



KYOWA HAKKO BIO CO., LTD.

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CERTIFICATE OF ANALYSIS

Commodity : COGNIZIN (CITICOLINE)
Lot No. : 230656
Manufacturing date : APR. 10. 2023
Analysis date : MAY. 23. 2023
Retest date : APR. 10. 2026

SPECIFICATION [METHOD]	ACCEPTANCE CRITERIA	RESULT
APPEARANCE [VISUAL OBSERVATION]	WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION [IR]	PASS TEST	PASS TEST
pH [JP]	2.5 to 3.5	3.1
STATE OF SOLUTION [JP]	COLORLESS AND CLEAR	COLORLESS AND CLEAR
AMMONIUM(NH ₄) [JP]	NOT MORE THAN 0.05 %	NOT MORE THAN 0.05 %
HEAVY METALS(Pb) [JP]	NOT MORE THAN 10 ppm	NOT MORE THAN 10 ppm
ARSENIC(As ₂₀₃) [JP]	NOT MORE THAN 2 ppm	NOT MORE THAN 2 ppm
FREE PHOSPHORIC ACIDS [JP]	NOT MORE THAN 0.1 %	NOT MORE THAN 0.1 %
CDP-EA [USP]	NOT MORE THAN 0.3 %	NOT MORE THAN 0.02 %
UDP-C [USP]	NOT MORE THAN 0.3 %	0.05 %
5'-CMP [USP]	NOT MORE THAN 0.3 %	0.04 %
ANY UNSPECIFIED IMPURITY [USP]	NOT MORE THAN 0.1 %	0.03 %
TOTAL IMPURITIES [USP]	NOT MORE THAN 2.0 %	0.14 %
RESIDUAL SOLVENTS (ETHANOL) [KYOWA]	NOT MORE THAN 500 ppm	300 ppm
RESIDUAL SOLVENTS (METHANOL) [KYOWA]	NOT MORE THAN 100 ppm	85 ppm
LOSS ON DRYING [JP]	NOT MORE THAN 5.0 %	3.7 %
TOTAL PLATE COUNT [JP]	NOT MORE THAN 1000 CFU/g	NOT MORE THAN 1000 CFU/g
FUNGI COUNT [JP]	NOT MORE THAN 100 CFU/g	NOT MORE THAN 100 CFU/g
E. COLI [JP]	NEGATIVE/g	NEGATIVE/g
ASSAY (DRY BASIS) [USP]	98.0 to 102.0 %	99.2 %

Not for API use.

COGNIZIN is Kyowa's trade name for Citicoline. This specification meets the current USP (DS) product monograph and the current residual solvents requirement as per USP and EP.

No animal origin raw materials/additives are used throughout the manufacturing process. Made in Japan.

The undersigned affirms that contents mentioned above are truly reported in accordance with the analysis by Quality Control Center.

KYOWAHAKKO BIO CO., LTD.

Kazuo Fukuda
Manager of Quality Assurance Center
Manufacturer

Date of issue : JUN. 05. 2023
(E762174)
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