Product Sheet - Specifications

galenIQ™ 900 (Isomalt Ph.Eur., USP-NF, JP)

Description

- galenIQ™ 900 is a sieved isomalt.
- galenIQ™ 900 meets the requirements of the monographs on isomalt of the Ph.Eur., USP-NF and JP.
- The content of 1,6-GPS in galenIQ™ 900 is between 43 and 57 % on the anhydrous basis.

Particle size distribution

Particle size	Limit	Method
500-3550 µm	min. 90 %	Ph. Eur.2.9.12, mechanical sieve shaker 100 g, 10 min, 1.5 mm amplitude

Pharmacopoeial parameters

Definition

Mixture of 6-O-α-D-glucopyranosyl-D-glucitol (6-O-α-D-glucopyranosyl-D-sorbitol; 1,6-GPS) and 1-O-α-D-glucopyranosyl-D-mannitol (1,1-GPM)

1,1-GPM contains two molecules of crystal water (dihydrate)

Characters

White or almost white powder or granules,
freely soluble in water, practically insoluble in ethanol

Identification

Test	Requirement	Method
HPLC Chromatogram	Retention time of the two principle peaks comply with those of the reference solution	Ph. Eur. 2.2.29 USP NF 621 JP 2.01
Thin layer chromatography	Position and colour of the principle spots comply with those of the reference solution	Ph. Eur. 2.2.27 USP NF 201
Pyrocatechol test	Pink colour formation	Ph. Eur. monograph 1531 JP monograph 1098

Specifications

Assay/content	Requirement	Applicable methods
1,6-GPS and 1,1-GPM, total of which 1,6-GPS 1,1-GPM	98.0-102.0 % (anhydrous basis) min. 3 % (anhydrous basis) min. 3 % (anhydrous basis)	Ph. Eur. 2.2.29 USP NF 621 JP monograph 1098
Test		
Conductivity	max. 20 µS/cm	Ph. Eur. 2.2.38 USP NF isomalt monograph JP 2.51
Optical rotation $[a]^{20}_{D}$	about 92° (90.0°-93.5°)	JP 2.49
Reducing sugars (as glucose)	max. 0.3 % (anhydrous basis)	Ph. Eur. monograph 1531 USP NF isomalt monograph JP 2.50
Related substances, total of which D-mannitol D-sorbitol trehalulose* isomaltulose* any other individual component	max. 2.0 % (anhydrous basis) max. 0.5 % (anhydrous basis) max. 0.5 % (anhydrous basis) max. 0.5 % (anhydrous basis) max. 0.5 % (anhydrous basis) max. 0.5 % (anhydrous basis)	Ph. Eur. 2.2.29 USP NF 621 JP 2.01
Water	max. 7.0 %	Ph. Eur. 2.5.12 USP NF 921, Method I JP 2.48
Nickel	max. 1 mg/kg (anhydrous basis)	Ph. Eur. 2.4.15 USP NF 852 JP monograph 1098
Heavy metals (as lead)	max. 10 mg/kg	JP 1.07

* specified in Ph.Eur. 2.2.29, only

Additional Information

INS/E number	953	
C.A.S. number	64519-82-0	
Chemical formula	1,6-GPS: $C_{12}H_{24}O_{11}$	M_r: 344.3
	1,1-GPM: $C_{12}H_{24}O_{11} \times 2\ H_2O$	M_r: 380.3

Microbial parameter	Limit	Method
Total mesophilic bacteria (aerobes)	max. 100 cfu/g	Ph. Eur. 2.6.12
Yeasts	max. 10 cfu/g	Ph. Eur. 2.6.12
Moulds	max. 10 cfu/g	Ph. Eur. 2.6.12
Coliforms (incl. E. coli)	negative/25 g	Ph. Eur. 2.6.13

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HS code (Customs tariff number)	2940 00
Storage	Store in well-closed or original packaging; no further requirements specified
Shelf life	5 years from production date in its original unopened packaging: validated for ICH climate zone II (20 °C, 60 % rel. humidity) and ICH climate zone IV (30 °C, 65 % rel. humidity)
Allergens	galenIQ™ is not produced from ingredients or using processing aids that would require allergen labelling as laid down in Regulation (EU) No 1169/2011.
GMO	In accordance with the applicable German Law, galenIQ™ is not derived from genetically modified organisms (GMO).
Elemental impurities/ metal catalysts	Compliance with ICH Q3D, EMEA/CHMP/SWP/4446/2000, Ph.Eur. 5.20, USP 232 (oral exposure)
BSE/TSE/Vegetarian/vegan	Production without raw materials or processing aids of animal origin
IPEC GMP compliance	Manufactured applying the specific cGMP rules as defined by IPEC-PQG (The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients) Compliant with the current isomalt monographs in the European (Ph.Eur.), US (USP-NF), British (BP) and Japanese (JP) pharma-copeias
Food compliance	Produced in Germany in compliance with applicable German and European Law (e.g. Regulation (EC) No 178/2002, Regulation (EC) No 852/2004). galenIQ™ complies with the requirements for isomalt established by Codex Alimentarius, Food Chemicals Codex (FCC) and Regulation (EU) No 231/2012.
Certifications	Kosher Halal ISO 9001

Document Code	Version	Valid from
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Disclaimer To the best of our knowledge, the information in this sheet is reliable.