

Certificate of Analysis

Product: Citicoline Sodium		
Batch No.: MB201005	Quantity:170kg	
Date of Manufacture: 2020-10-05	Date of Expire: 2022-10-04	
Date of Analysis: 2020-10-07	Date of Certificate: 2020-10-08	
Analysis according: Chinese Pharmacopeia 2010		
Items	Requirements	Results
Appearance	White powder or crystalline powder,smell-less.Easily soluble in water,insoluble in ethanol,acetone and chloroform.	Conforms
Identification	Conforms	Conforms
Acidity	6.0~7.5	6.5
Clarity and color of solution	Should be clear and colorless	Conforms
Chlorides	≤0.05%	Conforms
Ammonium	≤0.05%	Conforms
Iron	≤0.01%	Conforms
Phosphate	≤0.1%	Conforms
Related substance	1)5'-CMP: ≤0.3% 2)The other largest impurities: ≤0.2% 3)Total impurities: : ≤0.7%	1)0.069% 2)0.019% 3)0.040%
Residual Sovents	1) Methanol: ≤0.3% 2) Ethanol: ≤0.2% 3) Acetone: ≤0.5%	1) Not detected 2) Not detected 3) Not detected
Loss on drying	≤6.0%	1.9%
Heavy metals	≤10ppm	Conforms
Arsenic	≤0.0001%	Conforms
Endotoxin	≤0.3EU/mg	Conforms
Contents (on dry basis)	≥98.0%	99.7%
Conclusion: the product complies with specification.		

QA manager:

樊斌

Re-tester:

向亮

Analyst:

孙刚正

Recommend Storage: In an air tight container, protected from light at temperature 2-8°C.