



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. : 229299
Manufacturing date : OCT. 11. 2021
Analysis date : MAY. 09. 2022
Retest date : OCT. 11. 2024

SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION	PASS TEST	PASS TEST
SPECIFIC ROTATION(AT 20°C)	+23.0 to +24.0 °	+23.6 °
SPECIFIC ROTATION(AT 25°C)	+22.4 to +24.7 °	+23.7 °
pH	5.6 to 6.1	5.9
STATE OF SOLUTION	COLORLESS AND CLEAR	COLORLESS AND CLEAR
STATE OF SOLUTION(T%)	NOT LESS THAN 98.0 %	NOT LESS THAN 98.0 %
CHLORIDE(CI)	NOT MORE THAN 0.017 %	NOT MORE THAN 0.017 %
SULFATE(SO4)	NOT MORE THAN 0.020 %	NOT MORE THAN 0.020 %
AMMONIUM(NH4)	NOT MORE THAN 0.019 %	NOT MORE THAN 0.005 %
HEAVY METALS(Pb)	NOT MORE THAN 5 ppm	NOT MORE THAN 5 ppm
ARSENIC(As203)	NOT MORE THAN 1 ppm	NOT MORE THAN 1 ppm
IRON(Fe)	NOT MORE THAN 10 ppm	NOT MORE THAN 10 ppm
RELATED COMPOUNDS, TOTAL(AAA)	NOT MORE THAN 0.5 %	NOT MORE THAN 0.03 %
UNSPECIFIED IMPURITIES, EACH(HPLC) (EP)	NOT MORE THAN 0.10 %	NOT MORE THAN 0.015 %
TOTAL IMPURITIES(HPLC) (EP)	NOT MORE THAN 0.3 %	NOT MORE THAN 0.015 %
METHIONINE SULFOXIDE(HPLC) (USP)	NOT MORE THAN 0.1 %	NOT MORE THAN 0.05 %
N-ACETYL-D, L-METHIONINE(HPLC) (USP)	NOT MORE THAN 0.2 %	NOT MORE THAN 0.05 %
ANY UNSPECIFIED IMPURITY(HPLC) (USP)	NOT MORE THAN 0.1 %	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 : JUL. 13. 2022
Original Manufacturer:
Sekisui Medical Co., Ltd.
Original manufacturer' s lot number :
440WJSM
(G763244)
00030



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CERTIFICATE OF ANALYSIS

Commodity : L-METHIONINE
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SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
TOTAL UNSPECIFIED IMPURITIES(HPLC) (USP)	NOT MORE THAN 0.30 %	NOT MORE THAN 0.05 %
LOSS ON DRYING	NOT MORE THAN 0.20 %	0.01 %
RESIDUE ON IGNITION	NOT MORE THAN 0.10 %	0.01 %
ENDOTOXIN	LESS THAN 3.0 EU/g	LESS THAN 3.0 EU/g
TOTAL AEROBIC MICROBIAL COUNT(TAMC)	NOT MORE THAN 100 CFU/g	NOT MORE THAN 100 CFU/g
TOTAL YEASTS AND MOULDS COUNT(TYMC)	NOT MORE THAN 10 CFU/g	NOT MORE THAN 10 CFU/g
E. COLI	NEGATIVE/g	NEGATIVE/g
ASSAY(DRY BASIS)	99.0 to 101.0 %	100.0 %

This specification meets 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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Original manufacturer's lot number :
440WJSM
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KYOWAHAKKO BIO CO., LTD.

K. Fukuda

Kazuo Fukuda
Manager of Quality Assurance Center
Manufacturer