Certificate of Analysis

Product Name:	Citicoline Sodium	CAS No.:	33818-15-4
Batch Number:	LYPH220712	Manufacture Date:	Jul.12, 2022
Batch Quantity:	500 KG	Certificate Date:	Jul.16, 2022
Analysis Standard:	ChP 2015 Part II	Expiration Date	Jul.11, 2024
Grade:	Pharmaceutical Grade	Molecular Formula	C ₁₄ H ₂₅ N ₄ NaO ₁₁ P ₂

Appearance White powder or crystalloid powder, smell less. Soluble easily in water, insoluble in ethanol, acetone. Positive reaction The retention time of a major peak meets the requirements. IR: consistent with the spectrum obtained with reference substance. Show sodium flame Positive reaction	Item		Standard	Results	
The retention time of a major peak meets the requirements. IR: consistent with the spectrum obtained with reference substance. Show sodium flame Positive reaction	Appearance)			
Identification	Identification		Chemical reaction	Positive reaction	
IR: consistent with the spectrum obtained with reference substance. Show sodium flame Positive reaction				e Complied	
Acid Value 6.0~7.5 6.4 Clarity and color of solution Clarifying, colorless Complied Chlorides ≤0.05% Complied Ammonium ≤0.05% Complied Iron ≤0.01% Complied Phosphate ≤0.1% Complied Related substance 5'-CMP ≤0.3% 0.005% The other largest impurities ≤0.2% 0.002% The other total impurities ≤0.7% 0.006% Residual solvents ≤0.3% No detected Residual solvents ≤0.5% No detected Heavy metals ≤5.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%				ith Complied	
Clarity and color of solution Clarifying, colorless Complied Chlorides ≤0.05% Complied Ammonium ≤0.05% Complied Iron ≤0.01% Complied Phosphate ≤0.1% Complied Related substance 5'-CMP ≤0.3% 0.005% The other largest impurities ≤0.2% 0.002% The other total impurities ≤0.7% No detected Residual solvents Methanol ≤0.3% No detected Ethanol ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%			Show sodium flame	Positive reaction	
Chlorides ≤0.05% Complied Ammonium ≤0.05% Complied Iron ≤0.01% Complied Phosphate ≤0.1% Complied Related substance 5'-CMP ≤0.3% 0.005% The other largest impurities ≤0.2% 0.006% The other total impurities ≤0.7% 0.006% Methanol ≤0.3% No detected Ethanol ≤0.5% No detected Actione ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	Acid Value		6.0~7.5	6.4	
Ammonium ≤0.05% Complied Iron ≤0.01% Complied Phosphate ≤0.1% Complied Related substance 5'-CMP ≤0.3% 0.005% The other largest impurities ≤0.2% 0.006% The other total impurities ≤0.7% 0.006% Residual solvents Methanol ≤0.3% No detected Ethanol ≤0.5% No detected Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	Clarity and	color of solution	Clarifying, colorless	Complied	
Iron ≤0.01% Complied	Chlorides	nlorides ≤0.05%		Complied	
Phosphate ≤0.1% Complied Related substance 5'-CMP ≤0.3% 0.005% The other largest impurities ≤0.2% 0.002% The other total impurities ≤0.7% 0.006% Residual solvents Methanol ≤0.3% No detected Ethanol ≤0.5% No detected Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	Ammonium	/	≤0.05%	Complied	
Si-CMP ≤0.3% 0.005%	Iron		≤0.01%	Complied	
Related substance The other largest impurities ≤0.2% 0.002% The other total impurities ≤0.7% 0.006% Residual solvents Methanol ≤0.3% No detected Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	Phosphate		≤0.1%	Complied	
substance impurities 0.002% The other total impurities ≤0.7% 0.006% Residual solvents Methanol ≤0.3% No detected Ethanol ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	- \	5'-CMP	≤0.3%	0.005%	
The other total impurities Residual solvents Methanol ≤0.3% Ethanol ≤0.5% Acetone ≤0.5% Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Free phosphoric acids ≤0.1% Loss on drying ≤6.0% Endotoxin ≤0.3EU/mg Complied Assay(Dry content) ≥98% Conform with specification. Storage Storage Methanol ≤0.3% No detected Complied Tourise Storage Storage Storage No detected N		impurities	≤0.2%	0.002%	
Residual solvents Ethanol ≤0.5% No detected Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%			≤0.7%	0.006%	
Ethanol ≤0.5% No detected Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%	Danidual	Methanol	≤0.3%	No detected	
Acetone ≤0.5% No detected Heavy metals ≤5ppm Complied Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%		Ethanol	≤0.5%	No detected	
Arsenic ≤0.0001% Complied Free phosphoric acids ≤0.1% <0.1%		Acetone	≤0.5%	No detected	
Free phosphoric acids ≤0.1% <0.1% Loss on drying ≤6.0% 1.6% Endotoxin ≤0.3EU/mg Complied Assay(Dry content) ≥98% 100.4% Conclusion Conform with specification. Storage Store in cool & dry place not freeze, keep away from strong light and heat	Heavy metals		≤5ppm	Complied	
Loss on drying ≤6.0% 1.6% Endotoxin ≤0.3EU/mg Complied Assay(Dry content) ≥98% 100.4% Conclusion Conform with specification. Storage Store in cool & dry place not freeze, keep away from strong light and heat	Arsenic		≤0.0001%	Complied	
Endotoxin ≤0.3EU/mg Complied Assay(Dry content) ≥98% 100.4% Conclusion Conform with specification. Storage Store in cool & dry place not freeze, keep away from strong light and heat	Free phosphoric acids		≤0.1%	<0.1%	
Assay(Dry content) ≥98% 100.4% Conclusion Conform with specification. Storage Store in cool & dry place not freeze, keep away from strong light and heat	Loss on drying		≤6.0%	1.6%	
Conclusion Conform with specification. Storage Store in cool & dry place not freeze, keep away from strong light and heat	Endotoxin		≤0.3EU/mg	Complied	
Storage Store in cool & dry place not freeze, keep away from strong light and heat	Assay(Dry content)		≥98%	100.4%	
	Conclusion		Conform with specification.		
Shelf life 2 years when properly stored.	Storage		Store in cool & dry place not freeze, keep away from strong light and heat.		

Quality Assurance Officer: ±3

Corrector: 贺强 Analyst:李丽