

BATCHES IDENTIFICATION

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

PACKAGING

Bag	25 Kg net	Pallet of 900 Kg net	12 layers of 3 bags
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Soft container (Big Bag with internal bag)	1000 Kg net
	1200 Kg net

DATE DE RETEST

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

On the basis of a stability study, a retest date of 5 years was established

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® SUCRE RAFFINE :

- Is compliant to European Pharmacopoeia; 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 1083
- 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 produced and packaged on site of Bazancourt (FR) are IPEC certified.

Our factories producing PHARMASUGAR® range sites have declared the substance Sugar (sucrose) as Raw Material for Pharmaceutical Use to the ANSM. Cristaloo has declared itself as a distributor of its Raw Material for Pharmaceutical Use to the ANSM



DESCRIPTION

PHARMASUGAR® SUCRE RAFFINÉ is a white sugar produced from French sugar beets, in one French manufacturing site.

USES

PHARMASUGAR® SUCRE RAFFINÉ is recommended for all applications requiring a sugar a very fine particle size ("powdered sugar"). PHARMASUGAR® SUCRE RAFFINÉ is suitable for used every application as excipient, for which sugar is used as sweet bulking agent. It can be used in powder mixtures or tableting.

For specific requirements for size, qualities PHARMASUGAR® SUCRE CALIBRES are recommended.

CHARACTERISTICS

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

Parametres	Specifications	Analysis method
Appearance	White cristals	ICUMSA GS2-11*
Solubility	In water and ethanol	European Pharmacopeia method
Solubility	In water and ethanol	United states Pharmacopeia Method
Solubility	In water	Japanese Pharmacopeia Method
IR Identification spectrophotometer	Identical to the reference	European Pharmacopeia method 2.2.24
IR Identification spectrophotometer	Identical to the reference	United states Pharamacopeia Method 197K
IR Identification spectrophotometer	Identical to the reference	Japanese Pharmacopeia Method 2.25
Appearance of the solution	Clear	USP/EP/JP/JP
Conductivity at 20°C	≤ 35 μS.cm-1	ICUMSA GS2/3-17*
Specific optical rotation	+ 86,3 à + 87,0	USP/EP/JP/JP
Colour value	≤ 22,5 UI	ICUMSA GS2/3-10*
Reducing sugars	Persistent blue colour	USP/EP/JP/JP
Sulfites	≤ 10 ppm	ICUMSA GS2/3-35*
Loss on drying	≤ 0,1 %	ICUMSA GS2/1/3/9-15*

INDICATIVE GRAIN SIZE

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

NUTRITIONAL 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".