



NUCOREBIO · FORMULA DOSSIER · SAMPLE DOCUMENT

FORMULA REFERENCE: NCB-MH-001

ProVital M24™

Premium Men's Testosterone Support Formula

NCB-DOS-042 · v2.0 · 2026

Dossier Classification:

SAMPLE

Full specs under NDA only

SAMPLE DOCUMENT — CONCENTRATIONS PARTIALLY REDACTED

SAMPLE DOSSIER: This document demonstrates the depth and structure of NuCoreBio's formula dossier. Ingredient concentrations and certain clinical references are shown in representative form only. Full concentration data released under executed NDA. This sample uses our ProVital M24™ (NCB-MH-001) Men's Performance formula.

Parameter	Detail
Formula Name (Brand)	ProVital M24™
NuCoreBio Code	NCB-MH-001
Health Category	Men's Testosterone Support & Vitality
Target Consumer	Men 30–60, active lifestyle, career-focused; total T and free T optimization
Primary Mechanism	Triple-axis: HPG stimulation (LH↑) + SHBG reduction + cortisol suppression
Bio-Speed™ Classification	Level 5 — Perceivable effect 30–45 minutes post-ingestion (first dose)
Dosage Form	Hard capsule (HPMC — vegan), 2 capsules per serving
Serving Size	2 capsules / 1,100mg total fill per serving
Servings Per Container	30 (60-capsule bottle) or 45 (90-capsule bottle)
Recommended Daily Dose	2 capsules with breakfast
Shelf Life	24 months (supported by ICH accelerated stability data)
Storage	Below 25°C, away from moisture and direct sunlight
License Availability	Non-exclusive (global) · Exclusive (by territory) · Full IP Transfer
Exclusivity Status	Territory exclusivity available — enquire for specific markets

— SECTION 01

Formula Concept & Scientific Rationale

ProVital M24™ was designed to address the three primary mechanisms responsible for declining bioavailable testosterone in men over 30: reduced LH-driven testosterone synthesis, elevated SHBG reducing free testosterone fraction, and elevated cortisol creating a catabolic hormonal environment. Most single-ingredient testosterone products address only one of these axes. ProVital M24™ is mechanistically complete.

Axis	Mechanism	Ingredients Targeting This Axis	Clinical Outcome
Axis 1: HPG Stimulation	Stimulate LH/FSH release → Leydig cell T synthesis	Tongkat Ali 200:1 (primary), D-Aspartic Acid (secondary)	+18–27% total testosterone in 8–12 weeks (RCT evidence)
Axis 2: SHBG Reduction	Reduce SHBG binding → increase free testosterone fraction	Fenugreek 50% saponins, Boron glycinate	+15–22% free testosterone; +6.6% (Wilborn 2010)
Axis 3: Cortisol Suppression	HPA axis modulation → cortisol ↓ → T-suppression removed	Ashwagandha 5% withanolides (600mg)	–14–32% cortisol; enables full T synthesis (Chandrasekhar 2012)
Axis 4: Synthesis Cofactors	Essential cofactors for T synthesis enzyme (17β-HSD)	Zinc bisglycinate 25mg, Vitamin D3 3000IU	Deficiency correction; foundational for Axes 1–3 to function
Axis 5: Bioavailability Enhancement	Maximize absorption of all actives	Piperine 95% (BioSpeed™ component)	+20–200% bioavailability of key actives depending on ingredient

— SECTION 02

Ingredient Specification Sheet

Full concentrations are available under executed NDA. This table shows the ingredient specification framework, analytical methods, and quality standards for each active.

Ingredient	Extract / Form	Concentration	Standardisation	Analytical Method	Grade	COA Parameter
Tongkat Ali Root Extract	200:1 hot water extract	[RESTRICTED under NDA]	Eurycomanone ≥1.0% (min)	HPLC-UV (validated method)	Pharmaceutical	Eurycomanone % by HPLC
Ashwagandha Root Extract	Root-only, KSM-66® spec	[RESTRICTED under NDA]	Withanolides ≥5.0% (min)	HPLC-DAD (USP method)	Pharmaceutical	Withanolides % by HPLC
Fenugreek Seed Extract	Water-alcohol extract	[RESTRICTED under NDA]	Furostanolic saponins ≥50%	UV spectrophotometry / HPLC	Supplement Grade	Saponins % by UV/HPLC
Boron (as Glycinate)	Boron glycinate chelate	[RESTRICTED under NDA]	Boron content ≥3% (elemental)	ICP-MS	Food Grade	Boron mg by ICP
Zinc (as Bisglycinate)	Zinc bisglycinate chelate	[RESTRICTED under NDA]	Zinc content ≥20% (elemental)	ICP-MS or FAAS	Food Grade	Zinc mg by ICP
Vitamin D3	Cholecalciferol (oil-based)	[RESTRICTED under NDA]	≥100,000 IU/g (concentrate)	HPLC-UV (USP <1150>)	Pharmaceutical	IU/g potency
Maca Root Extract	4:1 cold extraction	[RESTRICTED under NDA]	Glucosinolates ≥0.6%	HPLC-PDA	Supplement Grade	Glucosinolate % by HPLC
Black Pepper Extract	Piperine 95% standardized	[RESTRICTED under NDA]	Piperine ≥95.0%	HPLC-UV (USP)	Pharmaceutical	Piperine % by HPLC

FULL CONCENTRATIONS — UNDER NDA



Full concentration data (mg per serving for each active) is released only under executed NDA. Upon NDA execution, the complete specification sheet including exact doses, batch analytical data, and supplier identity is provided.

— SECTION 03

Clinical Evidence Base

ProVital M24™ is formulated exclusively from ingredients with Level 1 or Level 2 clinical evidence (RCT or meta-analysis) for the stated mechanisms. The following table summarises the primary clinical references for each key active.

Ingredient	Primary RCT	n	Duration	Primary Outcome	Effect Size	Evidence Level
Tongkat Ali	Tambi et al. (2012), Asian J Androl	76	12 weeks	Serum testosterone	+26.8% (p<0.01)	Level 1 RCT
Tongkat Ali	Hamzah & Yusof (2003), Br J Sports Med	14	5 weeks	Lean body mass	+2.3 kg (p<0.05)	Level 1 RCT
Ashwagandha	Wankhede et al. (2015), J Int Soc Sports Nutr	57	8 weeks	Total testosterone	+15.4% vs placebo	Level 1 RCT
Ashwagandha	Chandrasekhar et al. (2012), Indian J Psychol Med	64	8 weeks	Cortisol (ELISA)	-27.9% (p<0.001)	Level 1 RCT
Fenugreek	Wilborn et al. (2010), Int J Sport Nutr Exerc Metab	49	8 weeks	Free testosterone	+6.57% (p<0.05)	Level 1 RCT
Boron	Naghii et al. (2011), J Trace Elem Med Biol	8	7 days	Free testosterone	+28.3% (p<0.05)	Level 2 RCT
Zinc	Kilic et al. (2010), Neuro Endocrinol Lett	10	4 weeks	Total testosterone	+24.7% (p<0.05)	Level 2 RCT
Vitamin D3	Pilz et al. (2011), Horm Metab Res	54	12 months	Total testosterone	+25.2% (p<0.001)	Level 1 RCT
Piperine	Shoba et al. (1998) Planta Med (curcumin model)	Various	Various	Bioavailability (AUC)	+2000% for curcumin	Level 1 (mechanism)



Ingredient	Primary RCT	n	Duration	Primary Outcome	Effect Size	Evidence Level
Tongkat Ali (meta)	Leisegang et al. (2022), J Integr Med	172 (pooled)	Various	Testosterone (SMD)	SMD +0.83 (p<0.001)	Meta-analysis Level 1

— SECTION 04

Quality Control & Stability Data Summary

Test	Method	Specification	Batch Result (representative)	Frequency
Tongkat Ali potency (eurycomanone)	HPLC-UV validated	≥1.0% per formula spec	1.18% (batch NCB2026-001)	Every batch
Ashwagandha (withanolides)	HPLC-DAD (USP)	≥5.0% per formula spec	5.34% (batch NCB2026-001)	Every batch
Capsule fill weight	Gravimetric, n=10	1,100mg ±3%	1,098mg avg; CV 0.8%	In-process + QC release
Lead (Pb)	ICP-MS (USP <232>)	≤1.0 ppm (batch total)	0.042 ppm	Every batch
Cadmium (Cd)	ICP-MS (USP <232>)	≤0.3 ppm	< 0.010 ppm (LOD)	Every batch
Arsenic (As)	ICP-MS (USP <232>)	≤1.0 ppm	0.089 ppm	Every batch
Mercury (Hg)	ICP-MS (USP <232>)	≤0.1 ppm	< 0.005 ppm (LOD)	Every batch
TPC (Total Plate Count)	USP <2021>	≤10,000 CFU/g	420 CFU/g	Every batch
Yeast & Mold	USP <2021>	≤1,000 CFU/g	< 10 CFU/g	Every batch
E. coli	USP <2021>	Absence per g	Absent	Every batch
Salmonella spp.	USP <2021>	Absence per 25g	Absent	Every batch
Capsule disintegration	USP <701>	< 30 min at 37°C	9 min 22 sec	Per lot
Moisture (LOD)	Karl Fischer	≤ 5.0%	3.2%	Per lot
Pesticide multi-residue	GC-MS/LC-MS (EU MRL)	All within EU MRL limits	No residues detected	Per raw material lot

— SECTION 05

Stability Study Summary — ICH Q1A(R2)

ProVital M24™ has completed accelerated stability testing per ICH Q1A(R2). Real-time stability is ongoing at 25°C/60%RH. The following summarises accelerated study results supporting the 24-month shelf-life claim.



Test Parameter	T=0 (Initial)	T=1 Month	T=3 Months	T=6 Months (40°C/75%RH)	Specification	Verdict
Tongkat Ali potency	1.18%	1.17%	1.15%	1.12%	≥ 1.00%	PASS ✓
Ashwagandha potency	5.34%	5.31%	5.28%	5.19%	≥ 5.00%	PASS ✓
Appearance	White-off HPMC cap; tan fill	Unchanged	Unchanged	Unchanged	No change	PASS ✓
Odor	Characteristic; no off-notes	Unchanged	Unchanged	Unchanged	Characteristic	PASS ✓
Moisture (LOD)	3.2%	3.3%	3.4%	3.6%	≤ 5.0%	PASS ✓
Disintegration	9 min 22 sec	9 min 35 sec	9 min 48 sec	10 min 12 sec	< 30 min	PASS ✓
Microbial TPC	420 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	≤ 10,000 CFU/g	PASS ✓
Heavy metals	All within limits	—	—	All within limits	USP <232>	PASS ✓

STABILITY VERDICT: 24-MONTH SHELF LIFE SUPPORTED

STABILITY CONCLUSION: At the 6-month accelerated condition (40°C/75%RH), ProVital M24™ retains ≥95% of initial potency for all key actives. Predicted shelf life at 25°C/60%RH = 24+ months using Arrhenius modelling. Real-time data to 12 months available upon NDA execution.



— SECTION 06

Regulatory Pathway & Compliance Status

Market	Regulatory Framework	Ingredient Status	Label Claims (Pre-Validated)	Status
United States	FDA DSHEA · 21 CFR 111	All ingredients GRAS or established dietary supplement ingredients	"Supports healthy testosterone levels" · "Helps maintain vitality" · "Supports energy and endurance"	READY ✓
Australia	TGA ARTG (AUST L)	All ingredients on TGA Permitted Ingredients List	Per TGA permitted indications for each active — full list under NDA	READY ✓
Canada	Health Canada NHP (NPN)	All ingredients in NHP monographs	Per NHP monograph for testosterone support — bilingual EN/FR	NPN application support available
United Kingdom	FSA · UK food supplements regs	All ingredients permitted in UK supplement regulations (post-Brexit)	Structure/function claims — no disease claims. No EU Novel Food issues.	READY ✓
European Union	EFSA · Reg. 1169/2011	All ingredients EU-compliant — NO Novel Food triggers in this formula	EU authorized health claims for Zinc (testosterone maintenance) · Vit D3 · Selenium	READY ✓
Halal Markets	JAKIM / MUI / SFDA	Halal production line available — all ingredients Halal-compliant	Full Halal certificate per batch; JAKIM and MUI compatible	READY ✓

— SECTION 07

Commercial Terms & Licensing Options

Option	Description	License Fee (Indicative)	Royalty	Minimum Volume
Non-Exclusive License — Any Territory	License to manufacture/sell ProVital M24™ under your brand, any territory. NuCoreBio may license same formula to others.	USD \$10,000–\$18,000 one-time	Optional: 4% Net Sales	None (recommended 5,000 units/year)
Exclusive License — Single Country	Sole right to sell ProVital M24™ under your brand in one country for term of agreement.	USD \$25,000–\$50,000 one-time	Optional: 5% Net Sales	Min. 20,000 units/year



Option	Description	License Fee (Indicative)	Royalty	Minimum Volume
Exclusive License — Regional (e.g. DACH, ANZ)	Sole rights across a defined regional market for the agreement term.	USD \$45,000–\$90,000 one-time	Optional: 5% Net Sales	Min. 50,000 units/year
Exclusive License — Global	Worldwide exclusivity on ProVital M24™ formula. NuCoreBio cannot license to anyone else.	USD \$120,000–\$200,000 one-time	Optional: 5% Net Sales	Min. 150,000 units/year
Full IP Transfer	Complete ownership transfer of Formula IP. NuCoreBio retains production rights only if agreed. No royalties after transfer.	From USD \$250,000 (negotiable)	None — full ownership	Production volume negotiable

LICENSE ProVital M24™ — NEXT STEPS

NEXT STEPS TO LICENSE ProVital M24™: 1. Execute NDA → receive full ingredient concentrations + complete specification sheet 2. Request pilot sample (60 capsules) with full COA — 10-14 day lead time 3. Evaluate sample + COA using our Sample Evaluation Checklist (NCB-EVAL-020) 4. Confirm territory, exclusivity level, and production volume 5. Receive formal license agreement and pricing confirmation within 48 hours Email: Mc5896538@outlook.com | WhatsApp: +86 15866920149 | Reference: NCB-DOS-042