



Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product Name	Mirabegron		
Batch No.	D5401-21-001	Batch Size	52.58Kg
Batch Type	Commercial	Report Date	2021-12-16
Retest Date	2024-10	Storage Condition	Preserved in a well-closed container
Manufacture Date	2021-11-25	Reference	EDMF standard
Test Items	Specifications	Results	
Appearance	White or off-white crystalline powder	Off-white crystalline powder	
Identification	1) The infrared absorption spectrum is in accordance with the spectrum obtained with Mirabegron RS.	Conforms	
	2) The retention time of the major peak in the chromatogram obtained with test solution conform to that in the chromatogram obtained with reference solution as Assay test.	Conforms	
Water	≤0.5%	<0.1%	
Sulfated ash	≤0.1%	<0.1%	
Isomer (HPLC)	≤0.15%	0.08%	
Related substances(HPLC)	Phenethylamine amino thiazole	≤0.15%	
	Amino compound	≤0.15%	
	Any unspecified impurity	≤0.10%	
	Total impurities	≤0.5%	
Assay (HPLC)	98.0%-102.0%(on anhydrous basis)	99.7%	
Elemental Impurities	Pd	≤10ppm	
Residual Solvents (GC)	Methanol	≤3000ppm	
	Ethanol	≤5000ppm	
	Dichloromethane	≤600ppm	
	Ethyl acetate	≤5000ppm	
	Tetrahydrofuran	≤720ppm	
	Toluene	≤890ppm	
Conclusion	Complies with EDMF standard		

