Statement on Site and Quality System Status

Capsugel® empty capsule products

Empty capsules are considered as an excipient for medicinal products or as an ingredient for a food supplement, depending on the final application.

Lonza empty capsule manufacturing sites are certified according to the Quality Management System ISO 9001 and the Environmental Management System ISO 14001.

Additionally:

- Within the scope of excipients:
    - Capsugel® empty capsules are manufactured under carefully controlled Good Manufacturing Practices, in accordance with the IPEC's (International Pharmaceutical Excipient Council) Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients.
    - Our sites in Bornem, Belgium, and Colmar, France, have obtained EXCiPACT™ excipient GMP Certification from SGS, a third-party accredited certification body. This excipient GMP certification provides independent validation that Lonza applies excipient GMP in the manufacture of empty two piece hard capsules at these sites.

      This independent third party excipient GMP certification can be considered as an alternative to an on-site audit to demonstrate GMP compliance of Lonza as starting material supplier for medicinal products, as required by current European Union regulations.
    - As required by the French Public Health Code, and more specifically the French Decree n°2008-109 of 05 February 2008 and the French Decision of 08 April 2008 related to raw materials for pharmaceutical products, our Colmar, France, manufacturing site has registered its activities and has been successfully audited as excipient manufacturer by the French Health Authority ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé).
- Within the scope of **food supplement** ingredients:
    - In Europe – Lonza confirms compliance of our empty capsule manufacturing processes to the principles as outlined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs and subsequent amendments. As such, we confirm having a HACCP (Hazard Analysis and Critical Control Points system) in place in our quality system as part of the legislative requirements.

- Under the control of the respective competent authorities, our European empty capsules manufacturing sites have been granted the following official establishment numbers:

Empty capsule manufacturing site	Competent Authority	Official Establishment number
Capsugel France SAS 10, rue Timken F-68027 Colmar Cedex France	Direction Départementale de l'Emploi, du Travail, des Solidarités et de la Protection des Populations (DDETSPP)	Non-animal: 612 050 518 0036 Animal (gelatin): 68-066-002
Capsugel Belgium NV Rijksweg 11 B-2880 Bornem Belgium	Federal Agency for the Safety of the Food Chain (FASFC)	Non-animal: AER/ANT/000557 Animal (gelatin): B106301

In this context, Lonza has extended surveillance programs on several control points in place at all stages of our operations, from raw materials to finished products, and guarantees full traceability for each capsule batch, supporting a high-quality and safe capsule product in the market.

The information contained herein corresponds to Lonza's knowledge on the subject at the date of publication and is, to the best of our knowledge, accurate. However, Lonza refuses any liability for the application and use of further processed material containing our products. According to the relevant regulations, the manufacturer of the final product is solely responsible for the use and commercialization of the Lonza product and the information contained herein.

For further information, please contact your Lonza Capsugel account representative.

Products: Hard Gelatin, DRcaps®, Vcaps®, Vcaps® Plus
Sites: Bornem BELGIUM, Colmar FRANCE

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