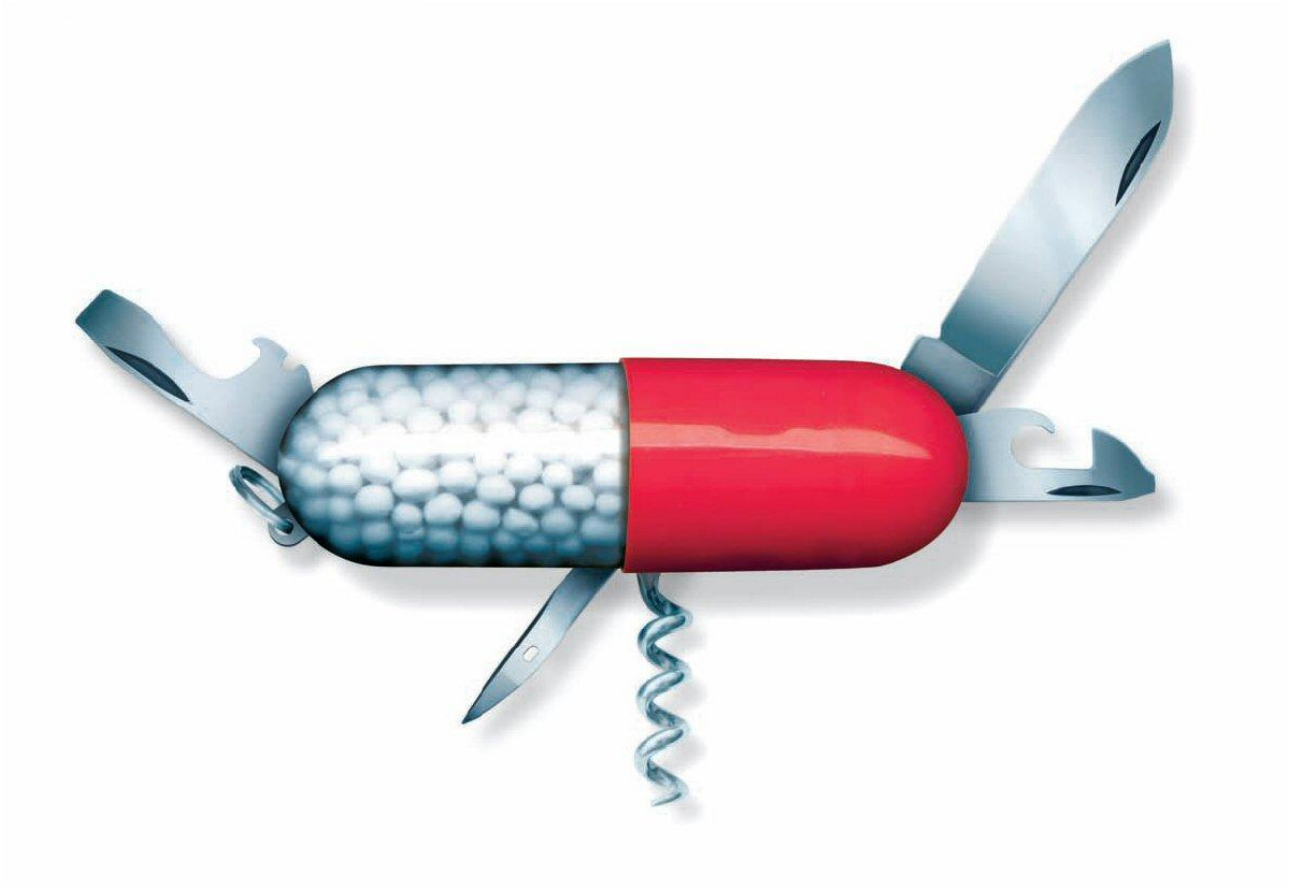
galenIQ™ – The smart excipient

(Isomalt Ph. Eur., BP, USP-NF)



galenIQ™

BENEO-Palatinit GmbH

Gottlieb-Daimler-Strasse 12
68165 Mannheim
Germany

Phone +49 621 421-150
Fax +49 621 421-160

galenIQ@beneo-palatinit.com
www.galenIQ.com

beneo palatinit

A new definition of a multifunctional excipient

galenIQ™ combines a multitude of outstanding characteristics and is suitable for a wide range of pharmaceutical applications. galenIQ™ can be used as more than just a bulk excipient. It also serves as an anti-caking agent, anti-humectant agent, stabilizer or oral care and taste agent to mention just a few additional functions.

galenIQ™ is ideal for oral solid dosage forms:

- Tablets
- Granules
- Pellets
- Capsule fillings
- Powder mixtures
- Pan coatings
- High-boiled lozenges
- Low boilings
- Medical gums

Non-animal origin and GMO free

The manufacturing process

galenIQ™ qualities are derived from sucrose in a two stage production process. First, sucrose is converted to the disaccharide 6-0-α-D-glucopyranosyl fructose (isomaltulose), a significantly more stable reducing compound, in an enzymatic transglucosidation process.

In the second step, the hydrogenation of isomaltulose leads to the stereoisomer disaccharide alcohol 1-O-α-D-glucopyranosyl-D-mannitol dihydrate (1,1-GPM dihydrate) and 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) in an approximate equimolecular mixture. The ratio between the main components can be varied with an additional special crystallization process.

As a result, specific galenIQ™ qualities are obtained, e.g. enriched in 6-O-α-D-glucopyranosyl-D-sorbitol (1,6-GPS) providing higher solubility. Depending on the quality, the mixture contains approximately 3-5 % crystal water, which is strongly bound to the GPM crystal.

In its final state, galenIQ™ is a white, odorless, water soluble, crystalline substance that complies with the isomalt monographs of the current Ph Eur, BP and USP-NF.

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Physical backbones of galenIQ™

Sorption isotherms

galenIQ™ has a very low hygroscopicity. At 25 °C, it adsorbs virtually no additional water up to 65 % RH. Significant water uptake begins only above 85 % RH (Figure 1).

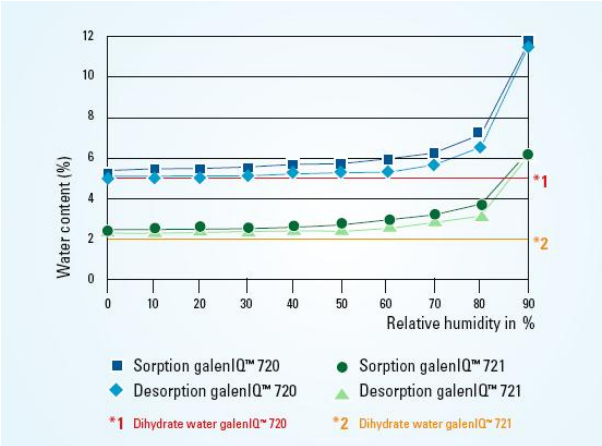

Figure 1: galenIQ™ sorption isotherms (at 25°C)

This characteristic enables galenIQ™ to provide optimal protection even for moisture sensitive active pharmaceutical ingredients (APIs), which is a decisive advantage over other bulk excipients. Furthermore, the low hygroscopic nature combined with an anti-caking property eases production processes such as mixing, agglo-meration or tableting and helps to reduce the need for costly protective packaging.

Solubility and dissolution kinetics

galenIQ™ is soluble in water as well as in mixtures of water and ethanol. The solubility in water ranges, depending on the type, from about 24 g to 42 g in 100 g solution at 20 ºC and in creases at higher temperatures (Figure 2).

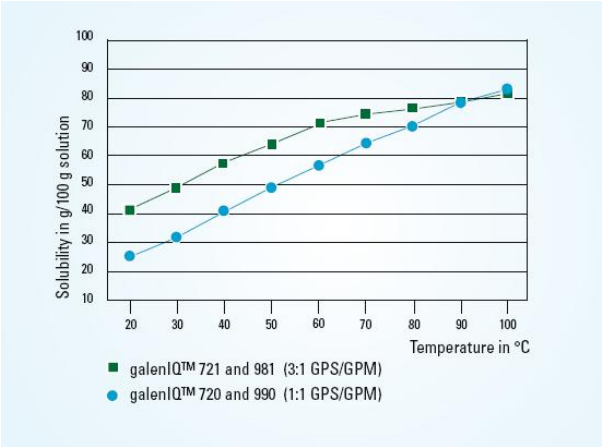

Figure 2: galenIQ™ flexibility in solubility

The release rate of active ingredients can be adjusted with the different solubility grades. This flexibility makes galenIQ™ a superior filler binder and facilitates its use for a wide range of pharmaceutical applications.

Specific grades of galenIQ™ give applications like hard-boiled lozenges (galenIQ™ 990) a slow dissolution kinetic. Studies have shown that lozenges take about one third longer to dissolve compared to products made of sugar/glucose. With this unique property, galenIQ™ allows the manufacture of slowly dissolving dye-formed or molded high-boiled lozenges, which provide a slow, sustained release of actives in the oral cavity.

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Inertness and stability

Based on its stable glycosidic bond, galenIQ™ demonstrates excellent stability either by itself or against chemical changes. In addition, no incompatibilities between galenIQ™ and active ingredients have been found. Based on its chemical structure, it does not react with other components and is highly resistant to degradation by enzymes and acids. Unlike other carbohydrates galenIQ™ does not contain reducing groups. Therefore, it does not undergo reactions with other ingredients containing amino groups ("Maillard reaction").

No changes in the molecular structure occur even when the material is heated above the melting range or when aqueous solutions are heated above the boiling point, for example to create high-boiled lozenges.

Global partner to the pharmaceutical industry

galenIQ™ is made by BENEO-Palatinit

BENEO-Palatinit GmbH, Mannheim is a member of the Südzucker Group, the world's largest sugar producer. BENEO-Palatinit develops, manufactures and markets unique carbohydrates like ISOMALT and PALATINOSE™.

Isomalt is used as a nutritive sweetener, bulking agent, carrier, anti-caking agent and glazing agent as well as texturizer, stabilizer, oral care agent and anti-humectant agent. Large scale commercial production of isomalt started in the early 1990s in a state-of-the-art production facility at Offstein, Germany.

BENEO-Palatinit devotes considerable R&D capacity to continually broadening and refining the spectrum of its products. BENEO-Palatinit is upgrading its quality polyol range to reach new heights in the field of pharmaceutical excipients with galenIQ™, which comprises a range of isomalt qualities tailor-made for pharmaceutical applications. It offers the combined advantages of existing bulk excipients and can thus facilitate pharmaceutical development and formulation. galenIQ™ fulfills the high quality standards that today's pharmaceutical industry expects.

galenIQ™ is listed in a number of reference books for pharmaceutical excipients under its generic name "isomalt". BENEO-Palatinit supplies galenIQ™ to international markets through a network of sales agencies. BENEO-Palatinit applies the highest quality control standards to all its operations and manufactures its products in accordance with GMP. BENEO-Palatinit is ISO 9001 accredited and manufactures according to IPEC-PQG GMP standards.

Call today and order your sample package!

Whether tablet or capsule, lozenge or gum, galenIQ™ opens entirely new doors to the development of innovative pharmaceutical products. Learn more about the full range of advantages offered by galenIQ™.

Order your free galenIQ™ test package today!

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