gotab®
BY GOLDEN OMEGA

Technical Sheet

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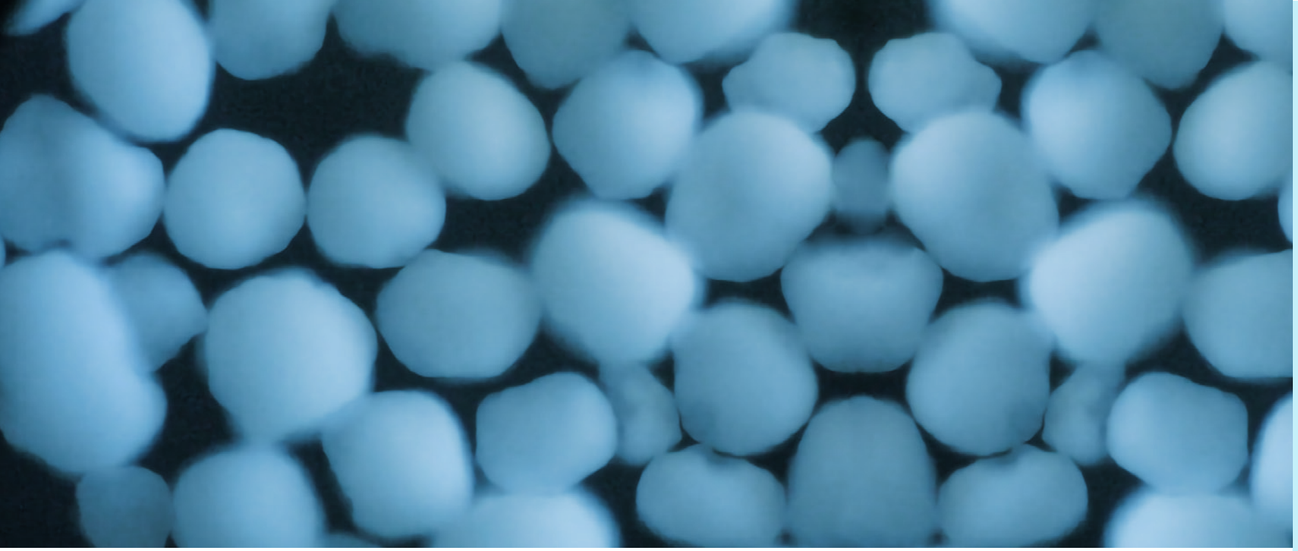

Gotab Formulation and Manufacturing Advice.

Product: GoTab® powders

Composition breakdown

Highly refined fish oil with mixed tocopherols	(29.9% w/w)
B-cyclodextrin	(69.6% w/w)
Ascorbic acid	(0.5% w/w)

The technology behind GoTab® is based on Omega-3 fatty acids included in cyclic modified starch, beta-cyclodextrin, forming a complex. Beta-cyclodextrin is in its pure form a direct compressible powder and the successful complexation of the long-chained Omega-3 fatty acids from fish oil concentrates with beta-cyclodextrin transfer the direct compressible property to the GoTab® powders.

Tableting (compaction) of the powder

The Omega-3 powder is specifically developed as direct compactible, however, a powder comprising as much as 30 % (w/w) oil will be more challenging to compress than DC grade powders without oil. We want you to succeed with your formulation and the following pointers may give you the additional information you need to complement your own tableting experience.

Equipment- tableting machine and punches

Any tableting machine can be used, however, it has been observed that the tablet dies to use are un-tapered. Several dies today are tapered, a design where the opening in the matrise (where the upper and lower punch meet to form the tablet) is somewhat convex; the idea behind this design is that air trapped in the powder mix to be tableted shall be able to escape. We have found that powder may also escape through this narrow opening during tableting of the Omega-3 powder. The solution is to use un-tapered dies, dies where the opening is straight all the way through, not curved.

Surroundings

- Store the powder chilled (4-15oC) until production. Once the original container with powder is opened the entire powder amount should be compressed to tablets as soon as possible.
- Control the residual humidity (RH) in your production environment if possible- as most powders GOtab is slightly hygroscopic.
- Control the temperature in your production environment if possible (below 19oC)- omega-3 is susceptible to oxidation and exposure to elevated temperatures triggers oxidation.
- Avoid unnecessary production steps, the extra mechanical stress may initiate oxidation. GoTab® powder is DC grade and should simply be mixed into the formulation, followed by tableting.
- Avoid hold-ups under production.
- Once compressed to tablet cores, keep the tablet cores in a sealed, air-tight container kept cool (4-15oC) until coating or blister-packaging.

Formulation

The powder can be compressed as the single ingredient to plain Omega-3 tablets or combined with other actives. Below is a recommended formulation for the allowance of as much Omega-3 powder as possible in the tablets. The formulation can also be used as a base for the addition of other actives.

Material	Amount % (w/w)
GoTab®	96
Avicel HFE-102	2,5
Talc	1,0
Magnesium stearate	0,5
Total	**100**

→ The suggested lubricants and amounts added must be adjusted to each individual tableting machine and production environment. Talc is especially recommended if the tablet punches are worn. Avicel HFE-102 is a co-dried material of mannitol and MCC that has proven **more beneficial for this formulation than plain MCC.**

Protection against oxidation for the tablets

The tablet cores will oxidize over time if not protected against oxidation, stability studies have revealed that the best protection against oxidation is achieved by blistering the tablet cores. If blister-packaging is not an option, coating of the tablets is recommended.

If coating is to be applied, the coating of the tablet cores should take place as soon as possible after the tableting of the cores and at least within one week. The surface of the tablet cores is sensitive towards type coating material, because molecules of Omega-3 fatty acids are exposed to the environment on the surface. Hence, choice of polymer and ingredients added to the coating formulation is of importance.

Coating formulation considerations

- Use a clear coating material, e.g. polyvinyl alcohol (PVA) or hyroxypropylmethyl cellulose (HPMC):
    - Most colored coatings contain opacifier, most commonly used are titanium dioxide (TiO2) or other metal-based substances. These substances are repelled from the surface of the GoTab® tablets and cause the coating to lose the barrier properties or, in worse case, to peel off the tablets.
    - If a colored coating is desired, apply an additional layer on top of a clear coating.
- A barrier coating is necessary for sufficient protection against oxidation- apply a minimum of 6-8% (w/w) weigh gain of coating material.
- Avoid titanium dioxide (TiO2) completely. A reaction happens between the cores and the TiO2 causing the TiO2 to cluster, thereby leaving the coating unevenly distributed and the distinct Omega-3 smell will penetrate the coating.

Coating process considerations

- Initiate the coating process with a low spray rate and low pan speed- increase speed when the cores have received the first, protective layer of polymer.
- Avoid hold-ups during spraying- apply the intended coating layer in one continuous operation.
- Bed temperatures ranging around 45C° during coating are considered safe with regards to the oxidative stability of the final product, the coated tablet.

→ Once sufficiently coated the tablets withstand normal storage at ambient temperatures.

**Defined in the commission regulation (EU) 2022/63 of 14 January 2022 amending annexes II and III to regulation (EC) 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E171), titanium dioxide is not authorised in the food categories listed in Part D and E of the regulation. Titanium dioxide is hence forbidden in foods in the European Union.*

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