

galenIQ<sup>™</sup> – Sweet tasting filler-binder Great choice. Great taste.

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

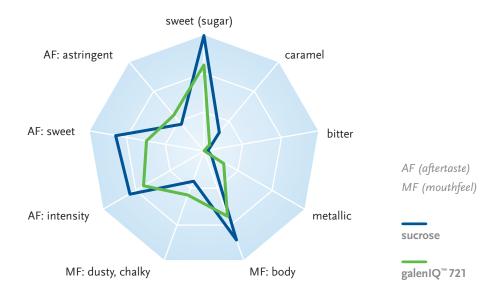


## galenIQ<sup>™</sup> – the sweet pharmaceutical excipient.

### galenIQ™ has a sugar-like taste profile.

The galenIQ™ taste profile is very close to sucrose, it has an intense and well-balanced sweet taste. galenIQ™ provides a pleasant mouthfeel for chewable tablets, suckable tablets, stick packs and many more dosage forms.

Isomalt is the only sugar alcohol that is derived from sucrose. It is mainly due to this reason that galenIQ™ has a sweetness and taste profile very close to sucrose. Isomalt does not have any significant off-taste or aftertaste.



## Good reasons for galenIQ™

Non-hygroscopic

Promotes high content uniformity

High flowability

Sugar-free

Tooth friendly

Chemically stable Easy to use

Water soluble

High dilution potential

Suitable for diabetics

Well defined particle size distributions

Different solubilities for different disintegration profiles

Non animal origin derived from sugar beet

# galenIQ<sup>™</sup> has a great taste and an excellent functionality.

galenIQ $^{TM}$  is characterized by its ease of use and applicability to a great variety of solid and liquid dosage forms such as tablets, sachets, lozenges and syrups.

## The excipient of choice for



**Chewable Tablet** 



Sachet / Stick Pack



**Powder Blend** 



**Lozenge Tablet** 



**Probiotic Tablet** 



Mini Tablet



**Effervescent Tablet** 



**Wet Granulation** 



**High Boiled Lozenge** 





Pan Coating



Syrup

## Great choice. Great taste.

galenIQ<sup>™</sup> Isomalt (Ph. Eur., BP, USP-NF, JP) is designed to meet the very specific expectations of the pharmaceutical industry. It is a filler-binder, that combines a multitude of outstanding characteristics, suitable for a wide range of pharmaceutical applications.

## Physical properties<sup>\*</sup> of galenIQ<sup>™</sup>

	galenIQ <sup>™</sup> 720	galenIQ <sup>™</sup> 721	galenIQ <sup>™</sup> 800	galenIQ <sup>™</sup> 801	galenIQ <sup>™</sup> 810	galenIQ <sup>™</sup> 900	galenIQ <sup>™</sup> 960	galenIQ <sup>™</sup> 981
Grade	agglomerated	agglomerated	milled	milled	milled	sieved	sieved	sieved
Preferred application	direct compression	direct compression, powder blend	wet granulation, agglomeration	wet granulation, agglomeration	wet granulation, agglomeration	high-boiled lozenge	capsule filling, dry blend, HME	pan coating, syrup
Composition GPS/GPM	1:1	3:1	1:1	3:1	1:1	1:1	1:1	3:1
Solubility in water at 20 °C (g/100 g)	25	42	25	42	25	25	25	42
Particle size distribution (µm)	$\begin{array}{ccc} d_{10} & d_{50} & d_{90} \\ 95 & 200 & 350 \end{array}$	$d_{10}$ $d_{50}$ $d_{90}$ $d_{90}$ $d_{90}$	$     \begin{array}{cccc}       d_{10} & d_{50} & d_{90} \\       9 & 22 & 41     \end{array} $	$d_{10}$ $d_{50}$ $d_{90}$ $d_{11}$ $d_{24}$ $d_{5}$	$\begin{array}{ccc} d_{10} & d_{50} & d_{90} \\ 5 & 28 & 80 \end{array}$	d <sub>10</sub> d <sub>50</sub> d <sub>90</sub> 560 1240 1910	$\begin{array}{ccc} d_{10} & d_{50} & d_{90} \\ 270 & 380 & 470 \end{array}$	$\begin{array}{ccc} d_{10} & d_{50} & d_{90} \\ 340 & 770 & 1290 \end{array}$
Method	mechanical sieve shaker	mechanical sieve shaker	laser diffraction	laser diffraction	laser diffraction	mechanical sieve shaker	mechanical sieve shaker	mechanical sieve shaker
Bulk density (g/l)	400	400	500	500	590	850	820	780
Total water K. F. (%)	5,0	2,9	2,7	2,6	3,0		2,3	2,8
Loss on drying (%) (10 <sup>5</sup> pa, 7 h at 25 °C)	0,21	0,12	0,26	0,21	0,42		0,12	0,02

<sup>\*</sup>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<sup>™</sup>.

## Physical properties of galenIQ™ DC grades\*

	galenIQ <sup>™</sup> 720	galenIQ™ 721
Tapped density (g/l) n = 1250	448	448
Hausner ratio	1,12	1,12
Carr index	10	10
Angle of repose (°)	33	31
Flowability (s/100 g) (orifice d = 6 mm)	55	57

#### Structural formula of Isomalt

galenIQ $^{\text{m}}$  is produced from sucrose derived from sugar beet.

6-0-α-D-Glucopyranosyl-D-sorbitol (1,6-GPS)

1-0-α-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)

## Monograph of Isomalt

	Ph.Eur.	USP-NF	JP			
Definition	Isomalt contains not less than 98.0 % and not more than 102.0 % of a mixture of 6- $O$ - $\alpha$ -D-glucopyranosyl-D-sorbitol (1,6-GPS) and 1- $O$ - $\alpha$ -D-glucopyranosyl-D-mannitol dihydrate (1,1-GPM), and neither of the two components is less than 3.0 % of the mixture, calculated on the anhydrous basis.					
Characterisation/ Description	A white or almost white powder or granules, freely soluble in water, practically insoluble in ethanol	not applicable	Isomalt Hydrate occurs as a white powder or grains. It is freely soluble in water and practically insoluble in ethanol			
Packaging and storage	not applicable	Preserve in well-closed containers. No storage requirements specified	Preserve in well-closed containers			
Labelling	The percentage of 1,6-GPS and 1,1-GPM is stated on the label					
Reference standard	Isomalt CRS	USP Isomalt RS	Isomalt RS			
Identification	A = HPLC assay B = TLC test C = Color test	A = TLC test B = HPLC assay	A = Colour test B = HPLC			
Optical rotation	_	_	about +92°			
Conductivity	≤ 20 µS/cm	≤ 20 µS/cm	≤ 20 µS/cm			
Water	≤ 7.0 %	≤ 7.0 %	≤ 7.0 %			
Nickel	≤ l ppm	≤ 1 ppm	≤ 1 ppm			
Lead	≤ 0.5 ppm	not applicable	not applicable			
Heavy metals	not applicable	not applicable	≤ 10 ppm			
Reducing sugars	≤ 0.3 %	≤ 0.3 %	≤ 0.3 %			
Assay	98.0 – 102.0 %	98.0 – 102.0 %	98.0 – 102.0 %			
Related products/ compounds	Sorbitol ≤ 0.5 % Mannitol ≤ 0.5 % any other unspecified impurity ≤ 0.5 % Sum of all ≤ 2.0 %	Sorbitol ≤ 0.5 % Mannitol ≤ 0.5 % any other unspecified impurity ≤ 0.5 % Sum of all ≤ 2.0 %	Sorbitol $\leq 0.5\%$ Mannitol $\leq 0.5\%$ any other unspecified impurity $\leq 0.5\%$ Sum of all $\leq 2.0\%$			
Impurities	A = Isomaltulose B = Mannitol C = Sorbitol D = Trehalulose	not applicable	not applicable			

BENEO is a member of the International Pharmaceutical Excipients Council (IPEC) and produces galenIQ $^{\text{TM}}$  under GMP conditions for pharmaceutical excipients. Whether tablet or capsule, lozenge, chewing gum or syrup, galenIQ $^{\text{TM}}$  opens entirely new doors to the development of innovative pharmaceutical products.

Contact one of our experts today for your product development with galen  $IQ^{^{\prime\prime}}\!.$ 

BENEO GmbH
Phone +49 621 421-150
Fax +49 621 421-160
www.galenIQ.com
galenIQ@beneo.com



