

galenIQ™

Sweet tasting filler-binder



galenIQ™ – the smart excipient.

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

galenIQ™
a brand of beneo

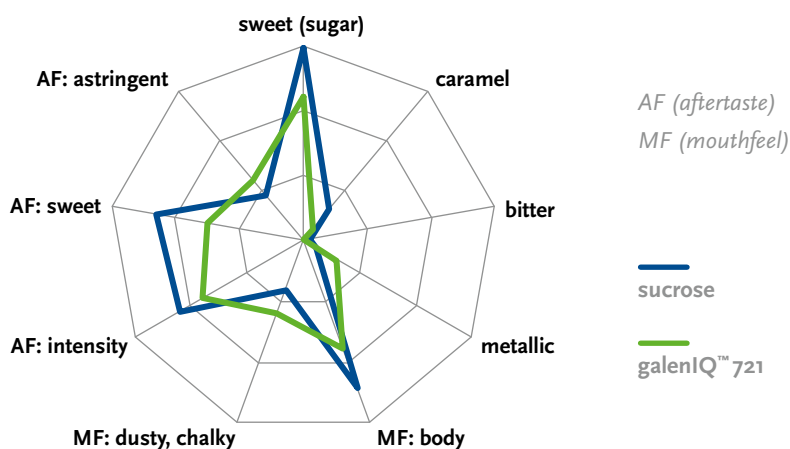
Great choice. Great taste. Great versatility.

galenIQ™ is a high quality Isomalt, 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.

galenIQ™ – the multifunctional excipient for bulk applications

- Low hygroscopicity
- Optimal protection for moisture sensitive APIs
- No incompatibilities
- Well defined particle size distribution
- Excellent flow and mixing properties
- High content uniformity even in low dosage formulations
- High dilution potential
- Different solubilities for different disintegration and API release profiles
- Non animal origin – derived from sucrose
- No GMO-technology involved
- Sugar-free
- Suitable for diabetics

galenIQ™ has a sweet sugar-like taste profile



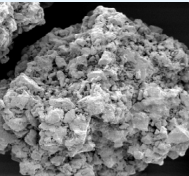
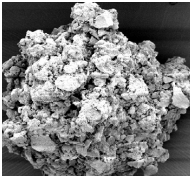

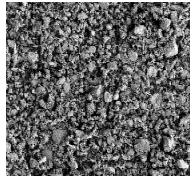
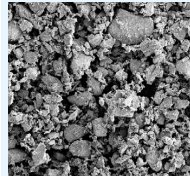
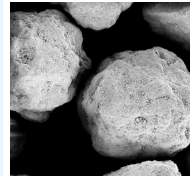
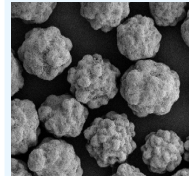
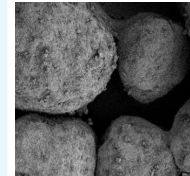
galenIQ™ has a great taste and an excellent functionality

It is the perfect excipient for:

- Oral intake tablets
- Effervescent tablets
- Sachets, stick packs
- Medicated confectionery
- Dragees (sugar-free coated pill)
- and many more



Physical properties* of galenIQ™

	galenIQ™ 720	galenIQ™ 721	galenIQ™ 800	galenIQ™ 801	galenIQ™ 810	galenIQ™ 960	galenIQ™ 981	galenIQ™ 990																
Grade	<i>agglomerated</i>	<i>agglomerated</i>	<i>milled</i>	<i>milled</i>	<i>milled</i>	<i>sieved</i>	<i>sieved</i>	<i>sieved</i>																
Preferred application	direct compression	direct compression, powder blend	wet granulation, agglomeration	wet granulation, agglomeration	wet granulation, agglomeration	capsule filling, dry blend	pan coating, syrup	high-boiled lozenge (medicated candy)																
Composition GPS/GPM	1:1	3:1	1:1	3:1	1:1	1:1	3:1	1:1																
																								
Solubility in water at 20 °C (g/100 g)	25	42	25	42	25	25	42	25																
Particle size distribution (µm)	d ₁₀ 95	d ₅₀ 200	d ₉₀ 350	d ₁₀ 90	d ₅₀ 180	d ₉₀ 360	d ₁₀ 9	d ₅₀ 22	d ₉₀ 41	d ₁₀ 11	d ₅₀ 24	d ₉₀ 45	d ₁₀ 5	d ₅₀ 28	d ₉₀ 80	d ₁₀ 270	d ₅₀ 380	d ₉₀ 470	d ₁₀ 340	d ₅₀ 770	d ₉₀ 1290	d ₁₀ 480	d ₅₀ 980	d ₉₀ 1540
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	820	780	850																
Tapped density (g/l) n = 1250	448	448																						
Hausner ratio	1,12	1,12																						
Carr index	10	10																						
Angle of repose (°)	33	31				33																		
Flowability (s/100 g) (orifice d = 6 mm)	55	57				27																		
Total water K. F. (%)	5,0	2,9	2,7	2,6	3,0	2,3	2,8	2,4																
Loss on drying (%) (10⁵ pa, 7 h at 25 °C)	0,21	0,12	0,26	0,21	0,42	0,12	0,02	0,08																

* 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™.

Monograph of Isomalt

	Ph.Eur.	USP-NF	JPE
Definition	Isomalt contains not less than 98.0 % and not more than 102.0 % of a mixture of 6-O- α -D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O- α -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	A white or almost white powder or granules, freely soluble in water, practically insoluble in ethanol	not applicable	Isomalt occurs as a white or almost white powder or granules, freely soluble in water, 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	The percentage of 1,6-GPS and 1,1-GPM is stated on the label	not applicable
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 = TLC C = HPLC
Optical rotation	—	—	$[\alpha]_D^{20}$: +90.0° ~ +93.5°
Conductivity	$\leq 20 \mu\text{S}/\text{cm}$	$\leq 20 \mu\text{S}/\text{cm}$	$\leq 20 \mu\text{S}/\text{cm}$
Water	$\leq 7.0 \%$	$\leq 7.0 \%$	$\leq 7.0 \%$
Nickel	$\leq 1 \text{ ppm}$	$\leq 1 \text{ ppm}$	$\leq 1 \text{ ppm}$
Lead	$\leq 0.5 \text{ ppm}$	not applicable	not applicable
Heavy metals	not applicable	$\leq 10 \text{ ppm}$	$\leq 10 \text{ ppm}$
Reducing sugars	$\leq 0.3 \%$	$\leq 0.3 \%$	$\leq 0.3 \%$
Assay	98.0 – 102.0 %	98.0 – 102.0 %	98.0 – 102.0 %
Related products/ compounds	Sorbitol $\leq 0.5 \%$ Mannitol $\leq 0.5 \%$ Sum of all $\leq 2.0 \%$	Sorbitol $\leq 0.5 \%$ Mannitol $\leq 0.5 \%$ Sum of all $\leq 2.0 \%$	Sorbitol $\leq 0.5 \%$ Mannitol $\leq 0.5 \%$ 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™ under GMP conditions for pharmaceutical excipients. Whether tablet or capsule, lozenge, chewing gum or syrup, galenIQ™ opens entirely new doors to the development of innovative pharmaceutical products.

Contact one of our experts today for your product development with galenIQ™.

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Find us on:   

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