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TECHNICAL SPECIFICATION - PDt 214859-7.0EN

XIVIA™ C

Xylitol

Description

Mol. Wt: 152.15

Food Grade, Crystalline Product complies with USP/NF, FCC and Ph. Eur. monographs for Xylitol

White crystalline powder; practically odourless, with a very sweet, cool taste.

Particle size: > 2.4 mm = 0% - sieving method < 0 .15 mm = max 7% - laser diffraction

Solubility: very soluble in water (approximately 1.6 g/ml @ 20°C); sparingly soluble in ethanol.

Physical/chemical specifications

(Dry substance abbreviated to d.s. in below table)

Max. 15 ICUMSA [1] Colour pH (10% w/v solution) 5.0-7.0 [2] 98.5 - 101.0 % [3] Assay (on dry substance) Other polyols (on d.s): singly Max. 0.5 % [46] Other polyols (on d.s.): - total Max. 1.0 % [46] Reducing sugars Max. 0.2 % [4] Max. 0.2 % [5] Moisture Ash/Residue on Ignition Max. 0.1 % [24] Melting point 92°C-96°C [6] Chloride Max. 40 mg/kg [9] Sulphate Max. 50 mg/kg [9]

The numbers in brackets refer to the following methods:

[1] ICUMSA

[2] pH meter

[3] HPLC [4] Luff Schoorl

[5] Karl Fischer

[6] European Pharmacopoeia (Ph. Eur.)

[9] USP

[24] ICUMSA conductivity/USP

[46] Gas Liquid Chromatography/HPLC

Heavy metal specifications

 Arsenic
 Max. 0.5 mg/kg [8]

 Heavy Metals
 Max. 1 mg/kg [47]

 Lead
 Max. 0.3 mg/kg [8]

 Nickel
 Max. 1 mg/kg [25]

The numbers in brackets refer to the following methods:

[8] ICP [25] ICP/AAS

[47] European Pharmacopoeia (Ph. Eur.)/USP

Storage

Recommended storage:

XIVIA™ is stable to air and heat but is marginally hygroscopic. Goods in the original sealed packaging stored at temperatures below 25°C and relative humidity less than 65% can be expected to retain stability for at least three years.

The information contained in this publication is based on our own research and development work and is to the best of our knowledge reliable. Users should, however, conduct their own tests to determine the suitability of our products for their own specific purposes and the legal status for their intended use of the product. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for the infringement of any patents.

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Additional information

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