



KYOWA HAKKO BIO CO., LTD.

Head Office: 1-6-1, Ohtemachi, Chiyoda-ku, Tokyo, 1008185, Japan (+81-3-3282 0979)
Hofu Plant: 1-1, Kyowa-cho, Hofu-shi, Yamaguchi, 7478522, Japan

CERTIFICATE OF ANALYSIS

Commodity : L-METHIONINE
Lot No. : 219235
Manufacturing date : DEC. 19, 2020
Analysis date : MAY. 14, 2021
Retest date : DEC. 19, 2023

SPECIFICATION [METHOD]	ACCEPTANCE CRITERIA	RESULT
APPEARANCE [VISUAL OBSERVATION]	WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION [IR]	PASS TEST	PASS TEST
SPECIFIC ROTATION(A1 20°C) [JP]	+23.0 to +24.0	+23.3
SPECIFIC ROTATION(A1 25°C) [KYOWA]	+23.4 to +24.7	+23.4
pH [JP]	5.6 to 6.1	5.8
STATE OF SOLUTION [JP]	COLORLESS AND CLEAR	COLORLESS AND CLEAR
STATE OF SOLUTION(1%) [KYOWA]	NOT LESS THAN 98.0 %	NOT LESS THAN 98.0 %
CHLORIDE(CL) [JP]	NOT MORE THAN 0.017 %	NOT MORE THAN 0.017 %
SULFATE(SO4) [JP]	NOT MORE THAN 0.020 %	NOT MORE THAN 0.020 %
AMMONIUM(NH4) [KYOWA]	NOT MORE THAN 0.019 %	NOT MORE THAN 0.003 %
HEAVY METALS(Pb) [JP]	NOT MORE THAN 5 ppm	NOT MORE THAN 5 ppm
ARSENIC(As2O3) [KYOWA]	NOT MORE THAN 1 ppm	NOT MORE THAN 1 ppm
IRON(Fe) [KYOWA]	NOT MORE THAN 10 ppm	NOT MORE THAN 10 ppm
LEAD(Pb) [KYOWA]	NOT MORE THAN 5 ppm	NOT MORE THAN 5 ppm
RELATED COMPOUNDS, TOTAL [KYOWA]	NOT MORE THAN 0.5 %	NOT MORE THAN 0.03 %
UNSPECIFIED IMPURITIES, EACH [BP]	NOT MORE THAN 0.10 %	NOT MORE THAN 0.016 %
TOTAL IMPURITIES [BP]	NOT MORE THAN 0.3 %	NOT MORE THAN 0.015 %
METHIONINE SULFOXIDE [USP]	NOT MORE THAN 0.1 %	NOT MORE THAN 0.05 %
N-METHYL-D,L-METHIONINE [USP]	NOT MORE THAN 0.2 %	NOT MORE THAN 0.05 %
ANY UNSPECIFIED IMPURITY [USP]	NOT MORE THAN 0.1 %	NOT MORE THAN 0.05 %
TOTAL UNSPECIFIED IMPURITIES [USP]	NOT MORE THAN 0.30 %	NOT MORE THAN 0.05 %

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

Date of issue : JUN. 23, 2021
(J768074)
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SPECIFICATION [METHOD]	ACCEPTANCE CRITERIA	RESULT
LOSS ON DRYING [JP]	NOT MORE THAN 0.20 %	0.00 %
RESIDUE ON IGNITION [JP]	NOT MORE THAN 0.10 %	0.00 %
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) [JP]	99.0 to 101.0 %	100.0 %

This specification meets the quality requirements of the current JP, USP and EP product monographs 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.

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KYOWAHAKKO BIO CO., LTD.

K. Fukuda

Kazuo Fukuda
Manager of Quality Assurance Center
Manufacturer

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