
Sulphate	Positive	Positive	
Impurity HPLC	The single impurity ≤0.50%	0.05%	
	The total impurity ≤0.1%	0.1%	
Residue on ignition	≤0.1%	0.04%	
Heavy metals	≤20ppm	conform	
Water	≤0.50%	0.1%	
Assay	≥98.5%	99.7%	
Conclusion: This batch meets enterprise standard			

Tested by: Esther

Checked by: Alice

Approved by: Mich