

SEM photograph of galenIQ™ 990, magnification 130 x

### Description

galenIQ™ 990 is a special type of pharmaceutical graded isomalt for high-boiled lozenge applications. Chemically it is a disaccharide alcohol in a 1:1 GPM/GPS composition.

### Properties

- **Ideal base for amorphous drug delivery systems such as high-boiled lozenges**
- **Solubility 25 g/100 g solution at 20 °C in water**
- **Narrow particle size distribution**
- **High chemical and temperature stability**
- **Low hygroscopicity – reduced adsorption of moisture**
- **High glass transition temperature**
- **Non-sticky lozenges – ideal for blister packaging**
- **Outstanding shelf-life**
- **Extended/sustained release of API's in oral cavity**
- **Adds good taste to formulations**
- **Cariostatic and low glycemc/insulinemic**
- **Non-animal origin and GMO free**



### High-boiled lozenges – an attractive dosage form

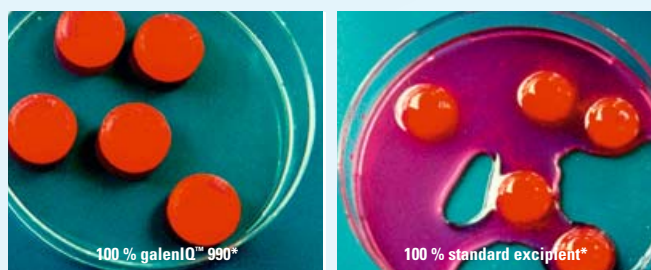
Lozenges can provide an effective unit dosage amount of e.g. an antitussive, decongestant, antihistamine or expectorant ingredient which is effectively released by sucking the lozenge. Thanks to their smooth surface and the possibility to design any taste, high-boiled lozenges belong to the group of patient-friendly drug delivery systems. This is especially true, when it comes to dosage forms which have to be sucked and the API's used are heat stable up to about 140 °C. From a technological point of view a wide range of lozenges whether deposited, stamped or filled with a variety of shapes, weight and taste can be manufactured to serve patients expectations and to differentiate within a range of products.

### galenIQ 990™ in pharmaceutical high-boiled lozenges

Its physiological and physical properties as well as its chemical stability makes galenIQ™ 990 the excipient of choice for high-boiled lozenges. High-boiled lozenges with an outstanding shelf-life are obtained. These lozenges are very stable against water absorption and temperature influence.

As a cariostatic and low glycemc/insulinemic substance, galenIQ™ 990 is ideal for oral solid-dosage forms, which have to be applied in a number of units throughout the day to provide a slow, sustained release treatment of e.g. nasal congestion, sore throats, coughs or inflammations such as stomatitis.

Taking some specific physical properties of galenIQ™ 990 into consideration, the production process is quite similar to that of high-boiled lozenges based on sucrose/corn syrup.



**Figure 1: galenIQ 990 – high-boiled lozenges storage stability**  
(\*after 24 h stored at 25 °C/80 % r.h., unwrapped; standard excipient, e.g. sucrose/glucose syrup)

### Chemical stability

Based on its glycosidic bond, galenIQ™ 990 shows an excellent stability by itself and against chemical changes. In addition, no incompatibilities between galenIQ™ 990 and active ingredients have been examined. Unlike other carbohydrate-based excipients used in high-boiled lozenges, galenIQ™ 990 does not contain reducing groups. Therefore, it does not undergo reactions with other ingredients containing, e.g. amino groups (“Maillard reaction”).

No changes in the molecular structure occur even when the material is heated above the melting range (145 – 150 °C), e.g. by melt-extrusion or when aqueous solutions are heated above the boiling point to create high-boiled lozenges.

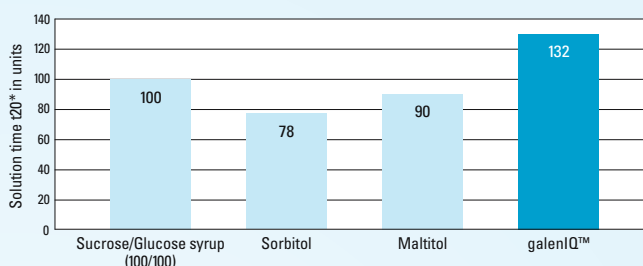
In acid and alkaline environment too, the excipient displays a very high level of resistance. Furthermore, galenIQ™ 990 is resistant to enzymatic hydrolysis.

### Best shelf-life – galenIQ™ 990 in high-boiled lozenges

Crystalline galenIQ™ 990 has a very low hygroscopicity. At 25 °C, it hardly absorbs any additional water below 65 % RH. Significant water uptake begins only above 85 % RH. With this characteristic, galenIQ™ 990 provides optimal protection even for moisture-sensitive active pharmaceutical ingredients.

Also in an amorphous state, galenIQ™ 990 shows highest stability against temperature influences or moisture pick-up compared to all other excipients (see Figure 1). While boiled lozenges based on hygroscopic excipients have to be packed immediately after cooling in moisture protective packaging materials, galenIQ™ 990-based lozenges can be stored before packaging if required. This might be helpful with respect to the packaging capacity. Due to the very low moisture absorption of galenIQ™ 990 lozenges, the shelf-life with respect to e.g. oxidation or hydration of actives can be extended.

This information on average values is presented in good faith, but warranty to accuracy of results is not given. It is offered solely for your consideration, investigation and verification. Typical analysis data fall within the range of specification of galenIQ™.



**Figure 2: Dissolution kinetics of galenIQ™ 990 high-boiled lozenges**  
(\*t20 is the time to reach a concentration of 20 % (d.m.))

### Slowly dissolving for sustained release of actives in oral cavity

The low solubility of galenIQ™ 990 influences the dissolution of the final high-boiled lozenge. Dissolution tests have shown, that a galenIQ™ 990 lozenge lasts approximately one third longer in the oral cavity compared to a sucrose/glucose syrup-based lozenge of the same weight, size and shape (see Figure 2).

With this unique property, galenIQ™ 990 allows the production of hard, slowly dissolving boiled or molded lozenges which provide a slow, sustained release of actives.

### Preferred application

#### a) High-boiled lozenges

- Deposited, stamped or filled lozenges
- Antitussive, decongestant, antihistamine or expectorant API's
- Treatment of nasal congestion, sore throats, coughs or inflammations etc.

#### b) Melt extrusion

- Base material for amorphous matrixes

### Additional information

Isomalt is listed in FDA's inactive ingredient database  
<http://www.accessdata.fda.gov/scripts/cder/iig>

### For more information please contact:

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