

## CERTIFICATE OF ANALYSIS

<b>Product Name:</b>	<b>Aripiprazole</b>		
<b>Batch No.</b>	5735-23-001	<b>Batch Size</b>	86.005kg
<b>Manufacturing Date</b>	April 5, 2023	<b>Expiry Date TO</b>	April 4, 2027
<b>Report Date</b>	October 27, 2023	<b>Reference</b>	USP
<b>Analytical results</b>			
<b>Items</b>	<b>Specifications</b>		<b>Results</b>
<b>Appearance</b>	White to off-white crystalline powder		Off-white crystalline powder.
<b>Identification</b>	The infrared absorption spectrum is in accordance with the spectrum obtained with Aripiprazole RS		Conform
	The retention time of the major peak in the chromatogram obtained with sample solution is similar to the retention time of the major peak in the chromatogram obtained with standard solution as Assay test		Conform
<b>Loss on drying</b>	≤0.5%		0.1%
<b>Residue on ignition</b>	≤0.1%		<0.1%
<b>Related substances (HPLC)</b>	Aripiprazole related compound F ≤0.10%		<LOD
	Aripiprazole related compound G ≤0.10%		<LOD
	Aripiprazole 4,4 - Dimer ≤0.10%		<LOQ
	Any other individual impurity ≤0.10%		0.04%
	Total impurities ≤0.50%		0.04%
<b>Assay (HPLC)</b>	98.0~102.0% (on dried basis)		99.90%
<b>Residual solvents(GC)</b>	Ethanol ≤5000ppm		<LOD
	n-Hexane ≤290ppm		N.D
	Butanone ≤5000ppm		373ppm
	Acetone ≤5000ppm		27ppm
	DMF ≤880ppm		N.D
<b>Storage Condition</b>	Preserve in tight containers, store at controlled room temperature		
<b>Conclusion</b>	Complies with USP		

Inspector: Carlifor Wu

Verifier: Jack He