E X C I P I E N T P H A R M A C E U T I Q U E

COMPRESSUC PS
SUCROSE EP/USP-NF/JP

Definition	α-D-Glucopyranoside, β-D-Fructofuranosyl C_{12} H_{22} O_{11}
CAS number	[57-50-1]
Geographical origin	France
Plant origin	Beet root (*Beta vulgaris*)

Physical and chemical characteristics according to the harmonized "sucrose" monographs of currently applicable European Pharmacopoeia (EP), United States Pharmacopoeia (USP-NF) and Japanese Pharmacopoeia (JP)

Parameter	Unit	Standard	Method
Characters			
Aspect	-	White or almost white crystalline powder or lustrous, colorless or white or almost white crystals	EP JP
Solubility	-	Very soluble in water, sparingly soluble in ethanol 96%, practically insoluble in anhydrous alcohol	EP JP
Identification: First identification, method A	-	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with the reference spectrum of sucrose CRS	EP 2.2.24 USP <197> JP 2.25
Assay			
Appearance of solution	-	Solution S is clear	EP 2.2.1
	-	Opalescence of solution ≤ Opalescence of reference suspension 1	USP, JP
Conductivity	µS/cm	Maximum 35 at 20°C	EP 2.2.38 USP JP 2.51

Physical and chemical characteristics according to the harmonized "sucrose" monographs of currently applicable European Pharmacopoeia (EP), United States Pharmacopoeia (USP-NF) and Japanese Pharmacopoeia (JP) - *continued*

Parameter	Unit	Standard	Method
Specific optical rotation	-	+ 66,3 to + 67,0	EP 2.2.7 USP <781> JP 2.49
Color value	ICUMSA	Maximum 45	EP 2.2.25 USP JP 2.24
Reducing sugars	-	The blue color does not disappear completely	EP, USP, JP
Sulfites	ppm	Maximum 10 ppm calculated as SO_2	EP, USP, JP
Loss on drying	%	Maximum 0,1	EP 2.2.32 USP <731> JP 2.41

Physical and chemical characteristics

Parameter	Unit	Standard	Method
Loose density	g/cm³	0,50 to 0,65	Stampfvolumeter : 100 g in a 250 ml test tube, 1250 strokes
Tapped density	g/cm³	0,60 to 0,75	
Passed through 80 µm sieve	%	≤ 25	Internal method
Retained on 600 µm sieve	%	≤ 3	Internal method
Flowability	s/100g	≤ 16	Pharmatest, D 10 m nozzle, according to European Pharmacopeia
Size distribution D (v,0,5)	µm	100 to 200	Laser

Microbiological characteristics

Parameter	Unit	Standard	Method
TAMC	CFU/g	≤ 10^3	European and American Pharmacopeia*
TYMC	CFU/g	≤ 10^2	European and American Pharmacopeia*
Escherichia coli	CFU/g	Absence	European and American Pharmacopeia*
Salmonella	CFU/10g	Absence	European and American Pharmacopeia*

*Current version

TAMC: Total Aerobic Microbial Count.
TYMC: Total Combined Yeast and Mould Count.

Nutritional characteristics

	For 100 g
Energy value	1700 kJ 400 kcal
Fat of which saturates	0 g 0 g
Carbohydrates of which sugars	100 g 100 g
Protein	0 g
Salt	0 g

Packaging

Boxes (25 kg)

Pallets :
ISPM15 treated (heat treatment) pallets

. 80x120 lost pallets (non-returnable)

Storage conditions

Compressuc PS must be stored avoiding moisture and temperature variations.

Quality guarantees

RESIDUAL SOLVENTS — Compressuc PS complies with the requirements of the current version of EMEA guide "*Impurities: Guideline for Residual Solvents"* and with the requirements of currently applicable European, United States and Japanese pharmacopoeia.

METAL TRACES — Compressuc PS complies with the current version of the EMEA guide "*Guideline on the specification limits for residues of metal catalysts or metal reagents*" and with the requirements of currently applicable European and United States pharmacopoeia.

GMO — The Compressuc PS which we manufacture does not come from genetically modified organisms and consequently, by virtue of current European

regulation (Regulations 1829/2003/CE and 1830/2003/CE), no labeling regarding GMOs is necessary.

GENOTOXIC IMPURITIES

Compressuc PS does not contain genotoxic impurities and is in full compliance with the requirements of the FDA guide "*Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches"* and with the requirements of the EMEA guide *"Guideline on the Limits of Genotoxic Impurities".*

BSE/TSE

No product of animal origin is used or is likely to be used in the Compressuc PS which we manufacture. Therefore, Compressuc PS complies with the EMEA/410/01 guide *"Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products"*.

SAFETY DATA SHEET

We inform you that we do not establish any safety data sheet for Compressuc PS. Indeed, this sheet requested by European and French regulations (REACH regulation 1907/2006/CE) specifically concerns toxic or dangerous substances or chemical preparations.
Compressuc PS is therefore not concerned by these provisions, which was confirmed by the French Office of Technological Risks and of Chemical and Oil Industries, following a request made by our trade association, SNFS (French Sugar Manufacturer Union).

ALLERGENS

European Union regulation R1169/2011 on food information to consumers (INCO) specifies in annex II the list of substances or products causing allergies or intolerances. Substances or ingredients which are listed must be mentioned and labelled according to the terms of article 21 of the above mentioned regulation.
Considering this information, we declare that Compressuc PS does not contain allergenic ingredients requiring labelling.

EXPIRY DATE

Manufacturing date + 3 years

TEREOS FRANCE
RCS Saint-Quentin 533 247 979
Etablissement de Moussy-le-Vieux
Rue de Senlis
Tél : +33 (0)1 64 66 55 00