VITASPHERE™B12: ENCAPSULATION TECHNOLOGY

UMANG GLOBAL GROUP | Technical Paper

1. Abstract

Vitamin B12 (cobalamin) is utilized in minute quantities in food and dietary products, where consistency, stability and accurate analysis are crucial. B12 test results may be affected by exposure to bright light, heat, moisture, pH conditions and interactions with ascorbic acid, other B vitamins and minerals. This report reviews the issues regarding B12 as a material and the formulation challenges involved in encapsulating B12, and provides general tips and guidelines regarding the handling and verification of B12 sources.

2. Key takeaways for formulators

- For microgram doses, the particle size, the active loading and the particle count are responsible for the uniformity of the content.
- Several environmental factors, like light, temperature, acidic pH, humidity and the presence of co-ingredients, may cause instability in B12.
- Encapsulation can provide barrier protection and improvements in handling and release, but all benefits should be established in the final matrix.
- Release is an *in vitro* property and can be determined according to the appropriate compendial methodology.
- It is important to know the particle size, the active loading, uniformity and stability of every grade.

3. Introduction

The B12 formulation must ensure that the stated dosage is achieved in all the tablets, that it is maintained for the entire duration of its shelf life and that it can be verified through various methods. This is important because B12 at a dosage of 2.5 mcg in a 1,000 mg tablet translates into 2.5 ppm. A small loss or unevenness in particle distribution matters because the resulting change in the dosage amount would be significant. Encapsulation protects the active substance inside the capsule, minimizes its exposure to external factors and optimizes handling and release. Evidence to support the formulation should be collected from general scientific facts, relevant published research and authoritative information about the product in question.

4. Vitamin B12 as an ingredient

4.1 Structure and commercial forms

Cobalamin refers to a group of compounds that have a cobalt atom at their center. The upper ligand attached to the cobalt ion determines the type of cobalamin. Cobalamin can take the forms of cyanocobalamin, hydroxocobalamin, methylcobalamin and 5′-deoxyadenosylcobalamin. Cyanocobalamin is often the preferred option because of its stability properties.

Form	Upper ligand	Key consideration
CNCbl	–CN	Common commercial form; comparatively stable in published comparisons.

Form	Upper ligand	Key consideration
OHCbl	–OH / $–H_2O$	Stability depends on stress conditions; photolysis remains relevant.
MeCbl	$–CH_3$	Co–C bond; sensitive to light and certain acidic/reactive conditions.
AdoCbl	5′-deoxyadenosyl	Co–C bond; light-sensitive; application and regulatory context matter.

4.2 Regulatory framing

Different jurisdictions and product categories allow various forms of vitamins and impose different preconditions. Applicable law includes EU food supplement and fortified food regulations, US GRAS regulations and dietary supplement cGMP, Codex recommendations and India's FSSAI regulations. Verify the current requirements for your intended product or market.

5. Formulation challenges

5.1 Microgram dosing and content uniformity

To estimate the random distribution of active particles, we can calculate the sampling coefficient of variation using the formula:

$$\mathbf{CV\ (\%) = 100 / \sqrt{N} \quad | \quad N = D / (w \times m_p)}$$

where N is the mean number of B12-bearing particles in a dose, D is the B12 dose, w is the B12 content of a given particle, and m_p is the particle mass. A random sampling variability of 5% is achieved with about 400 particles, and 2,500 particles are required for 2% random sampling variability.

5.2 Red color speckling

In pale-colored products, concentrated cyanocobalamin particles may appear as red or pink specks. It is possible for a few large, intensely colored particles to create noticeable speckling. The small size of the active particles, the presence of a shell layer or the colored nature of products may lower the visibility of the specks, yet speckling may also be an indication of low particle number or poor distribution.

5.3 Light

Cobalamins can degrade under light irradiation. Different forms of cobalamin may have different sensitivities, and different types of reactive species may also affect them. Proper protection procedures should be applied during processing, storage and analytical investigation.

5.4 Heat, pH and moisture

Temperature and pH stresses can cause losses of B12; the degree of these losses depends on the form of cobalamin and the matrix. Moisture and water activity influence molecular mobility and stability in dry systems; hence, the processing temperature, pH, exposure to moisture and packaging should be controlled and evaluated in product-relevant stability studies.

5.5 Interactions with vitamin C, other B vitamins and minerals

Ascorbic acid is known to have incompatibility issues, and its degradation is sensitive to the formula and pH. Other ingredients, such as vitamins B1, B2 and B3 and trace minerals, could impact the activity of the product. Analyze the formulation as a whole and document the source of the minerals.

5.6 Analysis at parts-per-million levels

Basic B12 evaluation necessitates a validated method that allows for complete extraction and sufficient sensitivity. While microbiological tests assess B12 bioactivity, they do not provide information on the type of cobalamin that is present. However, chromatographic techniques such as ultra-performance liquid chromatography (UPLC-UV) or reversed-phase high-performance liquid chromatography (RP-HPLC) are able to quantify B12 compounds.

6. Encapsulation technology

Encapsulation can use reservoir-type coatings or a matrix structure in which B12 is enclosed or dispersed within a carrier. When choosing wall materials and processes, criteria such as compatibility, barrier properties, thermal and moisture exposure, desired particle characteristics and intended release should all be considered. While the encapsulation literature offers useful principles, such evaluations should not be construed as evidence of specific product performance.

6.1 Manufacturing approaches

Approach	Process role / potential benefit	Critical considerations
Spray drying	Forms matrix particles from a feed dispersion; suited to scalable powder production.	Inlet/outlet conditions, wall composition, moisture and particle recovery.
Spray chilling / cooling	Solidifies a molten carrier around or with the active; can avoid aqueous drying.	Melt temperature, cooling rate and carrier compatibility with B12.
Fluid-bed coating	Deposits a coating onto cores or particles to create a barrier layer.	Coating uniformity, process conditions, attrition and particle integrity.
Hot-melt / lipid coating	Applies a lipid-based protective layer without solvent-based coating.	Thermal exposure, coating thickness, adhesion and release profile.
Matrix / other encapsulation	Distributes the active through a carrier and can tailor handling or release.	Loading, particle size, process reproducibility and validated performance.

Process selection should be grade- and application-specific. Confirm the active form, wall materials, particle size distribution, loading, process tolerance and desired release profile before scale-up.

6.2 VitaSphere™B12 technology platform

The technology codes TM, GR, SR, IR, LC, DE, MB, ME and MP have been identified, with a platform active-content range of 0.1–10%. The definitions of DE, MB, ME and MP have not been confirmed in this document and must be validated with Umang. Product-specific performance claims are subject to data validation.

7. Applications

Format	Key formulation considerations
Tablets / capsules	Blend uniformity, flow, compression or filling performance, particle integrity and content uniformity.
Vitamin / mineral premixes	Compatibility with ascorbic acid, other B vitamins, minerals and moisture; shelf-life assay.
Beverage powders	pH, dispersion, moisture exposure and analytical recovery in the final matrix.
Gummies / acidic formats	Acid and process-temperature exposure; stability and release in the actual formulation.

8. Quality evaluation

Quality attribute	Evaluation / purpose
Particle size and loading	Characterize active-bearing particles and assess dose-level particle count.
Blend and content uniformity	Verify distribution in the blend and individual dosage units using applicable compendial criteria.
Assay and extraction recovery	Validate extraction from encapsulated particles and quantify B12 at the intended level.
Stability / photostability	Assess assay retention under relevant light, temperature, pH, moisture and premix conditions.
Dissolution / release	Measure release using suitable methods; compare profiles where appropriate.
Particle / coating integrity	Examine physical integrity and compare release or coating condition before and after processing.
Documentation	Review grade-specific specifications, analytical methods, batch data and supporting validation.

9. Conclusion

VitaSphere™B12 is an encapsulated B12 ingredient platform suitable for formulations where low-dose uniformity, stability and processing efficiency are the main target parameters. A sound

selection strategy should match particle size and active loading to the anticipated dosage and include compatibility analysis with the overall formulation, as well as assay retention, extraction recovery, release properties and particle integrity during processing and storage of the product. Ultimately, the assessment should be based on grade-specific information and product testing; literature cases can be helpful but should not serve as a substitute for the results of direct testing.