



Kore Magnesium

CoA SPECIFICATION

BIOTECHNOLOGY & BIOACTIVE NUTRACEUTICALS

DocCode:TS-KORE-USA-001 | Rev. 04

KORE MAGNESIUM — HORMONE HARMONY*

A premium dietary supplement engineered with a highly bioavailable Tri-Active Magnesium Chelate Matrix, strategically combined with the targeted probiotic strain *Lacticaseibacillus paracasei* LMB1 and standardized cofactors (Vitamins C, B6, and D3). Formulated specifically to optimize hormonal balance, support the gut- brain axis, promote neuromuscular relaxation, and assist deep sleep cycles.*

1. General Product Specifications (US Market)

TECHNICAL PARAMETERS & TRACEABILITY MAPPING

Product Name	Kore Magnesium (Hormone Harmony*)
Product Category	Dietary Supplement (US FDA 21 CFR Compliant)
Brand Name	Éter Anima
Manufacturing Origin	Made in Spain (Distributed Internationally)
Dosage Form	Hard Veggie Capsules
Packaging Presentation	Amber bottle containing 60 veggie capsules
Serving Size	2 Capsules per day (Provides 30 servings per container)
Net Weight	44.28 g (1.56 oz)
Control Batch Number	251105
Expiration Profile (Best By)	11/2027
Distributed By	EJM Farming Investments S.L. — 15 Can Pau Birol Street, Unit 2, Lower Level, 17005 Girona, Spain
Technical Contact	hello@eteranima.com www.eteranima.com

2. Supplement Facts: Qualitative & Quantitative Composition

In accordance with US FDA 21 CFR 101.36 standards, the qualitative and quantitative composition per daily serving size (2 capsules) is certified below. This matrix reflects exact raw material load inputs, elemental chemical yields, and raw material purity specifications:

Active Ingredient Input	Mass per Serving	Certified Raw Purity / Assay	Elemental Active Yield	% Daily Value (% DV)	Primary Bioactive Pathway
Dimagnesium Malate Trihydrate	320 mg	14.3% - 15.8% (as Mg base)	49.7 mg (Elemental Mg)	12%	Mitochondrial ATP generation, muscle cell recovery.
Magnesium Bisglycinate	320 mg	18.0% (as Mg base)	57.6 mg (Elemental Mg)	14%	Neuromuscular relaxation and sleep cycle support.
Magnesium N-Acetyltaurinate	280 mg	≥ 98.0% (9.5% Mg base)	26.5 mg (Elemental Mg)	6%	Brain bio-availability via lipophilic BBB crossing.
Lactobacillus paracasei LMB1	160 mg	3.7 × 10 ⁹ CFU/g (Pure culture)	6 × 10 ⁸ CFU	†	Epithelial barrier homeostatic optimization.
Vitamin C (as ascorbic acid)	40 mg	≥ 99.0% (USP/Ph. Eur.)	40 mg	89%	Free-radical scavenging and cellular defense.
Vitamin B6 (as pyridoxine HCl)	0.7 mg	98.0% - 101.0% (Dry basis)	0.7 mg	82%	Intracellular magnesium trapping cofactor.
Vitamin D (as cholecalciferol)	2.5 µg	≥ 100,000 IU/g (Standardized)	2.5 µg (110 IU)	25%	Endocrine homeostasis and calcium/magnesium regulation.

† Daily Value (% DV) not established. Total Elemental Magnesium per serving: 133.8 mg (accumulating a comprehensive nutritional density of **32% DV** for adult populations).

3. Certified Raw Material Technical Monographs (Assay & Purity Audited)

3.1. Dimagnesium Malate Trihydrate

- **Chemical Parameters:** CAS Number: 869-06-7. Molecular Formula: $MgC_4H_4O_5 \cdot 3H_2O$. Molecular Weight: 156.38 g/mol (anhydrous basis).
- **Purity & Assay Standard:** **Guaranteed total Purity / Assay range of 14.30% to 15.80%** expressed as net active elemental Magnesium content. Loss on drying parameters: $\leq 8.0\%$ (processed at 105 °C, 4 h). pH scale in solution: 8.0 - 11.0.
- **Physical Profile:** Fine, uniform white crystalline powder, slightly soluble in water. Bulk density: ~ 0.68 g/mL; Tapped density: ~ 0.82 g/mL. Particle size distribution: 100% through 30 MESH screen matrix.
- **Compliance Estatus:** Pure synthetic mineral chelate (Origin: India). Residual solvent-free, non-irradiated, 100% allergen-free, and fully certified for strictly vegan consumer applications.

3.2. Buffered Magnesium Bisglycinate Chelate

- **Chemical Structure:** CAS Number: 14783-68-7. Description: Premium magnesium bisglycinate chelate structurally buffered with high-purity magnesium oxide.
- **Purity & Assay Standard:** **Certified Purity / Active Mineral Assay of 18.0%** net elemental Magnesium density. Complies completely with all established USP and FCC pharmacopeia monographs.
- **Processing Inert Coagents:** Citric acid, maltodextrin, silica, and purified water (utilized strictly as manufacturing or texturizing coagents). Technology origin: USA (Audited via Nutrifoods S.L.).

3.3. Magnesium N-Acetyltaurinate

- **Chemical Identification:** CAS Number: 75350-40-2. Product Code: P02026. Molecular Matrix: $C_8H_{20}MgN_2O_{10}S_2$. Molecular Mass: 392.677 g/mol.
- **Purity & Assay Standard:** **Absolute Chemical Purity / Assay of $\geq 98.0\%$ (on a dry basis)**, yielding a standardized elemental Magnesium load of 6.5% - 7.2% (typically calibrated to 9.5% in formulation dry-mix batches).
- **Physicochemical Profile:** Fine white crystalline powder, completely odorless, showing a light characteristic metallic taste. Soluble in water (1 g per 15 g of H_2O). Bulk density: 1 g/cm³.
- **Neurobiological Mechanism:** The acetylated lipophilic structure provides advanced tissue affinity, allowing it to efficiently cross the blood-brain barrier (BBB) to act directly on central NMDA and GABA receptor networks.*

3.4. Lacticaseibacillus paracasei LMB1 (Precision Probiotic Strain)

- **Taxonomy & Origin:** Pure single-strain microflora biomass (Origin: Microlab Biotech, Code: R. 01/07). Cultured under strict, temperature-controlled anaerobic lactic acid fermentation. (Note: Validated under strict internal quality nomenclature as *Lacticaseibacillus paracasei LMB1*).
- **Purity & Potency Assay:** **Microbiological Purity / Viable Strain Potency of 3.7×10^9 CFU/g** at the time of manufacture. Contaminant screening verifies absolute absence of micotoxinas, microcistinas, and plaguicidas. Inert carrier matrix: Non-GMO corn maltodextrin.

- **Physiological Impact:** Restores healthy microbiome balance, mitigates low-grade mucosal irritation, and strengthens the tight junctions of the intestinal epithelium to accelerate cellular magnesium absorption.

3.5. Essential Vitamins and Cofactor Complex

- **Vitamin C (as ascorbic acid):** CAS No: 50-81-7. **Chemical Purity / Assay: ≥ 99.0%.** Meets all BP, USP, FCC, and European Regulation (EU) No 231/2012 quality thresholds. White crystalline matrix with exceptional structural stability.
- **Vitamin B6 (as pyridoxine hydrochloride):** CAS No: 58-56-0. Molecular Formula: $C_{8}H_{12}ClNO_{3}$. **Chemical Purity / Assay: 98.0% to 101.0% (on a dry basis).** High-purity crystalline powder matrix compliant with Ph. Eur., FCC, and USP guidelines. Functions dynamically to lock magnesium inside cells.
- **Vitamin D (as cholecalciferol):** CAS No: 67-97-0. **Standardized Purity / Potency Assay: ≥ 100,000 IU/g** active Cholecalciferol load. Fine, micronized white powder matrix engineered for cold water dispersibility (≥90% at 60 mesh) to secure absolute formula integration.

4. Encapsulation System & Other Ingredients

Clean-label manufacturing profile containing zero synthetic lubricants, magnesium stearate, or artificial polymers:

- **Other Ingredients (Microcrystalline Cellulose):** Heweten® Grade (JRS Pharma, Germany). **Excipient Purity: 100% pure chemical alpha-cellulose** obtained through controlled acid hydrolysis of softwood biomass. Completely free from preservatives, coloring agents, or artificial starches (Zero parabens, BHT, or dairy derivatives).
- **Veggie Capsule Structure (Hypromellose):** Inprocaps Brand (Hypromellose E464). **Polymer Purity: Meets all strict safety parameters of the current EP, USP, JP, and EU directive (EC) 231/2012.** Formulated entirely from plant wood-cellulose fibers. Disintegration profile: ≤ 15 minutes. Manufactured under strict NSF-GMP validation protocols.

5. Impurities, Heavy Metals, & Microbiological Control Limits

Critical Parameter Target	US FDA / USP Specification Limits	Analytical Verification Methodology
Lead (Pb)	≤ 1.0 ppm (mg/kg)	ICP-MS (Mass Spectrometry)
Arsenic (As)	≤ 1.0 ppm (mg/kg)	ICP-MS
Cadmium (Cd)	≤ 0.5 ppm (mg/kg)	ICP-MS
Mercury (Hg)	≤ 0.1 ppm (mg/kg)	ICP-MS
Total Plate Count (TAMC)	≤ 1,000 CFU/g	USP <2021> Standard Plate Agar

Critical Parameter Target	US FDA / USP Specification Limits	Analytical Verification Methodology
Total Yeast & Mold (TYMC)	≤ 100 CFU/g	USP <2021> Selective Culture Induction
Escherichia coli	Negative in 10g	USP <2022> Enriched Growth Validation
Salmonella spp.	Negative in 25g	USP <2022> Automated Enrichment Method
Staphylococcus aureus	Negative in 10g	USP <2022> Coagulase Test Matrix
Residual Solvents	Absent / Compliant	GC-MS (Headspace Gas Chromatography)

6. Comprehensive Allergen Screen & Regulatory Compliance Matrix

6.1. FALCPA Allergen Screening Profile

Regulated Allergen Class	Formula Presence	Analytical Evidence & Traceability Mapping
Gluten / Wheat derivatives	ABSENT	Certified Gluten-Free across all raw material input lines.
Crustaceans / Shellfish	ABSENT	No marine source structures utilized; 100% synthetic/mineral.
Egg and egg-derived fractions	ABSENT	Probiotic culture mediums strictly avoid aviar peptones or matrices.
Fish fractions / Marine proteins	ABSENT	Mineral-chelate matrices are synthetically pure and animal-free.
Peanuts & peanut oils	ABSENT	Processing facilities are completely isolated from legumes and nut oils.
Soybeans & soy fractions	ABSENT	Fermentation matrix for L. paracasei uses purely synthetic growth factors.
Milk / Dairy fractions (Lactose)	ABSENT	Probiotic strain is harvested dairy-free; suitable for lactose-intolerant usage.
Tree Nuts (Almonds, Walnuts, etc.)	ABSENT	Zero plant-nut materials present in the microcrystalline wood cellulose chain.
Sesame seeds and derivatives	ABSENT	No botanical seed interactions during production, handling, or packaging.

6.2. Bio-Chemical Integrity Declarations

SAFETY & COMPLIANCE TARGET	OFFICIAL ESTATUS	REGULATORY FRAMEWORK & SCIENTIFIC SPECIFICATIONS
GMO Status	GMO FREE (Non-GMO)	Complies with federal standards and (EC) 1829/2003. Probiotic carrier maltodextrin is entirely derived from non-modified corn matrices.
Ethylene Oxide (ETO)	ETO FREE	Validated 100% free from Ethylene Oxide gas decontamination or 2-Chloroethanol residual traces.
BSE / TSE Risk Profile	BSE / TSE FREE	No animal tissues are processed. Capsule shells are formulated entirely from plant-derived HPMC (cellulose ether polymer).
Irradiation Treatments	NON-IRRADIATED	Raw materials maintain biochemical integrity without exposure to ionizing or radioactive sterilization channels.
Nanomaterial Profiles	NANOMATERIAL FREE	Formula contains zero engineered nanoparticles or sub-micron dispersion technologies.
WADA Anti-Doping Limit	COMPLIANT	Contains zero compounds listed on the World Anti-Doping Agency Prohibited List. Safe for competitive athletic consumption.

7. Warnings, Suggested Use, & Expiration Dynamics

- **Suggested Use:** Take 2 capsules 30-60 minutes before bedtime on an empty stomach with a full glass of water.
- **Storage Conditions:** Keep tightly closed in a cool, dry place (store below 25 °C / 77 °F). Protect from direct light, excessive heat, and humidity.
- **Federal Warning Matrix:*** Consult your healthcare provider before use if you are pregnant, nursing, taking medication (especially bisphosphonates, antibiotics, diuretics, or medications for heart conditions), or have a medical condition (e.g., kidney disease). Magnesium may interact with certain medications or be contraindicated in renal impairment. Do not exceed the recommended dose. Keep out of reach of children. Not intended for use by persons under 18 years of age.
- *** FDA Disclaimer:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

US SPECIFICATION AUTHORIZATION & QUALITY SIGN-OFF

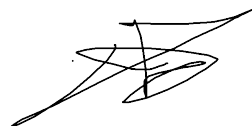
By signing below, it is formally certified that the audited chemical profiles, quantitative Percent Daily Values (% DV), and strict microbiological thresholds detailed in this specification document fully reflect the final product requirements for the United States marketplace.

Technical Director: Enric Romero

Title: Founder & CEO / Head of Laboratory & Quality Control

Organization: Laboratorios Éter Anima

Date of Approval: June 22, 2026



Authorized Digital Signature / Sello



Serenity-Pro — DAILY BALANCE*

A high-performance neuro-digestive adaptogenic nutraceutical engineered to modulate the gut-brain axis, stabilize the enteric nervous system, and intercept systemic inflammatory cascades induced by biological stress. Specially formulated for patients requiring neuro-visceral stabilization and mucosal defense, Serenity-Pro acts as a functional switch that mitigates the high-cortisol signaling pathway, reduces visceral hypersensitivity, and reinforces the intestinal epithelial barrier against hyperpermeability (Leaky Gut) from within.*

1. General Product Specifications (US Market)

TECHNICAL PARAMETERS & TRACEABILITY MAPPING	
Product Name	Serenity-Pro (Daily Balance* / Biological Stress Management)
Product Category	Dietary Supplement (US FDA 21 CFR Compliant Labeling)
Brand Name	Éter Anima
Manufacturing Origin	Made in Spain (Distributed Internationally)
Dosage Form	Hard Veggie Capsules (Hypromellose System)
Packaging Presentation	Amber bottle containing 60 veggie capsules
Serving Size	2 Capsules per day (Provides 30 servings per container)
Net Weight	40.68 g (1.43 oz) 678 mg per capsule
Control Batch Number	251101
Expiration Profile (Best By)	11/2027
Distributed By	EJM Farming Investments S.L. 15 Can Pau Birol Street, Unit 2, Lower Level, 17005 Girona, Spain
Technical Contact	hello@eteranima.com www.eteranima.com

2. Supplement Facts: Qualitative & Quantitative Composition

In strict accordance with USFDA 21CFR 101.36 standards, the qualitative and quantitative composition per daily serving size (2 capsules) is certified below. This matrix reflects the official US label specifications, including calibrated Active Daily Values (% DV):

Active Ingredient Input	Mass per Serving	Certified Raw Purity / Assay	Elemental Active Yield	% Daily Value (% DV)	Primary Bioactive Pathway
Ashwagandha Root Extract (Withania somnifera Dunal)	400 mg	Ratio 5-7:1 (≥ 1.5% Withanolides)	6.0 mg (Pure Withanolides)	†	Regulates the HPA axis, down-regulates cortisol release, and shields intestinal villi from stress degradation.
Black Garlic Powder (Allium sativum L. fermented)	200 mg	100% Pure Liofilizado (Slow-Matured Bulb)	200 mg (SAC & Glutamic Acid)	†	Provides deep cellular neuroprotection and blocks systemic oxidative cascades.
L-Glycine	200 mg	100% Pure Grade (USP / Food Grade)	200 mg (Pure Amino Acid)	†	Acts as an inhibitory central neurotransmitter to induce parasympathetic rest-and-digest state.

Active Ingredient Input	Mass per Serving	Certified Raw Purity / Assay	Elemental Active Yield	% Daily Value (% DV)	Primary Bioactive Pathway
Griffonia Seed Extract (<i>Griffonia simplicifolia</i>)	120 mg	Standardized to 20% (Water Extraction)	24.0 mg (Active 5-HTP)	†	Direct serotonin precursor fueling the enteric system to alleviate visceral hypersensitivity.
L-Tryptophan	100 mg	≥ 98.5% High Purity (Vegetable Source)	100 mg (Pure Essential Acid)	†	Synergistic serotonin precursor stabilizing the neural gut infrastructure and smooth muscle reflexes.
Cordyceps Mycelium Powder (<i>Cordyceps sinensis</i> L.)	100 mg	100% Pure Organic Biomass (Low-Temp Dehydrated)	100 mg (Full Active Fungi)	†	Mitigates adrenal fatigue and exhaustion, maintaining cellular bio-energetics under metabolic stress.
Niacinamide (Vitamin B3)	16 mg	99.00% - 101.00% (Synthetic, Pure Grade)	16.0 mg Active B3	100%	Essential structural coenzyme for neuro-cellular respiration and mucosal barrier homeostasis.
Vitamin B6 HCl (Pyridoxine HCl)	1.4 mg	99.0% - 101.0% (Ph. Eur. / EP Grade)	1.15 mg Elemental	100%	Crucial enzymatic catalyst governing the endogenous synthesis of Serotonin, Dopamine, and GABA.
Riboflavin (Vitamin B2)	1.4 mg	≥ 98.0% Pure (Crystalline Grade)	1.4 mg Active B2	100%	Drives ATP generation via the mitochondrial respiratory chain and supports neurological tissue defense.
Folic Acid (Vitamin B9)	200 µg	95.0% - 102.0% Purity (CAS: 59-30-3 Grade)	200 µg Active B9	100%	Regulates myelin sheath structural safety and drives cellular methylation and tissue recovery pathways.
Vitamin B12 (Cyanocobalamin)	2.5 µg	96.0% - 102.0% Purity (Fermentation Origin)	2.5 µg Active B12	100%	Co-factor for neurological integrity, avoiding nerve burnout during chronic stress states.

† Daily Value (% DV) not established according to US FDA labeling requirements.

3. Certified Raw Material Technical Monographs (Assay & Purity Audited)

3.1. Standardized Ashwagandha Root Dry Extract (Ratio 5-7:1)

- **Taxonomy & Technical Mapping:** Derived exclusively from the roots of genuine *Withania somnifera* Dun. (Origin: India; Reference Code: MP0726, Provider Code: P00168). Extracted via clean water-ethanol processes. Physical form: free-flowing intense brown fine powder with a characteristic aroma. Particle size is calibrated to 300 microns.
- **Purity & Analytical Benchmarks:** Standardized to deliver ≥ 1.50% pure active Withanolides and ≥ 1.00% total Alkaloids via high-performance analysis. Total loss on drying parameter is restricted to ≤ 5.00%. Maximum carrier composition: 30% food-grade corn maltodextrin. Fully free of GMOs, gluten, alérgenos, or BSE/TSE risk markers.

3.2. Slow-Matured Fermented Black Garlic Powder (Freeze Dried)

- **Process & Concentration Profile:** Manufactured by Laboratorios Planes S.L. for Mouse Hill S.C. (Technical Code: FTT091 v00). Sourced from fresh bulbs of *Allium sativum* L. grown in Las Pedroñeras (Cuenca, Spain). Undergoes a prolonged thermal-humidity maturation profile (slow mellowing) without any chemical inputs, converting pungent organosulfurs into highly bioavailable S-allyl-cysteine (SAC) and glutamic acid (umami matrix).
- **Drying Benchmarks:** The matured garlic biomass is freeze-dried (lío-filizado), yielding exactly 50% of the initial concentrated input mass (reducing content by half). Certified 100% pure, free of gluten, GMOs, nanomaterials, or irradiation sterilization processes.

3.3. Pure Crystalline L-Glycine (100% Pure Grade)

- **Chemical Identification & Bulk Code:** 91503, Internal Code: 405647 (Guinama Crystalline Quality). IUPAC Name: 2-aminoacetic acid. CAS Number: 56-40-6. Molecular Formula: C₂H₅NO₂. Molecular Weight: 75.06 g/mol. Physical appearance: pure white crystalline powder. Easily soluble in water matrices.
- **Manufacturing Process & Purity:** Obtained through precise amination and crystallization of monochloroacetic acid and ammonia liquor via a urotropine catalyst phase, followed by decolorization and filtration with high-purity activated carbon. Dry vacuum-dried to yield 100.0% pure pharmaceutical/food grade Glycine. Melting point: 232 °C to 236 °C. Certified completely free of carbohydrates, starches, lactose, or animal vectors (vegan certified).

3.4. Standardized Griffonia Seed Dry Extract (20% 5-HTP, 5:1 Concentration)

- **Taxonomy & Identification parameters:** Sourced from the seeds of *Griffonia simplicifolia* (Origin: China / Provider Code: P00168, Bulk Reference: MP1098). Processed via advanced aqueous phase extraction. Botanical concentration ratio is fixed at 5:1. Physical profile: brown-yellowish fine powder.
- **Purity & Solvents:** Assay value strictly verified to contain 20.00% pure 5-Hydroxytryptophan (5-HTP). Particle size: 100% passes through an 80 MESH screen. Bulk density profile: 40 to 60 g/100mL. Loss on drying: ≤ 5.00%. Residual extraction solvents are fully compliant with Ph. Eur. 5.4 requirements. Excipient matrix: < 10% food-grade maltodextrin.

3.5. High-Purity Vegetable L-Tryptophan

- **Biochemical Monograph:** Sourced 100% from vegetable origin fermentation lines (Reference Code: MP0352, Provider: P00109). CAS Number: 73-22-3. Molecular Formula: C₁₁H₁₂N₂O₂. Molecular Weight: 204.23 g/mol. Form: white crystals or white-yellowish crystalline powder. Bulk density: 0.20 g/mL (tapped: 0.41 g/mL).
- **Assay Limits:** Absolute richness assay guaranteed between 98.50% to 101.50%. Specific optical rotation: -29.4° to -32.8°. pH profile: 5.5 to 7.0. Loss on drying: ≤ 0.30%. Residue on ignition: ≤ 0.10%. Metallo-contaminants strictly capped: Pb ≤ 1 ppm, As ≤ 0.5 ppm, Cd ≤ 0.5 ppm, Hg ≤ 0.1 ppm. Fully compliant with USP and Regulation (EU) 231/2012 monographs.

3.6. Organic Cordyceps Mycelium Powder (Full-Spectrum Biomass)

- **Mushroom Taxonomy & Sourcing:** 100% pure dehydrated whole mushroom powder of *Cordyceps sinensis* (Cultivated and processed by Setacor, Córdoba, Spain). Derived from internal organic agricultural cultivation lines. Processed via mechanical dicing to 10mm and continuous low-temperature clean dehydration at 45 °C for 24 hours, ensuring a verified moisture loss of at least 87% from initial fresh biomass weight. Free of any added excipients, fillers, or blending chemicals.

3.7. High-Assay Folic Acid (Vitamin B9 — USP Grade)

- **Chemical Parameters:** High-purity synthetic pteroylmonoglutamic acid (Nutrifoods Quality Grade, Code: VIT-036). CAS Number: 59-30-3. Molecular Formula: C₁₉H₁₉N₇O₆. Molecular Weight: 441.40 g/mol. Physical form: orangish-yellow fine powder.
- **Assay & Physical Calibration:** Richness assay strictly verified between 95.0% to 102.0% calculated on an anhydrous basis. Total water content (Karl Fisher): ≤ 8.50%. Particle size distribution profile: 90% passes through a fine 200 µm screen. Sulphated ash yield: ≤ 0.2%. Fully compliant with current USP and FCC monograph specifications.

3.8. Vitamin B3 (Pure Nicotinamide — Synthetic Food Grade)

- **Chemical Identification & Traceability:** Reference Number: VIT-014. CAS Number: 98-92-0. Molecular Formula: C₆H₆N₂O. Molecular Weight: 122.1 g/mol. Geographical Origin: Asia (Synthetic matrix). Appears physically as a high-purity white crystalline powder, freely soluble in water and ethanol systems.
- **Technical Quality Standards:** Richness assay verified between 99.00% to 101.00% by titration methodologies. Physical limits: pH calibrated between 6.0 to 7.5; melting point stable at 128.0 °C to 131.0 °C. Bulk density: 0.45-0.60 g/mL (Tapped density: 0.60-0.85 g/mL). Capped impurity boundaries: Chlorides ≤ 70 ppm, Sulphates ≤ 190 ppm, total heavy metals ≤ 30 ppm (As < 1 ppm, Pb < 3 ppm, Cd < 1 ppm, Hg < 0.1 ppm). Residual solvents: total organic solvents ≤ 0.5% (Methanol ≤ 3000 ppm, Benzene ≤ 2 ppm). Particle sizing: >85% passes through a fine 100 mesh screen. Fully free from dopamine-active ingredients, melamine, OGM, and nano-texturizers.

3.9. Vitamin B6 HCl (Pure Pyridoxine Hydrochloride — USP/Ph. Eur. Grade)

- Chemical Profile: Reference Number:** VIT-016. CASNumber:58-56-0. EINECS Number: 200-386-2. Molecular Formula: C8H12ClNO3. Molecular Weight: 205.60 g/mol. Origin: Synthetic (Asia). Physical aspect: white to almost white crystalline powder, completely soluble in water media.
- **Purity & Analytical Benchmarks:** Richness assay guaranteed at 99.0% to 101.0% under Ph. Eur./EP rules and 98.0% to 102.0% under USP boundaries. Physical testing: Loss on drying ≤ 0.5%; Sulphated ash yield ≤ 0.1%; pH range calibrated at 2.4 to 3.0. Elemental active chloride concentration is certified between 16.9% to 17.6% on dry substance. Residual solvents (Ethanol) ≤ 0.5%. Heavy metal limits: Lead ≤ 0.5 ppm, Cadmium ≤ 0.5 ppm, Arsenic ≤ 0.5 ppm, Mercury ≤ 0.1 ppm. Zero trace treatment with Ethylene Oxide (ETO), cross-contamination allergens, or irradiation.

3.10. Vitamin B2 (Pure Riboflavin — Crystalline Feed & Food Grade)

- Chemical Monograph & Origins:** Product Reference:MP0363. CAS Number: 83-88-5. Molecular Formula: C17H20N4O6. Molecular Weight: 376.36 g/mol. Provider Code: P01999. Country of Origin: China. Form: yellow to orange crystalline powder, sensitive to direct environmental light.
- **Assay Limits & Trace Bounds:** Absolute analytical assay value ≥ 98.0% calculated as Riboflavin active matrix. Optical specific rotation verified between (-)115° to (-)135°. Physical limits: Loss on drying ≤ 1.5%; residue on ignition ≤ 0.1%. Monographed impurities: Impurity A ≤ 0.025%, Impurity B ≤ 0.2%, Impurity C ≤ 0.2%, Impurity D ≤ 0.2% (total unified impurities capped at ≤ 0.5%, unknown singular markers ≤ 0.10%). Heavy metal threshold controls: Arsenic ≤ 1 ppm, Lead ≤ 2 ppm, Cadmium ≤ 1 ppm, Mercury ≤ 0.1 ppm. Safe compliance with Regulation (UE) 2023/915 and EP 2.8.13.

3.11. Vitamin B12 (Pure Cyanocobalamin — Fermentation Origin)

- BiochemicalProfile & MatrixTraceability:** Reference Number: VIT-010. CAS Number: 68-19-9. EINECS Number: 200-680-0. Molecular Formula: C63H88CoN14O14P. Molecular Weight: 1355.37 g/mol. Sourced 100% via biotechnological fermentation pathways (Origin: Asia). Physical aspect: highly hygroscopic dark purple-red crystalline powder.
- **Assay & Technical Benchmarks:** Guaranteed active richness assay of 96.0% to 102.0% calculated on dry parameters. Loss on drying (due to extreme hygroscopic behavior) is capped at ≤ 12.0%. Spectrophotometric light absorption ratio standards: 361/278 nm is 1.70 to 1.90; 361/550 nm is 3.15 to 3.45. Operating pH environment: 4.2 to 7.0. Impurity constraints: total structural related impurities ≤ 3.00% (7,8-Lactocyanocobalamin < 1.00%, Methylcyanocobalamin < 0.50%, 8-Epicyanocobalamin < 0.32%, any other single individual impurity < 0.20%). Organic volatile solvents: Acetone ≤ 5000 ppm, Ethanol ≤ 5000 ppm. Metal contaminants: As < 1.0 ppm, Pb < 3.0 ppm, Cd < 1.0 ppm, Hg < 0.1 ppm. Recommended strict storage condition: refrigerated climate (4 °C to 8 °C).

4. Clean-Label Encapsulation System & Excipients

- **Organic Bulking Agent:** Heweten® Cellulose Grade (JRS Pharma, Germany). Pure Microcrystalline Cellulose Type 102/200 obtained through controlled mineral-acid hydrolysis of softwood alpha-cellulose trees. 100% pure chemical composition: completely free of digestible carbohydrates, starches, fats, or dairy sugars (lactose). Recommended re-evaluation baseline: 4 years from production date.
- **Veggie Capsule Matrix:** Inprocaps Brand (Hypromellose E464). Crafted completely from plant-derived wood-cellulose fibers. Fully transparent capsule body and cap, completely odorless. Disintegration validation metric: ≤ 15 minutes (NMT 15 min under USP rules). Total loss on drying: < 8.0%. Certified Kosher, Halal, ISO, BRC, and NSF-GMP compliant.

5. Impurities, Heavy Metals, & Microbiological Safety Control Limits

Critical Parameter Target	Serenity-Pro Specification Upper Limits	Analytical Verification Methodology
Lead (Pb)	≤ 0.1 ppm (mg/kg) [Regulatory Limit ≤ 1.0 ppm]	ICP-MS (Mass Spectrometry)
Arsenic (As)	≤ 0.1 ppm (mg/kg) [Regulatory Limit ≤ 1.0 ppm]	ICP-MS
Cadmium (Cd)	≤ 0.05 ppm (mg/kg) [Regulatory Limit ≤ 0.3 ppm]	ICP-MS
Mercury (Hg)	≤ 0.01 ppm (mg/kg) [Regulatory Limit ≤ 0.1 ppm]	ICP-MS
Aflatoxins (B1 / Total)	≤ 2 ppb / ≤ 4 ppb	HPLC-FLD / High Sensitivity Immunoaffinity
Total Aerobic Microbial Count (TAMC)	< 100 CFU/g [Safety Benchmark ≤ 1,000 CFU/g]	USP <2021> / Standard Plate Agar

Critical Parameter Target	Serenity-Pro Specification Upper Limits	Analytical Verification Methodology
Total Combined Yeast & Mold (TYMC)	< 10 CFU/g [Safety Benchmark ≤ 100 CFU/g]	USP <2021> / Selective Sabouraud Matrix
Escherichia coli	Absent / Negativo in 1g	USP <2022> Enriched Growth Agar
Salmonella spp.	Absent / Negativo in 10g / 25g	USP <2022> Automated Enrichment Protocol
Residual Solvents	Absent / Compliant	GC-MS (Ph. Eur. & USP Headspace GC)

6. Allergen Screening & Biochemical Integrity Declarations

SAFETY & COMPLIANCE TARGET	OFFICIAL STATUS	REGULATORY FRAMEWORK & TRACEABILITY SPECIFICATIONS
1. Cereals containing gluten	COMPLIANT / ABSENT	100% free of wheat, rye, barley, oats, or spelt according to EU 1169/2011 and US FALCPA guidelines.
2. Crustaceans and derivatives	COMPLIANT / ABSENT	No marine-sourced components or wildlife derivatives are handled in the manufacturing area.
3. Eggs and derivatives	COMPLIANT / ABSENT	Complete exclusion of avian or egg-white albumin ingredients. Zero cross-contamination risk.
4. Fish and derivatives	COMPLIANT / ABSENT	Formula is strictly plant and fungal-derived; totally isolated from any marine or aquaculture matrices.
5. Peanuts and derivatives	COMPLIANT / ABSENT	Manufacturing plant lines are completely certified clean and free from any peanut handling.
6. Soybeans and derivatives	COMPLIANT / ABSENT	100% free of soy lecithin or soy protein fractions. Zero risk of botanical cross-contamination.
7. Milk and derivatives (Lactose)	COMPLIANT / ABSENT	Pure microcrystalline cellulose bulking agent is certified free of dairy sugars or starches.
8. Tree Nuts	COMPLIANT / ABSENT	Excludes almonds, walnuts, pecans, pistachios, or macadamias. Completely isolated facility.
9. Celery and derivatives	COMPLIANT / ABSENT	Botanical lines are audited and confirmed free from any raw Apiaceae allergen contamination.
10. Mustard and derivatives	COMPLIANT / ABSENT	Zero contact or presence of mustard seeds or powders across all raw input supply channels.
11. Sesame seeds and derivatives	COMPLIANT / ABSENT	Complies strictly with US FASTER Act and EU guidelines. Total absence across raw matrices.
12. Sulphur dioxide and sulphites	COMPLIANT / ABSENT	No chemical sulfurization or chemical preservative channels are applied to the active matrices.
13. Lupine and derivatives	COMPLIANT / ABSENT	Raw botanical extraction lines are fully isolated from any legume or lupine processing vectors.
14. Mollusks and derivatives	COMPLIANT / ABSENT	Formula contains zero marine wildlife, shellfish, or mollusk-derived processing catalysts.
GMO Status	GMO FREE	Complies with Directives CE 1829/2003 and 1830/2003. Mushroom and vitamin cultures are free of genetically engineered materials.
Ethylene Oxide (ETO)	ETO FREE	Sterilization strictly verified to be free from Ethylene Oxide gas parameters (≤ 0.01 mg/kg thresholds).

SAFETY & COMPLIANCE TARGET	OFFICIAL STATUS	REGULATORY FRAMEWORK & TRACEABILITY SPECIFICATIONS
BSE/TSE Risk Profile	BSE/TSE FREE	Complies with EEC 99/742/EC and 97/534/EC guidelines. Softwood excipients and plant HPMC capsules are fully isolated from contaminant vectors.
Irradiation Treatment	NON-IRRADIATED	Conforms to EU Directive 1999/2/CE. The biochemical structure has not been exposed to ionizing sterilization channels.
Nanomaterial Profile	NANOMATERIAL FREE	Formula contains zero engineered nanoparticles or sub-micron dispersion texturizers.

7. Warnings, Suggested Use, & Storage Matrix

- Suggested Use: Take 2 capsules daily, 30 to 60 minutes before bedtime on an empty stomach with a full glass of water, or as directed by your healthcare professional.
- Storage Conditions: Keep tightly closed in the original amber protective bottle. Store in a cool, dark, and dry place (below 25 °C / 77 °F, maximum threshold 30 °C). Vitamin B12 ingredient profile suggests optimal integrity when maintained in climate-controlled environments. Absolute isolation from direct light, humidity, and volatile chemical vapors is mandatory.
- Federal Warning Matrix:* Do not exceed the recommended daily dose. Dietary supplements must not be utilized as a substitute for a varied, balanced diet and a healthy lifestyle. Keep out of reach of children. Not suitable for pregnant or nursing women. Do not use if you are taking antidepressant medications (e.g., SSRIs, MAOIs, or SNRIs) due to a potential risk of serotonin syndrome. Consult your healthcare provider before use if you have a medical condition or are taking prescription medications. Discontinue use and seek medical help immediately if you experience headache, nausea, or irregular heartbeat.
- * FDA Disclaimer: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

US SPECIFICATION AUTHORIZATION & QUALITY SIGN-OFF

By signing below, it is formally certified that the audited chemical profiles, strict quantitative active assays, and microbiological safety limits detailed in this document fully reflect the final product requirements for international and United States marketplace distributions.

Technical Director: Enric Romero
Title: Founder & CEO / Head of Laboratory & Quality Control
Organization: Laboratorios Éter Anima
Date of Approval: June 22, 2026



Authorized Digital Signature/Sello