

|                                                                                   |                                 |                         |
|-----------------------------------------------------------------------------------|---------------------------------|-------------------------|
|  | <b>CERTIFICAT DE CONFORMITE</b> | <b>DATE</b><br>03/06/19 |
|                                                                                   |                                 | <b>VERSION N°1</b>      |

POUR LE CLIENT

NUV

NOVOMA SARL  
BATIMENT ZEPHYR AVENUE BERNARD  
31 400 TOULOUSE

Je soussigné M.WACRENIER, Président de Laboratoire PHYTOCOSMA SAS certifie que le produit cité ci-après est conforme aux spécifications établies.

Nous vous rappelons qu'il vous appartient de vérifier les conditions de distribution et d'utilisation de ces produits conformément à la législation en vigueur.

|                     |                               |
|---------------------|-------------------------------|
| Code interne        | NUVZIN01                      |
| Désignation interne | ZINC BISGLYCINATE 120 gélules |

|                    |                   |
|--------------------|-------------------|
| Code client        | 3 052351 247969   |
| Désignation client | ZINC BISGLYCINATE |

|               |        |              |       |
|---------------|--------|--------------|-------|
| Numéro de lot | D17697 | Numéro de BL | 21561 |
|---------------|--------|--------------|-------|

|                     |            |     |         |
|---------------------|------------|-----|---------|
| Date de fabrication | 06/12/2024 | DDM | 12/2027 |
|---------------------|------------|-----|---------|

|                            |                                                                                                                             |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Conditions de conservation | A conserver à l'abri de l'oxygène et de la lumière à une température comprise entre 15 et 25°C dans son emballage d'origine |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------|

|                                        |     |
|----------------------------------------|-----|
| Le produit contient de(s) Allergène(s) | Non |
|----------------------------------------|-----|

Liste des allergène(s) dans le produit

Non applicable

|                                      |     |
|--------------------------------------|-----|
| Le produit contient de(s) Additif(s) | Non |
|--------------------------------------|-----|

Liste de(s) additif(s) dans le produit

Non applicable

|                    |     |
|--------------------|-----|
| Le produit est BIO | Non |
|--------------------|-----|

(\*Produit issu de l'agriculture biologique FR-BIO-01 et process conforme à la fabrication de produits biologiques)

|                         |     |                       |     |
|-------------------------|-----|-----------------------|-----|
| Le produit est sans OGM | Oui | Le produit est Ionisé | Non |
|-------------------------|-----|-----------------------|-----|

|                            |     |
|----------------------------|-----|
| Le produit est sans Gluten | Non |
|----------------------------|-----|

|                     |     |                     |     |
|---------------------|-----|---------------------|-----|
| Conforme Végétarien | Oui | Conforme Végétalien | Oui |
|---------------------|-----|---------------------|-----|

|                |     |                 |     |
|----------------|-----|-----------------|-----|
| Conforme Halal | Oui | Conforme Casher | Oui |
|----------------|-----|-----------------|-----|

**CONDITIONNEMENT PRODUIT**

|                         |              |         |              |
|-------------------------|--------------|---------|--------------|
| Type de produit         | Gélules HPMC | Couleur | Transparente |
| PV interne gélules      | 25804        | Taille  | Taille 1     |
| Lot Fournisseur gélules | 1-000843     | Dosage  | 277mg        |

|                         |           |                    |        |
|-------------------------|-----------|--------------------|--------|
| Type de conditionnement | Piluliers | Quantité par colis | 102*50 |
| Quantité conditionnée   | 5100      | Cartons incomplets |        |

Autres (dont fond de bol)

|  |
|--|
|  |
|--|

**COMPOSITION PRODUIT**

| INGREDIENT(S)         | DOSAGE | PV interne    | N°LOT FOURNISSEUR       |
|-----------------------|--------|---------------|-------------------------|
| Bisglycinate de zinc  | 75mg   | 26044 + 26111 | BN12000005140           |
| Vitamine B6 bioactive | 2mg    | 26051 + 26074 | C042408815 + P5P-240530 |
| Amidon de riz Bio     | 200mg  | 26008         | 2420427350              |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |
|                       |        |               |                         |

PHYTOCOSMA Laboratoires  
23 Route du Burgaud  
82600 AUCAMVILLE  
Tél. : 05 63 02 71 07  
phytocosma@orange.fr  
SAS au capital de 13 720,41 euros  
RCS MONTAUBAN 432 694 354

11/12/24

Service qualité

# CERTIFICATE OF ANALYSIS



## Product and Batch Informations

### PYRIDOXAL 5'-PHOSPHATE

REF : PLP.001

DT V01 - 27/07/2022

|         |            |                            |              |
|---------|------------|----------------------------|--------------|
| Batch   | C042408815 | Origin (natural/synthetic) | Synthetic    |
| N° CAS  | 41468-25-1 | Country of manufacturing   | Asia - China |
| MF date | 13/08/2024 | Expiration date            | 13/08/2027   |

| ANALYSIS ITEM | SPECIFICATION | RESULT | TEST METHOD |
|---------------|---------------|--------|-------------|
|---------------|---------------|--------|-------------|

### Active Ingredients/Substance to control

|       |              |        |          |
|-------|--------------|--------|----------|
| Assay | 98.5 – 101 % | 99,00% | CP<0512> |
|-------|--------------|--------|----------|

### Physical/Chemical Control

|                     |                                                               |          |                    |
|---------------------|---------------------------------------------------------------|----------|--------------------|
| Appearance          | Slightly yellow or off-white powder                           | Complies | Visual             |
| Water by KF         | NMT 10%                                                       | 8,30%    | CP<0832>           |
| Melting point       | 140~145°C                                                     | 143°C    | CP<0612>           |
| B6 free Vitamin B6  | NMT 0.05%                                                     | 0,03%    | CP<0512>           |
| Particle size       | 90% through 30 mesh                                           | Complies | CP<0982>           |
| Solubility          | Very slightly soluble in water, soluble in alkali-OH solution | Complies | CP General Notices |
| pH (in 0.25% water) | 2.6 ~ 3.0                                                     | 2,80     | CP<0631>           |

### Contaminant Control\*

|                  |                                               |               |          |
|------------------|-----------------------------------------------|---------------|----------|
| Lead (Pb)        | NMT 3ppm                                      | Complies      | CP<0412> |
| Arsenic (As)     | NMT 1ppm                                      | Complies      | CP<0412> |
| Cadmium(Cd)      | NMT 1ppm                                      | Complies      | CP<0412> |
| Mercury (Hg)     | NMT 0,1ppm                                    | Complies      | CP<0412> |
| Residual solvent | Toluene : NMT 890ppm<br>Ethanol : NMT 5000ppm | 2ppm<br>22ppm | CP<0861> |

### Microbiological Control

|                         |                  |            |          |
|-------------------------|------------------|------------|----------|
| Total aerobic microbial | NMT 20 000 cfu/g | <100 cfu/g | CP<1105> |
| Tot. yeast and mould    | NMT 200 cfu/g    | <10 cfu/g  | CP<1105> |
| Salmonella              | Negative         | Complies   | CP<1106> |
| E.Coli                  | Negative         | Complies   | CP<1106> |
| Staphylococcus          | Negative         | Complies   | CP<1106> |

### Statements

|               |                    |
|---------------|--------------------|
| Allergens     | Allergen free      |
| GMO           | No OGM             |
| Irradiation   | No irradiation     |
| BSE/TSE       | BSE/TSE free       |
| Nanomaterials | Nanomaterials free |

### Packing and Storage

|         |                                                                      |
|---------|----------------------------------------------------------------------|
| Packing | Suitable for food industry                                           |
| Storage | Store in dry places and keep away from strong direct light and heat. |

\*According to a control plan



NATURAL  
12, avenue des carreaux – 49480 – St Sylvain d'Anjou – France  
Tel : +33 241 475 225 Fax : +33 241 476 044  
Mail : [quality@natural-ingredients.fr](mailto:quality@natural-ingredients.fr)

24/09/2024  
AGOSSOU Ariane  
Quality Department

#### General Information

|                  |                            |                        |                         |
|------------------|----------------------------|------------------------|-------------------------|
| <b>Product</b>   | Remy O DR6                 | <b>Production Date</b> | 31/07/2024 (dd/mm/yyyy) |
| <b>Batch</b>     | 2420427350                 | <b>Best before</b>     | 30/07/2028 (dd/mm/yyyy) |
| <b>Issued by</b> | Quality Control Management | <b>Date CoA Issued</b> | 26/09/2024 (dd/mm/yyyy) |

#### Results of analyses

| Parameter                               | Result   | Unit        | Method <sup>(1)</sup>   | LSL | USL      |
|-----------------------------------------|----------|-------------|-------------------------|-----|----------|
| <b>Physical and Chemical Parameters</b> |          |             |                         |     |          |
| Moisture                                | 6        | g/100g      | ISO 712                 | ≤   | 14       |
| Protein content (N*6,25) on DM          | 4,4      | g/100g d.m. | ISO 1871 <sup>(1)</sup> | ≤   | 7,0      |
| Ash content on DM                       | 0,2      | g/100g d.m. | ISO 3593                | ≤   | 1,0      |
| <b>Rheological Parameters</b>           |          |             |                         |     |          |
| Starting gel point, pH as is, 6%        | 82       | °C          | Brabender               | ≥   | 60       |
| End viscosity, pH as is, 6%             | 640      | BU          | Brabender               | ≥   | 500      |
| <b>Microbiological Parameters</b>       |          |             |                         |     |          |
| Salmonella (/375g)                      | Negative | /375g       | ISO 6579                |     | Negative |
| Total mesophilic bacteria (aerobic)     | 20.000   | cfu/g       | ISO 4833                | ≤   | 100.000  |
| Yeasts and Moulds                       | 270      | cfu/g       |                         | ≤   | 1.000    |
| Enterobacteriaceae                      | 80       | cfu/g       |                         | ≤   | 100      |

<sup>(1)</sup> or (acknowledged and) validated equivalent

#### Remarks

We herewith confirm that the product complies with the corresponding guarantees listed in its Product Sheet .

Rice starch issued from organic farming, Certisys BE-BIO-01

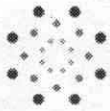


# Pyridoxal 5-Phosphate

## Certificate of Analysis

| General informations                                                                                                                                                                   | Batch        | Expiry Date |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------|
| Product name : Pyridoxal 5-Phosphate Monohydrate                                                                                                                                       | P5P-240530   | 29/05/2027  |
| Molecular formula : C <sub>8</sub> H <sub>10</sub> NO <sub>6</sub> P.H <sub>2</sub> O                                                                                                  |              |             |
| Molecular weight : 265,16 g/mol                                                                                                                                                        |              |             |
| CAS Number : 41468-25-1                                                                                                                                                                |              |             |
| Origin : China                                                                                                                                                                         |              |             |
| Organoleptic, Physical and Chemical properties                                                                                                                                         | Results      |             |
| Pale yellow white to yellow crystalline powder                                                                                                                                         | Conforms     |             |
| Identification positive by HPLC                                                                                                                                                        | Conforms     |             |
| Identification positive by IR                                                                                                                                                          | Conforms     |             |
| Melting point : 140-145°C                                                                                                                                                              | 143,0°C      |             |
| Loss on drying < 1,0%                                                                                                                                                                  | 0,14%        |             |
| Water by KF < 10,0%                                                                                                                                                                    | 8,4%         |             |
| Mesh size : > 90% pass through 30 mesh                                                                                                                                                 | Conforms     |             |
| Bulk density : 0,4-0,6 g/ml                                                                                                                                                            | 0,52 g/ml    |             |
| pH (0,25% water) : 2,6-3,0                                                                                                                                                             | 2,9          |             |
| Solubility : Slightly soluble in water                                                                                                                                                 | Conforms     |             |
| Free phosphoric acid < 0,5%                                                                                                                                                            | < 0,5%       |             |
| B6 Piridoxine HCl < 0,05%                                                                                                                                                              | Not Detected |             |
| Toluene < 100 ppm                                                                                                                                                                      | Not Detected |             |
| Ethanol < 5000 ppm                                                                                                                                                                     | 75 ppm       |             |
| Actives                                                                                                                                                                                | Results      |             |
| P5P purity > 99,0%                                                                                                                                                                     | 99,4%        |             |
| P5P content : 98,5 - 101%                                                                                                                                                              | 99,5%        |             |
| Heavy Metals                                                                                                                                                                           | Results      |             |
| Total Heavy Metals < 10 ppm                                                                                                                                                            | < 10 ppm     |             |
| Arsenic < 0,5 ppm                                                                                                                                                                      | 0,03 ppm     |             |
| Lead < 0,5 ppm                                                                                                                                                                         | Not Detected |             |
| Mercury < 0,1 ppm                                                                                                                                                                      | Not Detected |             |
| Cadmium < 0,5 ppm                                                                                                                                                                      | Not Detected |             |
| Microbiology                                                                                                                                                                           | Results      |             |
| Total plate count < 1000 CFU/g                                                                                                                                                         | < 100 CFU/g  |             |
| Yeasts & Moulds < 100 CFU/g                                                                                                                                                            | < 10 CFU/g   |             |
| Bile tolerant Gram - Bacteria : Absence                                                                                                                                                | Negative     |             |
| E. coli : Absence                                                                                                                                                                      | Negative     |             |
| Salmonella : Absence                                                                                                                                                                   | Negative     |             |
| Pseuomonas aeruginosa : Absnce                                                                                                                                                         | Negative     |             |
| Staphylococcus aureus : Absence                                                                                                                                                        | Negative     |             |
| Additional informations                                                                                                                                                                |              |             |
| Shelf Life : 3 years shelf life when stored under proper conditions (Must be stored in a tightly sealed bag/container and stored in a cool and dry place away from moisture and light) |              |             |
| Allergens : Absence conformity to Regulation 1169/2011 EC                                                                                                                              |              |             |
| Ionisation : Absence conformity to Regulation 1999/2 EC& 1999/3 EC                                                                                                                     |              |             |
| TSE/BSE : Absence conformity to Regulation 999/2001 EC                                                                                                                                 |              |             |
| Nanomaterials : Absence conformity to Decree 2012/232 & Decree dated August 6th, 2012                                                                                                  |              |             |
| GMO : Absence conformity to Regulation 1829/2003 EC & 1830/2003 EC                                                                                                                     |              |             |

Datas as received from the factory



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## CERTIFICATE OF ANALYSIS

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Document Print Date

14-Aug-2024

|                       |                 |                              |                                        |                                                             |
|-----------------------|-----------------|------------------------------|----------------------------------------|-------------------------------------------------------------|
| <b>Customer:</b>      | C90241          | Ideactifs                    | <b>Batch No:</b>                       | BN12000005140                                               |
| <b>Customer PO:</b>   | 2024072         |                              | <b>Manufacturing / Packaging Date:</b> | 11-Jul-2024                                                 |
| <b>Customer Item:</b> |                 |                              | <b>Exp. Date:</b>                      | 11-Jul-2027                                                 |
| <b>Order No:</b>      | S120034556      |                              |                                        |                                                             |
| <b>Product:</b>       | 03507-XX-KG0025 | Zinc Bisglycinate Chelate SF | <b>Ship To:</b>                        | Allee du Blossne, ZA de la Hallerais<br>Vern Sur Seiche FRA |

### Manufacturing Site Address:

ALBION LABORATORIES, INC.  
2774 S. 1760 W.

Phone:

Quality Contact: Tamera Rochell

Ogden, UT 84401 USA

Fax:

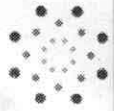
Email: trochell@balchem.com

### Analytical Results

| Test<br>Description  | Specification                                |       |      |       | Batch Analysis<br>Result |
|----------------------|----------------------------------------------|-------|------|-------|--------------------------|
|                      | Method                                       | Units | Min  | Max   |                          |
| QCL-Zn(%.)-ICP1      | Zinc - QC WI (Q 100)                         | %.    | 20   |       | 22                       |
| QCL-As(ppm)-ICPMS    | Arsenic - QC WI (Q 54)                       | ppm_  |      | 1.50  | <0.05                    |
| QCL-Cd(ppm)-ICPMS    | Cadmium - QC WI (Q 54)                       | ppm_  |      | 1.00  | 0.16                     |
| QCL-Hg(ppm)-ICPMS    | Mercury - QC WI (Q 54)                       | ppm_  |      | 0.10  | <0.05                    |
| QCL-Pb(ppm)-ICPMS    | Lead - QC WI (Q 54)                          | ppm_  |      | 3.00  | 1.53                     |
| QCL-N(%) -LECO       | Nitrogen - QC WI (Q 93)                      | %.    | 10.0 | 12.5  | 11.9                     |
| QCL-FTIR(Pass)-FTIR  | FTIR - QC WI (Q 36)                          |       |      |       | Pass                     |
| QCL-Color-Visual     | Color - QC WI (Q 26)                         |       |      |       | Pass                     |
| QCL-TapDen(g per cc) | Tap Density - QC WI (Q 25)                   | g/cc  | 0.90 |       | 0.96                     |
| QCL-pH-pH            | pH - QC WI (Q 24)                            | pH_1  | 6.5  | 8.0   | 7.2                      |
| QCL-Moisture-LOD (%) | Loss on drying - QC WI (Q 23)                | %.    |      | 6.0   | 2.6                      |
| QCL-TAM-Micros       | Total Aerobic Microbial Count - USP <2021>   | cfu/g |      | 1,000 | <100                     |
| QCL - Mold Yeast     | Molds and Yeasts Count - USP <2021>          | cfu/g |      | 100   | <10                      |
| QCL-Bacillus cereus  | B. cereus - QC WI (Q 170) - Absence per 10 g |       |      |       | Pass                     |
| QCL-Enterobacterial  | Enterobacterial Count - USP <2021>           | cfu/g |      | 100   | <100                     |
| QCL-E.coli-Micros    | E. coli - USP <2022> - Absence per 10 g      |       |      |       | Pass                     |
| QCL-Salmonella       | Salmonella - USP <2022> - Absence per 10 g   |       |      |       | Pass                     |
| QCL-Staph aureus     | S. aureus - USP <2022> - Absence per 10 g    |       |      |       | Pass                     |

### Customer Comments:

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## CERTIFICATE OF ANALYSIS

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Document Print Date

14-Aug-2024

|                       |                 |                              |                                        |                                                            |
|-----------------------|-----------------|------------------------------|----------------------------------------|------------------------------------------------------------|
| <b>Customer:</b>      | C90241          | Ideactifs                    | <b>Batch No:</b>                       | BN12000005140                                              |
| <b>Customer PO:</b>   | 2024072         |                              | <b>Manufacturing / Packaging Date:</b> | 11-Jul-2024                                                |
| <b>Customer Item:</b> |                 |                              | <b>Exp. Date:</b>                      | 11-Jul-2027                                                |
| <b>Order No:</b>      | S120034556      |                              |                                        |                                                            |
| <b>Product:</b>       | 03507-XX-KG0025 | Zinc Bisglycinate Chelate SF | <b>Ship To:</b>                        | Allee du Blosne, ZA de la Hallerais<br>Vern Sur Seiche FRA |

**Manufacturing Site Address:**

ALBION LABORATORIES, INC.  
2774 S. 1760 W.

Phone:

Quality Contact: Tamera Rochell

Ogden, UT 84401 USA

Fax:

Email: trochell@balchem.com

### Analytical Results

| Test<br>Description  | Specification                                |       |      |       | Batch Analysis<br>Result |
|----------------------|----------------------------------------------|-------|------|-------|--------------------------|
|                      | Method                                       | Units | Min  | Max   |                          |
| QCL-Zn(%.)-ICP1      | Zinc - QC WI (Q 100)                         | %..   | 20   |       | 22                       |
| QCL-As(ppm)-ICPMS    | Arsenic - QC WI (Q 54)                       | ppm_  |      | 1.50  | <0.05                    |
| QCL-Cd(ppm)-ICPMS    | Cadmium - QC WI (Q 54)                       | ppm_  |      | 1.00  | 0.16                     |
| QCL-Hg(ppm)-ICPMS    | Mercury - QC WI (Q 54)                       | ppm_  |      | 0.10  | <0.05                    |
| QCL-Pb(ppm)-ICPMS    | Lead - QC WI (Q 54)                          | ppm_  |      | 3.00  | 1.53                     |
| QCL-N(%)-LECO        | Nitrogen - QC WI (Q 93)                      | %.    | 10.0 | 12.5  | 11.9                     |
| QCL-FTIR(Pass)-FTIR  | FTIR - QC WI (Q 36)                          |       |      |       | Pass                     |
| QCL-Color-Visual     | Color - QC WI (Q 26)                         |       |      |       | Pass                     |
| QCL-TapDen(g per cc) | Tap Density - QC WI (Q 25)                   | g/cc  | 0.90 |       | 0.96                     |
| QCL-pH-pH            | pH - QC WI (Q 24)                            | pH_1  | 6.5  | 8.0   | 7.2                      |
| QCL-Moisture-LOD (%) | Loss on drying - QC WI (Q 23)                | %.    |      | 6.0   | 2.6                      |
| QCL-TAM-Micros       | Total Aerobic Microbial Count - USP <2021>   | cfu/g |      | 1,000 | <100                     |
| QCL - Mold Yeast     | Molds and Yeasts Count - USP <2021>          | cfu/g |      | 100   | <10                      |
| QCL-Bacillus cereus  | B. cereus - QC WI (Q 170) - Absence per 10 g |       |      |       | Pass                     |
| QCL-Enterobacterial  | Enterobacterial Count - USP <2021>           | cfu/g |      | 100   | <100                     |
| QCL-E.coli-Micros    | E. coli - USP <2022> - Absence per 10 g      |       |      |       | Pass                     |
| QCL-Salmonella       | Salmonella - USP <2022> - Absence per 10 g   |       |      |       | Pass                     |
| QCL-Staph aureus     | S. aureus - USP <2022> - Absence per 10 g    |       |      |       | Pass                     |

**Customer Comments:**

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## CERTIFICATE OF ANALYSIS EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

|                               |                           |                      |              |
|-------------------------------|---------------------------|----------------------|--------------|
| <b>CUSTOMER:</b> GOCAPS GMBH  |                           |                      |              |
| <b>LOT No.:</b>               | K2401001732               | <b>PRODUCT CODE:</b> | K00016G      |
| <b>SIZE:</b>                  | 1                         |                      |              |
| <b>PURCHASE ORDER NUMBER:</b> | PO2000627                 | <b>CHARGE No.:</b>   | 1-000843     |
| <b>ART No.:</b>               | 56-000992                 |                      |              |
| <b>CAPSULE COLOR / CODE:</b>  | <b>CAP -</b> NATURAL 1-OK | <b>/ BODY -</b>      | NATURAL 1-OK |
| <b>PRINT:</b>                 | N/A                       | <b>TEXT:</b>         | N/A          |
| <b>INK COLOR:</b>             | N/A                       |                      |              |

THIS IS TO CERTIFY THAT: The hard capsules of vegetable origin (K-CAPS) manufactured by C.I. FARMACAPSULAS S.A.S. are made from cellulose ethers, which are polymers derived from vegetable sources. Our capsules are certified as Kosher and Halal, and meet all requirements of current European Pharmacopoeia (EP) and United States Pharmacopoeia (USP). Hypromellose used in the manufacturing of capsules meet specifications as described in the current United States Pharmacopoeia. Cellulose ethers are considered as Generally Recognized As Safe (GRAS) by the FDA.

(% Ingredients to % Cellulose)

| Cap                                                                                                                                                                                                                                                                                                                                                                                                                    | % | Body | % |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|------|---|
| <p><i>Colorant and ingredients used in capsules are officially approved for use as dye in Foods, Drugs and Cosmetics and/or Drugs and Cosmetics, in the country of destination.</i></p> <p><i>Some changes in color are due to natural colorants or can occur/are within the specification. The above specifications apply to all capsules having the same size and code numbers, unless otherwise stipulated.</i></p> |   |      |   |

Date of Manufacture: 2024-01

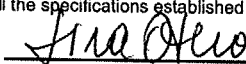
Expiration Date: 2029-01

| CRITERIA                      | METHOD / REFERENCE     | SPECIFICATIONS                                                   | RESULTS |
|-------------------------------|------------------------|------------------------------------------------------------------|---------|
| <b>PHYSICAL</b>               |                        |                                                                  |         |
| Average Capsule Weight        | DCC-MI-P003/ USP<2091> | 75.00-85.00 mg                                                   | 77.5    |
| Loss on drying                | DCC-MA-P027            | 3.00-8.00 %                                                      | 4.3     |
| Disintegration                | DCC-MA-P063/ USP<701>  | N.M.T. 15 min                                                    | PASSES  |
| Residue on Ignition *         | USP                    | N.M.T. 1.5% Transparent Capsules<br>N.M.T. 6.0% Colored Capsules | PASSES  |
| Identification of HPMC        | DCC-MA-P073 / USP      | Meets USP Requirements                                           | PASSES  |
| <b>ANALYTICAL</b>             |                        |                                                                  |         |
| Arsenic *                     | EXTERNAL               | N.M.T. 0.8 ppm                                                   | PASSES  |
| Chromium *                    | EXTERNAL               | N.M.T. 2 ppm                                                     | PASSES  |
| Cadmium *                     | EXTERNAL               | N.M.T. 0.5 ppm                                                   | PASSES  |
| Lead *                        | EXTERNAL               | N.M.T. 0.5 ppm                                                   | PASSES  |
| Mercury *                     | EXTERNAL               | N.M.T. 0.1 ppm                                                   | PASSES  |
| Cobalt *                      | EXTERNAL               | N.M.T. 5.0 ppm                                                   | PASSES  |
| Vanadium *                    | EXTERNAL               | N.M.T. 10.0 ppm                                                  | PASSES  |
| Nickel *                      | EXTERNAL               | N.M.T. 20.0 ppm                                                  | PASSES  |
| Total Aerobic Microbial Count | DCC-MA-P031 / USP <61> | N.M.T. 1000 cfu/g                                                | 9       |
| Total Yeasts and Molds Count  | DCC-MA-P040 / USP <61> | N.M.T. 100 cfu/g                                                 | <10     |
| Total Coliforms               | DCC-MA-P036 / USP <62> | Absence / 1 g                                                    | Absence |
| Salmonella                    | DCC-MA-P039 / USP <62> | Absence / 10 g                                                   | Absence |
| Escherichia Coli              | DCC-MA-P036 / USP <62> | Absence / 1g                                                     | Absence |
| Staphylococcus aureus         | DCC-MA-P037 / USP <62> | Absence / 1g                                                     | Absence |
| Pseudomonas aeruginosa        | DCC-MA-P033 / USP <62> | Absence / 1g                                                     | Absence |

\*Reduced Frequency Testing

Storage Conditions: Temperature: 15°C - 30°C / Relative Humidity: 35 % - 70 % RH N.M.T. = No More Than

NOTE: The VISUAL QUALITY is superior to the established figures in the sampling plans of the ANSI/ASQ Z1.4-2013 "Procedure of sampling to inspect for attributes", using simple sampling with level III of General Inspection and Acceptable Level of Quality (AQL) of 0.010 for Critical defects, 0.040 for Major defects and 0.250 for Minor defects. They also fulfill the specifications established in the Technical Information Manual in force.

Approval by:   
Quality Assurance

Date: 2024/02/16



Code: DCC-032G (Valid since January 1<sup>st</sup>, 2024)  
Edition 8

MANUFACTURER ADDRESS: VIA 40 85-48 BARRANQUILLA - COLOMBIA  
TELEPHONE: (57-60-5) 330-4100 FAX: (57-60-5) 330-4105