

PHARMASUGAR[®]

PARENTERAL SUCRE RAFFINE

DESCRIPTION

PHARMASUGAR[®] PARENTERAL SUCRE RAFFINÉ ("PARENTERAL REFINED SUGAR") is a white sugar produced from French sugar beets, in one French manufacturing site which is IPEC certified.

USES

PHARMASUGAR[®] PARENTERAL SUCRE RAFFINÉ is recommended for preparations administrated in big volume.

CHARACTERISTICS

PHYSICAL & CHEMICAL ACCORDING ACCORDING TO EUROPEAN, BRITISH, UNITED STATES AND JAPANESE PHARMACOPOEIAS

Parametres	Specifications	Analysis methode
Appearance	White cristals	ICUMSA GS2-11*
Solubility	In water and ethanol	European Pharmacopeia methode
Solubility	In water and ethanol	United states Pharmacopoeia Method
Solubility	In water	Japanese Pharmacopoeia Method
IR Identification spectrophotometer	Identical to the reference	European Pharmacopeia methode 2.2.24
IR Identification spectrophotometer	Identical to the reference	United states Pharamacopeia Method 197K
IR Identification spectrophotometer	Identical to the reference	Japanese Pharmacopoeia Method 2.25
Appearance of the solution	Clear	USP/EP/BP/JP
Conductivity at 20°C	≤ 35 μS.cm-1	ICUMSA GS2/3-17*
Specific optical rotation	+ 66,3 à + 67,0	USP/EP/BP/JP
Colour value	≤ 22,5 UI	ICUMSA GS2/3-10*
Reducing sugars	Persistent blue colour	USP/EP/BP/JP
Sulfites	≤ 10 ppm	ICUMSA GS2/3-35*
Loss on drying	≤ 0,1 %	ICUMSA GS2/1/3/9-15*
Dextrins	Yellow Solution	European Pharmacopoeia Method

INDICATIVE GRAIN SIZE

(Indicative) Mean Aperture	0,45 to 0,75 mm	ICUMSA GS2/9-37*
Variation margin	50 % Maxi	-

MICROBIOLOGY

Bacterial endotoxines	≤ 3 UI/g	European Pharmacopeia methode 2.2.24
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NUTRITIONNAL CHARACTERISTICS (PER 100g)

Energy	1700 kJ ; 400 kcal	Proteines	0 g
Carbohydrates	100 g	Fat	0 g
Carbohydrates of which Sugar	100 g	Fat of which Saturated Fatty Acids	0 g
		Salt	0 g

*ICUMSA methods are equivalent to the previously mentioned Pharmacopoeias.

COMPOSITION/INGREDIENTS

100% Sucrose

LABELLING

PHARMASUGAR[®] PARENTERAL SUCRE RAFFINÉ is to be included in the list of ingredients under the designation "sucrose".

BATCHES IDENTIFICATION

For packaged products it corresponds to the date of packaging and is composed as follows: **A U 7 SS J** (A = year, U = delivery centre, 7 = invariable figure, SS = week, J = 1 Monday, 2 Tuesday ...or 0 = whole week).

DATE

According to Directive 2000/13/EC on labelling, dry sugar is not subject to a "Best Before Date" (BBD), nor a "date of minimum durability" (DDM) expiry date.

A stability study was carried out on three batches of PHARMASUGAR[®] PARENTERAL SUCRE RAFFINE. None non-compliance was detected during these analyses.

PRESERVATION & USE CONDITIONS

Optimal storage is at a temperature of 15 to 25°C and a relative humidity below 65%.
Avoid all thermic shocks, contact with humid surfaces and strong-smelling products.

REGULATION / QUALITY GUARANTEES

PHARMASUGAR[®] PARENTERAL SUCRE RAFFINE :

- Is compliant to **European Pharmacopeia**; monograph Sucrose 01/2016: 0204
- Is compliant to **US Pharmacopoeia**, Monograph "Sucrose" 01/2017
- Is compliant to **Japanese Pharmacopoeia**, Monograph « Sucrose »
- Is a conventional product, not derived from **GMOs** according to regulations 1829/2003 and 1830/2003
- Has not undergone any **irradiation** treatment
- Is free of any ingredient in the form of manufactured **nanomaterials**, regulation 2015/2283 and 1223/2009
- Does not contain any of the **allergens** listed in the European regulation INCO UE N°1169/2011, ALBA, Ph.Eur. Monographie 1063
- Is compliant to regulation 396/2005 about maximum limits applicable to **pesticide** residues in or on foodstuffs
- Is compliant to Ph.Eur. 5.2.8: no risk of **TES-BSE** (bovine spongiform encephalopathy)

CERTIFICATIONS

Cristal Union group manufacturing sites have set up a risk analysis according to HACCP method (based on *Codex Alimentarius*) and hold FSSC 22000, ISO 9001, ISO 14001, and ISO 50001 certifications.

PHARMASUGAR[®] range products are produced and packaged on both sites of Bazancourt (FR) and Erstein (FR), IPEC certified.

These sites have declared the substance Sugar (sucrose) as Raw Material for Pharmaceutical Use to the ANSM. Cristalco has declared itself as a distributor of its Raw Material for Pharmaceutical Use to the ANSM

Last update: 2021/05/06

The information found in this document is provided in good faith. In spite of efforts to ensure accuracy, we cannot accept legal responsibility for this information. This document may be updated without warning.