

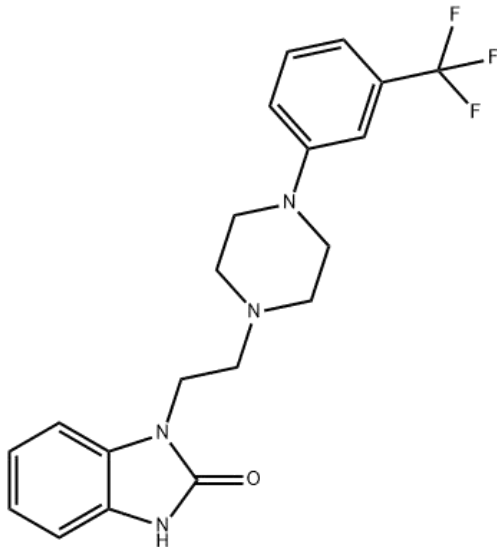


Wuhan HengHeDa Pharm Co., Ltd

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Wuhan Economic& Technological Development Zone, Wuhan, China

CERTIFICATE OF ANALYSIS

Product name	Flibanserin	
CAS NO	167933-07-5	
Molecular formul	C20H21F3N4O	
Molecular weight	390.4	
Quantity	30Kg	
Batch NO	HHD20220515	
Production date	2022.05.15	
Expiry Date	2024.05.14	
Test based on enterprise standard		
Test Item	Specification	Result
Appearance	White to off white powder.	Conforms
Identification	IR spectrum of the sample is concordant with the standard spectrum of Flibanserin.	Conforms
	Retention time of principle peak in the chromatogram obtained with the sample solution should match with that of the principal peak in	Conforms

	chromatogram obtained with standard solution in the test for “Assay by HPLC.”	
Assay (HPLC)	≥99.0%	99.8%
Melting range(°C)	158-165	160-162
Solubility	Soluble in dichloromethane and slightly soluble in methanol and ethanol.	Conforms
Heavy Metals (ppm)	Not more than 10	Conforms
Residue on ignition (% w/w)	Not more than 0.1	Conforms
Chromatographic purity by HPLC (% area) a)Any individual impurity b)Total impurities	Not more than 0.10 Not more than 0.50	0.06 0.11
Residual solvents by GC (ppm) a) Ethanol b) Isopropyl alcohol c) Acetone	Not more than 5000 Not more than 5000 Not more than 5000	Total200
Loss on drying (% w/w)	Not more than 0.5	0.3
XRD	XRD pattern of sample should confirm to polymorph form-A	Conforms
PSD (μm)	D (90): For information	Conforms

Storage	Store in cool & dry place, keep away from strong light and heat.
Shelf life	2 years when properly stored.
Conclusion: This product complies with above specification.	

Inspector

Shen Wu

Director

King Yang

