Hangzhou Huarong Pharm Co.,Limited

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Certificate of Analysis

Product Name	Aripiprazole		
Batch No.	5169-23-002M	**Batch Size**	90.98kg
Batch Type	Commercial	**Report Date**	2023-01-23
Retest Date	2025-01-03	**Storage Condition**	Preserved in an airtight container under room temperature (up to 25°C)
Manufacture Date	2023-01-04	**Reference**	R1-CEP 2014-011-Rev 00

Test	Specification	Results
Appearance	White or almost white crystals or crystalline powder	Almost white crystalline powder
Appearance of solution	The solution is clear and not more than intensely coloured than reference solutionGY5	Conforms
Identification	The infrared absorption spectrum is in accordance with the spectrum obtained with Aripiprazole RS	Conforms
Identification	The retention time of the major peak in the chromatogram obtained with test solution is similar to the retention time of the major peak in the chromatogram obtained with reference solution as Assay test.	Conforms
Identification	The x-ray power diffraction spectrum is in accordance with the spectrum obtained with Aripiprazole RS and has characteristic peaks at 2θ=11.0±0.2°, 16.6±0.2°, 19.3±0.2°, 20.3±0.2°, 22.1±0.2°	Conforms
Loss on drying	≤0.5%	0.1%
Sulfated ash	≤0.1%	<0.1%
Assay(HPLC)	98.0~102.0% (on dried basis)	99.9%
Impurity 7-CBQ	≤50ppm	N.D
Related substances(HPLC) Any unspecified impurity	≤0.10%	<LOQ
Related substances(HPLC) Total impurities	≤0.2%	<LOQ
Residual solvents(GC)	Ethanol≤5000ppm	N.D
Residual solvents(GC)	Toluene≤890ppm	N.D
Residual solvents(GC)	n-Hexane≤290ppm	N.D
Residual solvents(GC)	Butanone≤5000ppm	98ppm
Residual solvents(GC)	Acetone≤5000ppm	<LOD
Residual solvents(GC)	N,N-Dimethylformamide≤880ppm	N.D
Conclusion	Complies with R1-CEP 2014-011-Rev 00	

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