SAFC®
Pharma/Biopharma Raw Materials

API-grade Meglumine

A functional excipient & counterion that fulfills all of your needs

Opened in September 2016, our new state-of-the-art production site in Mollet, Spain manufactures API-grade Meglumine according to the latest regulatory guidelines, as advocated by the FDA and EMA.

We offer best-practice support throughout your entire registration process and boast an excellent track record facilitating our customers' compliance with international standards.

Benefits of our Meglumine:

- Enhances the solubility and bioavailability of actives
- An excellent substitute for sodium
- Manufactured under cGMP guideline ICH Q7* for active pharmaceutical ingredients (API)
- Only location in Europe where Meglumine is manufactured

*International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

MERCK

PRODUCT PROFILE

Product description	Meglumine is low in endotoxins suitable for use as Active Pharmaceutical Ingredient Emprove® API Ph Eur, JP, USP
Pack sizes	25 kg and 50 kg carton box and/or PE drums with double PE bags
Production process	Multiple synthesis steps in dedicated equipment
Regulatory status	GMP, validated process (according to ICH Q7)
Track record	Customer audits: no critical findings FDA audits: no major observations
Registrations	US-DMF*, CEP*
Production site	Mollet, Spain

*Registration is being processed to add Mollet as an additional manufacturing site

APPLICATION RANGE OF MEGLUMINE

As an advanced intermediate API

- Salt of Meglumine and the active is applied

→ Meglumine has to be considered as part of the API

pKa of Meglumine: 9.60

→ Suitable for APIs with a pKa of 6 or lower

API-grade material is mandatory

As a functional excipient

- pH modifier
- Alkalizer
- Stabilizer

→ A complex with the active formed in the body

→ Meglumine has to be considered as part of the API

API-grade material is strongly recommended

WHY API QUALITY?

Consequence from FDA and EMA statements:

According to the FDA, different salt forms of a drug substance MUST be considered as different APIs. → Consequently, the counterion MUST be considered as part of the API. → The manufacture of an API is performed according to ICH Q7. → **The manufacture of the counterion has to be performed according to ICH Q7**

The same is recommended for the application as a functional excipient, as a complex with the active formed in the body

The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: **www.merckmillipore.com**

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