

RAPPORT D'ANALYSES MICROBIOLOGIQUES

Objet de l'essai : Auto-contrôle
Référentiel d'essais : PE-5.1.8-C-COS

N° Dossier :
N° Echantillon :
Date d'analyse :

PRELEVEMENT ET RECEPTION

Prélevé le : Par : Vos soins
Site de prélèvement : NC Lieu de prélèvement : NC
Réception le : T°C Produit à réception : Amb.
T° C Produit Prélevé : NC T°C Meuble : NC

TRACABILITE ECHANTILLON - Données fournies par le Client

Dénomination : NOVOMA - GLUTAMINE

Fabricant : Nbre d'unités : 1
Fournisseur : NC N° CEE / Emb : NC
Marque : NC DLC / DLUO :
Emballage/poids : Pot N° Lot :
Date de fabrication : N° Bon de Commande : NC
Date d'emballage : NC Date de congélation : NC
Date Rupture chaîne du froid : NC Date de déconditionnement : NC

Observations diverses :

Tableau de résultats

Paramètres recherchés	Méthodes	Unités	Critères	Résultats	S/conclusion
Données d'applicabilité fournies par le client	PE 2.6.12			Non vérifiée	
DGAT	PE 2.6.12	UFC/g	100 000	<500	Satisfaisant
DMLT	PE 2.6.12	UFC/g	10 000	<50	Satisfaisant
Bactéries Gram- résistantes aux sels biliaires	PE 2.6.31	UFC/g	10 000	<1000	Satisfaisant
Escherichia coli (b-Glucuronidase +)	PE 2.6.31	/g	Absence	Absence	Satisfaisant
Salmonella	PE 2.6.31	/25g	Absence	Absence	Satisfaisant

BILAN

Conclusions :	Qualité Bactériologique Satisfaisante dans le cadre des critères déterminés.
Commentaires :	Référentiel : Critères microbiologiques des médicaments à base de plante pour usage orale (Catégorie C) de la Pharmacopée Européenne.

(#) : nombre estimé, (*) : nombre N°, (<n°) : micro-organisme détecté avec moins de n ufc/g. La valeur entre parenthèse est indicative, non couverte par l'accréditation. Les conclusions sont couvertes par l'accréditation si et seulement si l'ensemble des paramètres qui l'influent le sont également. NC : information non communiquée et/ou non renseignée. Le rapport d'essai ne concerne que les objets soumis aux essais, tels qu'ils nous ont été fournis par le client.

Données de Prélèvement fournies par le Client, excepté si prélèvement effectué par [redacted]. Données de réception en italique fournies par [redacted].

Le laboratoire [redacted] est exonéré de responsabilité sur les données fournies par le client.

La reproduction de ce rapport d'essais n'est autorisée que sous sa forme intégrale, sauf autorisation du laboratoire [redacted]. Les déclarations de conformité ne tiennent pas compte de l'incertitude de mesure sur les résultats. Les sous conclusions sont générées par défaut selon le plan défini dans les CGV, sauf accord spécifique.

To whom it may concern,

Statement: Absence of Contaminants
BioKyowa's L-Glutamine

We, , hereby certify that BioKyowa's **L-Glutamine** is considered as free from contaminants which are listed in annex of Commission Regulation (EU) 2023/915 of in its current valid version based on following reasons:

- To the best of our knowledge, throughout the manufacturing process of BioKyowa's **L-Glutamine**, no above mentioned contaminants are added, and the risk of contaminant formation is very unlikely.

- There is no risk of contamination of contaminants in BioKyowa's **L-Glutamine** during the strictly controlled manufacturing process or storage with respect to e.g. used raw materials or reagents.


- BioKyowa's **L-Glutamine** is a pure material with an assay value as mentioned in the corresponding specifications and no materials are added after the purification.

Sincerely yours;

Quality Assurance

To whom it may concern,

**Absence of ethylene oxide:
BioKyowa's L-Glutamine**

We,  hereby consider the risk of ethylene oxide contamination of BIOKYOWA's **L-Glutamine** is very low based on following reasons:

- BIOKYOWA's **L-Glutamine** is manufactured using fermentation, and no ethylene oxide is used throughout the manufacturing process.
- BIOKYOWA does not process or use any agricultural products such as sesame, wheat, maize, potato, some of which are known to be treated with ethylene oxide in some countries.
- BIOKYOWA's **L-Glutamine** is pure materials with an assay value as mentioned in the corresponding specifications and no materials is added after the purification.

According to the reasoning above, ethylene oxide is not expected in **L-Glutamine**; therefore, this substance is not tested.

In conclusion, and to the best of our knowledge, BIOKYOWA's **L-Glutamine** is not concerned by the alert on ethylene oxide.



Quality Assurance

CERTIFICATE OF ANALYSIS

GIC:
 PRODUCT: L-Glutamine
 LOT NUMBER:
 DATE OF MANUFACTURE:
 DATE OF ANALYSIS:
 RETEST DATE:

TEST	Method*	SPECIFICATION	RESULT
Appearance	Visual	White Crystalline Powder	White Crystalline Powder
Identification	USP	Conforms	Conforms
State of Solution	%T430nm	NLT 98.0%	100.0%
pH	USP	Between 4.0 and 6.0	5.1
Specific Rotation (at 20°C)	USP	Between +6.3 and +7.3	+7.2
Chloride	USP	NMT 0.020%	NMT 0.017%
Sulfate	USP	NMT 0.020%	NMT 0.020%
Iron	USP	NMT 10 PPM	NMT 10 PPM
Arsenic	USP	NMT 1.4 PPM	NMT 0.1 PPM
Cadmium	USP	NMT 0.5 PPM	NMT 0.1 PPM
Lead	USP	NMT 0.5 PPM	NMT 0.1 PPM
Mercury	USP	NMT 0.2 PPM	NMT 0.1 PPM
Foreign Amino Acids (TLC)**	USP	NMT 0.5%	NMT 0.4%
Loss on Drying	USP	NMT 0.20%	0.00%
Residue on Ignition	USP	NMT 0.10%	0.09%
Assay (Dried Basis)	USP	Between 99.0 and 101.0%	99.6%
Microbial Total Count	USP	NMT 1000 cfu/g	NMT 100 cfu/g
Microbial Count - Yeasts and Molds	USP	NMT 100 cfu/g	NMT 50 cfu/g
Microbial Count - Coliform	USP	Negative cfu/g	Negative cfu/g
Insoluble Foreign Matter	FCC	Conforms	Conforms

We hereby certify that the commodity described above meets the monograph requirements of the current USP and FCC; and meets the requirements of residual solvents on those pharmacopoeias. *METHOD-USP and FCC include cross validation with internal method. **Foreign Amino Acid Testing - Meets requirements for Related Compounds as required by USP, and Ninhydrin-positive substances as required by EP. Made in USA by fermentation using a non-pathogenic microbe, and without animal origin raw materials. Intended use for our product is as raw material or ingredient for further processing. Our product is not intended for API usage.

ANALYSIS APPROVED BY/DATE:

Quality Assurance

CERTIFICATE OF ANALYSIS

GIC: [REDACTED]
PRODUCT: L-Glutamine
 LOT NUMBER: [REDACTED]
 DATE OF MANUFACTURE: [REDACTED]
 DATE OF ANALYSIS: [REDACTED]
 RETEST DATE: [REDACTED]

TEST	Method*	SPECIFICATION	RESULT
Appearance	Visual	White Crystalline Powder	White Crystalline Powder
Identification	USP	Conforms	Conforms
State of Solution	%T430nm	NLT 98.0%	99.0%
pH	USP	Between 4.0 and 6.0	4.7
Specific Rotation (at 20°C)	USP	Between +6.3 and +7.3	+6.5
Chloride	USP	NMT 0.020%	NMT 0.017%
Sulfate	USP	NMT 0.020%	NMT 0.020%
Iron	USP	NMT 10 PPM	NMT 10 PPM
Arsenic	USP	NMT 1.4 PPM	NMT 0.1 PPM
Cadmium	USP	NMT 0.5 PPM	NMT 0.1 PPM
Lead	USP	NMT 0.5 PPM	NMT 0.1 PPM
Mercury	USP	NMT 0.2 PPM	NMT 0.1 PPM
Foreign Amino Acids (TLC)**	USP	NMT 0.5%	NMT 0.4%
Loss on Drying	USP	NMT 0.20%	0.01%
Residue on Ignition	USP	NMT 0.10%	0.08%
Assay (Dried Basis)	USP	Between 99.0 and 101.0%	99.6%
Microbial Total Count	USP	NMT 1000 cfu/g	NMT 100 cfu/g
Microbial Count - Yeasts and Molds	USP	NMT 100 cfu/g	NMT 50 cfu/g
Microbial Count - Coliform	USP	Negative cfu/g	Negative cfu/g
Insoluble Foreign Matter	FCC	Conforms	Conforms

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