

HANGZHOU HUADONG MEDICINE GROUP
ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD.
CERTIFICATE OF ANALYSIS
MIRABEGRON

Batch No.: C036-52104001	Manu. date: 2021.04.24
Packing: 1kg/bag	Anal. date: 2021.05.20
Quantity: 1kg	Ret. date: 2022.09

TESTS	SPECIFICATIONS	RESULTS
Appearance	White to off white powder	Conforms
Identification	IR Absorption: comply with the one of reference standard	Conforms
	By HPLC: The retention time of the major peak in the chromatogram of HPLC corresponds to that in the chromatogram of system suitability preparation.	Conforms
Water content	Not more than 0.5%	0.14%
Residue on ignition	Not more than 0.1%	0.04%
Heavy metal	Not more than 20ppm	Conforms
Palladium content	Not more than 10ppm	Conforms
Enantiomer	Not more than 0.2%	0.04%
Related substance	Z-168: not more than 0.10%	0.01%
	SC03610: not more than 0.1%	0.02%
	SC03612: not more than 0.1%	ND
	SC03621: not more than 0.1%	0.03%
	RRT1.06: not more than 0.10%	0.08%
	Other unknown impurity: not more than 0.10%	0.05%
	Total impurity: not more than 0.2%	0.08%
2-(2-aminothiazol-4-yl) acetic acid	Not more than 0.1%	ND
SC03653	Not more than 0.1%	0.004%
Residual solvent	Methanol not more than 0.3%	0.0003%
	Ethanol not more than 0.5%	0.0001%
	Isopropyl alcohol not more than 0.5%	ND
	Ethyl acetate not more than 0.5%	0.002%
	THF not more than 0.072%	ND
	Toluene not more than 0.089%	ND
	Dichloroethane not more than 0.0005%	ND
	Benzene not more than 0.0002%	ND
	Trethylamine not more than 0.032%	ND
	DMF not more than 0.088%	ND
	Acetic acid not more than 0.5%	0.01%
Assay	On anhydrous basis, C ₂₁ H ₂₄ N ₄ O ₂ S: 98.0%-102.0%	100.1%

Conclusion: Be up to the in-house standard

QC Director 方勇

Checked by 丁李花

Analyzed by 聂高强