

CERTIFICATE OF ANALYSIS

Product Name:	Mirtazapine (anhydrous)		
Batch No.	A125(B)-2209001	Standard	EP9.0
Specification	/	Manufacturing Date	September 19, 2022
Quantity	163.6KG	Retest Date	September 18, 2025
Analytical Results			
Items	Specifications	Results	
Character	White or almost white crystalline powder	Conforms	
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol	Conforms	
Identification	The IR absorption spectrum is accordant with the spectrum obtained with the reference standard	Conforms	
Specific rotation	-1.0° ~ +1.0°	0.0°	
Water	≤1.0%	0.50%	
Sulfated ash	≤0.10%	0.04%	
Residual solvents	Ethanol ≤5000ppm	87ppm	
Related substances	Impurity A ≤0.10%	<0.03%	
	Impurity B ≤0.10%	<0.03%	
	Impurity C ≤0.10%	<0.03%	
	Impurity D ≤0.10%	<0.03%	
	Impurity E ≤0.10%	<0.03%	
	Impurity F ≤0.10%	<0.03%	
	Individual impurity ≤0.10%	<0.03%	
	Total impurities ≤0.50%	<0.03%	
Assay	98.0~ 102.0%(anhydrous substance)	100.10%	

Conclusion: The product tested complies with the specification

Inspector: Carlifor Wu

