



武汉福鑫化工有限公司

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Certificate of Analysis

Product: Irbesartan

Batch No.: 20903

Manuf No.: 2020-09-29

Quantity: 720kgs

Expiry Date : 2025-08

TEST ITEMS	STANDARD PRESCRIBE	RESULTS
Appearance	White or off-white crystalline powder	White powder
Solubility	Slightly soluble in alcohol and methylene Chloride, practically insoluble in water	Qualified
Identification	IR	Similar to standard
	HPLC	The retention time is similar to standard
Related impurities(HPLC)	Related compound A: NMT 0.2% Individual impurities: NMT 0.1% Total impurities: NMT 0.5%	0.14% 0.08% 0.29%
Water	Not more than 0.5%	0.41%
Residue on ignition	Not more than 0.1%	0.08%
Residue Azide	Not more than 10ppm	Qualified
Assay(HPLC)	Not less than 98.0% and not more than 102.0% of Irbesartan Calculated on the anhydrous basis	99.68%
Particle size	90% < 50microns	Pass
Conclusion	It complies with the requirements of the USP standard.	

QC: Luo Xiaofeng

Test: AT02

Re-test: AT03