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

COMPRESSUC MS
COMPRESSIBLE SUGAR USP-NF

Definition

Compressuc MS is made of sucrose $C_{12}H_{22}O_{11}$ (95-98%), maltodextrines (1,8-2,8%) and invert sugar syrup (1,7% maximum).

Geographical origin

Sucrose and invert sugar syrup: France
Maltodextrines: European Union

Plant origin

Sucrose and invert sugar syrup: Beet root
Maltodextrines: Corn

Physical and chemical characteristics according to the "compressible sugar" monograph of currently applicable United States Pharmacopoeia (USP-NF)

Parameter	Unit	Standard	Method
Identification A	-	Meets the requirements of the test for Specific Rotation	USP
Identification B	-	Meets the requirements of the IR test	USP <197K>
Content of sucrose	%	95-98 of sucrose on the dried basis	USP
Residue on ignition	%	≤ 0,1	USP <281>
Limit of dextrose (glucose), fructose, maltose and lactose	-	NMT 5% for the sum of dextrose, fructose, maltose, and lactose	USP
Chloride	%	≤ 0,014	USP <221>
Sulfate	%	≤ 0,010	USP <221>
Calcium	-	The solution remains clear for not less than 1 min	USP

Physical and chemical characteristics according to the "compressible sugar" monograph of currently applicable United States Pharmacopoeia (USP-NF) - *continued*

Parameter	Unit	Standard	Method
Loss on drying	%	≤ 1,0	USP <731>
Specific rotation	-	The specific rotation determined from the uninverted solution: 62.6°-73.4°. The specific rotation determined from the acid-inverted solution: levorotatory.	USP

Physical and chemical characteristics

Parameter	Unit	Standard	Method
Loose density	g/cm^3	0,53 to 0,61	Stampfvolumeter : 100 g in a 250 ml test tube, 1250 strokes
Tapped density	g/cm^3	0,61 to 0,71	
Passed through 80 µm sieve	%	≤ 10	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	150 to 300	Laser

Microbiological characteristics according to the "compressible sugar" monograph of currently applicable United States Pharmacopoeia (USP-NF)

Parameter	Unit	Standard	Method
TAMC	CFU/g	≤ 10^3	USP current version « compressible sugar »
TYMC	CFU/g	≤ 10^2	USP current version « compressible sugar »
Escherichia coli	CFU/g	Absence	USP current version « compressible sugar »
Salmonella	CFU/10g	Absence	USP current version « compressible sugar »

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

Nutritional characteristics

	For 100 g
Energy value	1690 kJ 398 kcal
Fat of which saturates	0 g 0 g
Carbohydrates of which sugars	99.4 g 97.1 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 MS must be stored avoiding moisture and temperature variations.

Quality guarantees

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

METAL TRACES — Compressuc MS complies with the current 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 MS 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 MS 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 MS which we manufacture. Therefore, Compressuc MS 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 MS. Indeed, this sheet requested by European and French regulations (REACH regulation 1907/2006/CE) specifically concerns toxic or dangerous substances or chemical preparations. Compressuc MS 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 MS does not contain allergenic ingredients requiring labelling.
EXPIRY DATE	Manufacturing date + 3 years

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