



Anhui Ailead Pharmaceutical Co., Ltd.

Certificate of Analysis

Report No. :Y2022040601

Pimavanserin Tartrate

Cas # 706782-28-7

Batch No.	210406	Quantity	10.0 kg
Package	LDPE	Test Date	Apr.6. 2022
Storage	Preserve in tight containers	Retest Date	Apr.5. 2024

Test Standards: In-house Standards

Items	Specification	Results
【Appearance】	White to off-white powder	White powder
【Solubility】	Freely soluble in Hydrochloride solution (0.10mol/l);slightly soluble in EtOH and THF;nearly not soluble in MeCN and sodium hydroxide (0.1mol/l)	Conforms
【HPLC Identification】	The retention time of the main peak of the solution should be consistent with the retention time of the main peak of the reference solution	Conforms
【IR Identification】	The IRS should be consistent with that of standard sample	Conforms
【Chloride】	Not more than 0.05 %	Conforms
【Sulphate】	Not more than 0.02 %	Conforms
【Related Substance】	Impurity A not more than 0.15 %	Not detected
	Impurity B not more than 0.15 %	Not detected
	Impurity C not more than 0.15 %	Not detected
	Impurity D not more than 0.15 %	Not detected
	Impurity E not more than 0.15 %	0.04%
	Impurity F not more than 0.15 %	Not detected
	Impurity G not more than 0.15 %	0.02%
	Other unknown single impurity not more than 0.10 %	0.01%
	Total Impurity not more than 1.00%	0.11%
【Residual Solvents】	Methanol not more than 0.30%	Not detected
	Ethanol not more than 0.50 %	Not detected
	Dichloromethane not more than 0.06 %	Not detected
	Ethyl Acetate not more than 0.50 %	Not detected
	TetraHydroFuran not more than 0.072 %	Not detected
【Water】	Not more than 1.00 %	0.27%
【Residue on Ignition】	Not more than 0.10 %	0.04%
【Heavy metal】	Not more than 10 ppm	Conforms

【Microbial limits】	Total aerobic bacteria count (TAMC) not more than 1000 cfu/g	Conforms
	Total Yeast and Mold count (TYMC) not more than 100 cfu/g	
	Escherichia coli not detected	
【Tartrate acid】	It should be 13.4%~16.4%	15.2%
【Assay】	On dry basis, it should contain $C_{25}H_{34}FN_3O_2 \cdot 2 \cdot C_4H_4O_6$ 98.0% ~102.0%	99.50%
Analyst/Date	Apr. 6. 2022	
Checker/Date:	Apr. 7. 2022	
Supervisor/Date	Apr. 7. 2022	
FINAL BATCH DISPOSITION		
Approved (√) <input type="checkbox"/> By/Date: _____		