Naturalia
Fruit natural sugars

NUTRA SHEET

Chemical Name and CAS Registry Number: d-Fructose [57-48-7]

Empirical Formula and Molecular Weight: $C_6H_{12}O_6$; 180.16

Specifications: crystalFructoGrape complies with specifications of European Pharmacopoeia curr. ed. and US Pharmacopoeia curr. ed. for crystalline fructose (details in technical sheets)

Functional Category: Dissolution enhancer; flavor enhancer; sweetening agent; tablet diluent

Regulatory Status: Included in the FDA Inactive Ingredients Guide (oral solutions and suspensions; rectal preparations). Included in the Canadian List of Acceptable Non-medicinal Ingredients

Labelling: Fructose, Grape fructose, Fructose (extracted) from grape

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TYPICAL PROPERTIES

- **Description:** Odorless, colorless crystals or a white crystalline powder with a very sweet taste
- **Purity:** > 99.5%
- **Sweetening power:** higher than sucrose (130-150%)
- **Nutritional properties:** Energy value: 4 kcal/g (Calories saving since less amount is needed, for its high sweet intensity); low glycemic index (25). European health claim approved for fructose, referred to the glycemic control (see Regulation (EC) N° 1924/2006)
- **Stability and Storage Conditions:** Fructose is hygroscopic and absorbs significant amounts of moisture at relative humidities greater than 60% (see "Hygroscopicity"). Store at temperatures below 25°C and a relative humidity of less than 60%. Aqueous solutions are most stable at pH 3–4 and temperatures of 4–70°C; they may be sterilized by autoclaving.
- **Crystallinity:** Control* fructose crystals are very regular, while crystalFructoGrape crystals are not so regular. This may be the probable cause of some different rheological properties (see tableting)
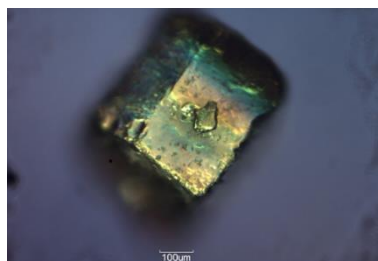
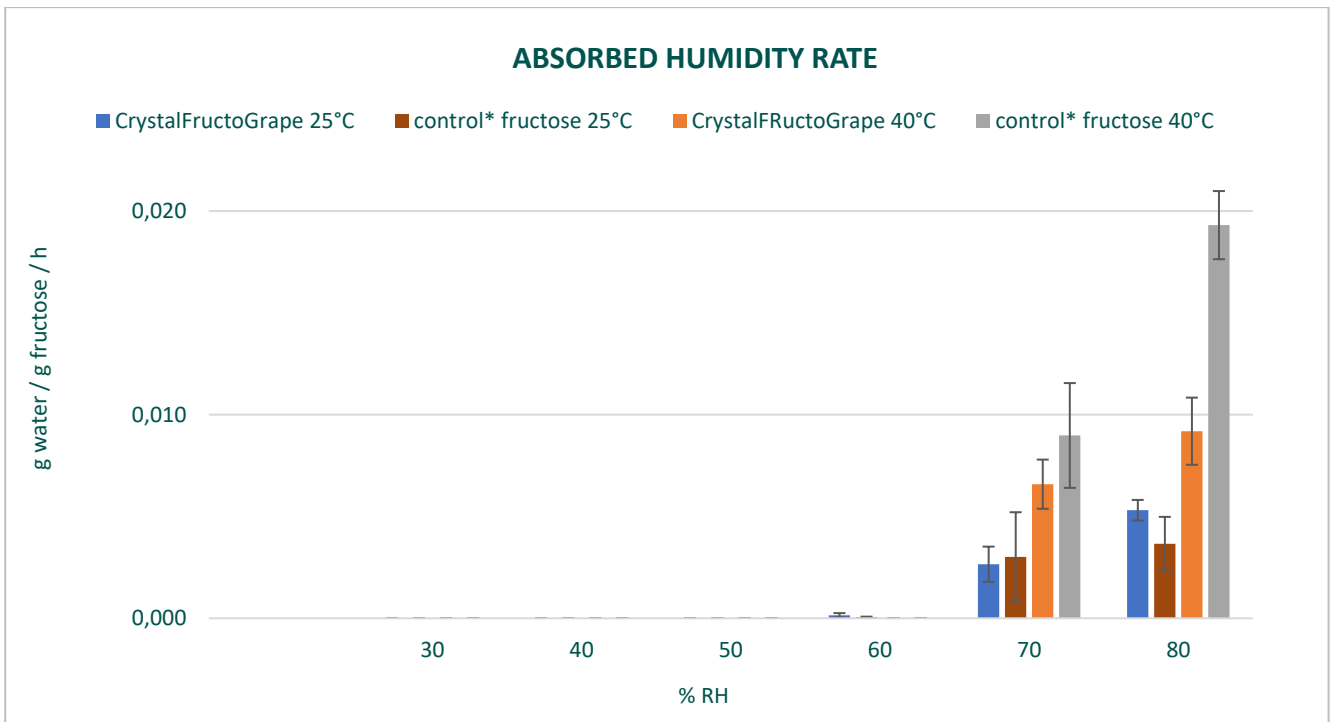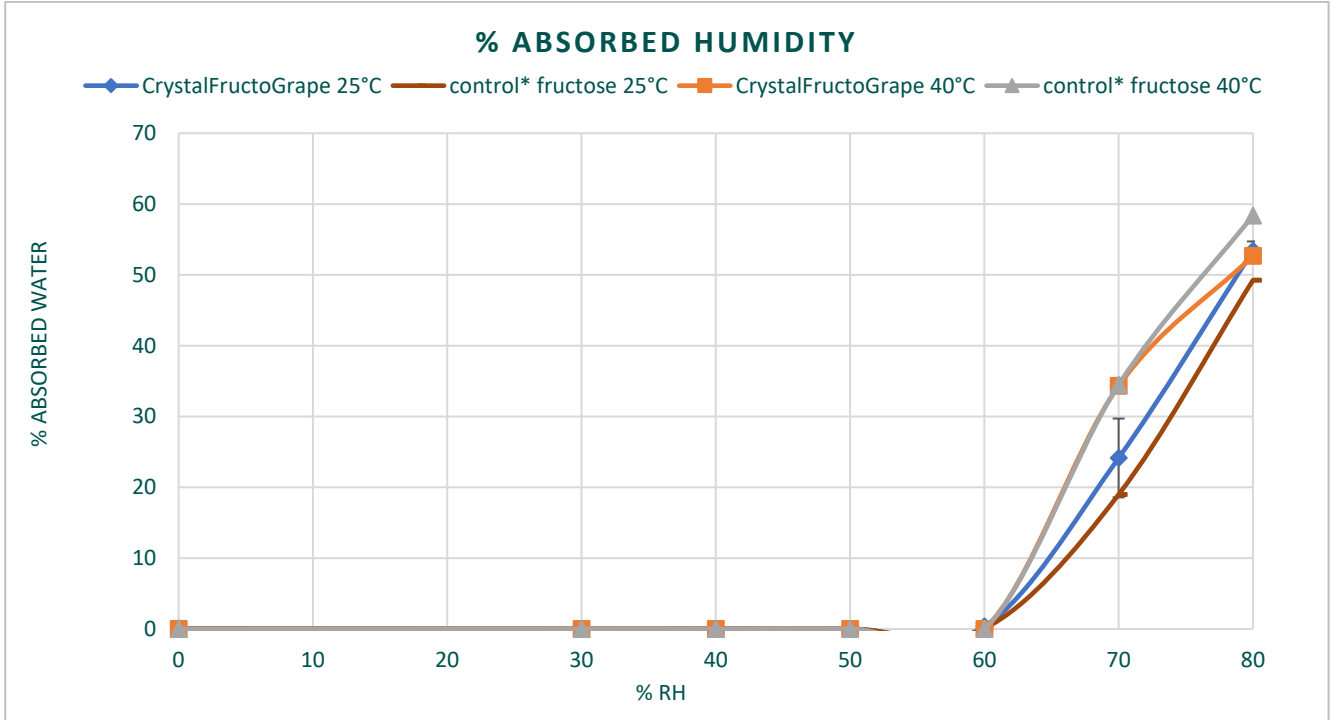control***** **fructose**
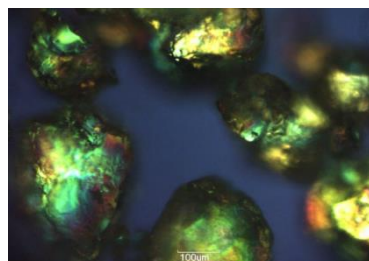
crystalFRUCTOGRAPE

- **Acidity/alkalinity:** pH = 4.5 – 7.0 (10% w/v aqueous solution)
- **Density:** There are not significant differences between control* fructose and crystalFructoGrape

Fructose concentration in water (% w/w)	control* fructose g/ml (20°C)	crystalFRUCTOGRAPE (avarage of 3 lots) g/ml (20°C)
10	1,04	1,04
20	1,08	1,08
30	1,13	1,14
40	1,19	1,18
50	1,23	1,22
60	1,28	1,29

- **Melting point:** ≈102–105°C (with decomposition)
- **Viscosity (dynamic):** There are not significant differences between contol* fructose and crystalFructogrape

Fructose concentration in water % w/w	control* fructose (cP) 25°C	crystalFRUCTOGRAPE (avarage of 3 lots) (cP) 25°C
10	2,10	2,10
20	2,60	2,83
30	3,30	3,60
40	5,40	5,40
50	9,60	9,77
60	26,70	26,50

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- **Hygroscopicity:** at 25°C and relative humidities above approximately 60%, fructose absorbs significant amounts of moisture. There are not significant differences between control* fructose and crystalFructoGrape

**% ABSORBED HUMIDITY**

ABSORBED HUMIDITY RATE

- **Water Activity (Aw):** There are not significant differences between control* fructose and crystalFructoGrape

  Aw control* fructose = 0.416 ± 0.035
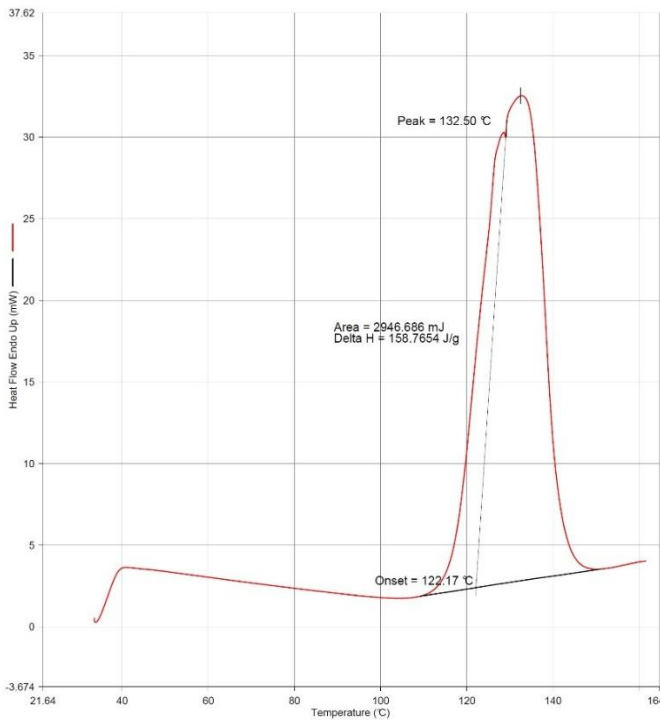
  Aw crystalFructoGrape = 0.425 ± 0.023

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- **Thermodynamic properties:**

  There are not significant differences between control* fructose and crystalFructoGrape

control* fructose

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DOC. RIF	REV.	VERIFICA	RGQ
NS-CFG	02	06-05-2024	VV

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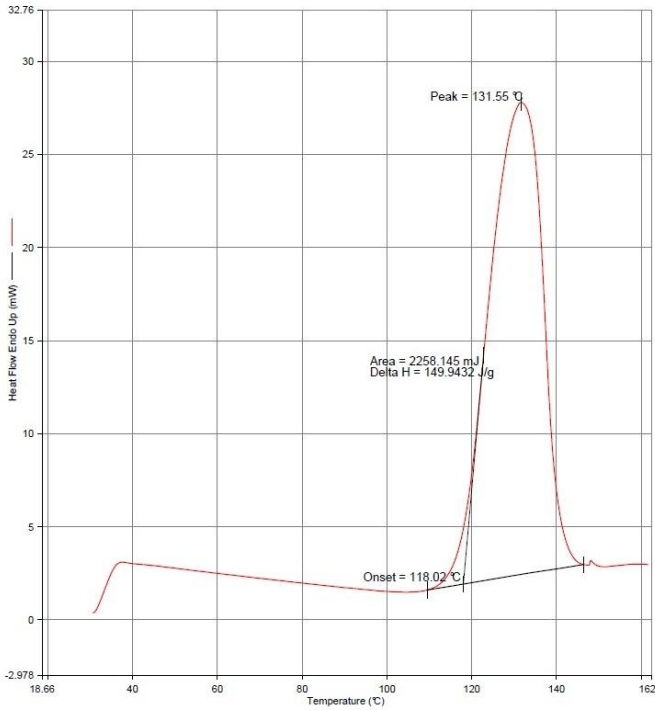
APPLICATIONS

Used in formulations as a flavoring and sweetening agent. The sweetness-response profile of fructose is perceived in the mouth more rapidly than that of sucrose and dextrose, which may account for the ability of fructose to enhance fruit flavors and mask certain unpleasant 'off-flavors'.

crystalFructogrape can be used not only in powder / granulated preparations, but also:

- In syrup / liquid formulations, where it performs an efficient action not only as dissolution enhancer and sweetener, but also as flavor modulator.
- In tablet formulations, having excellent rheological characteristics to be used as an ingredient / excipient for ODT or effervescent, large tablets.

TABLETING

Experimental details:

- Compression tests performed using 5 kg of sugar. No added excipients
- Control: a control* fructose of different origin, recommended by the manufacturer for tableting
- Compact rotary tablet press PZ-UNO (B&D Italia)
- External lubrication system machine (magnesium stearate)
- Compression forces tested: 10 kN , 20 kN , 30 kN , 40 kN , 50 kN, 60 kN and 70 kN
- Within each compression force, 200 tablets produced each of 2.0 grams
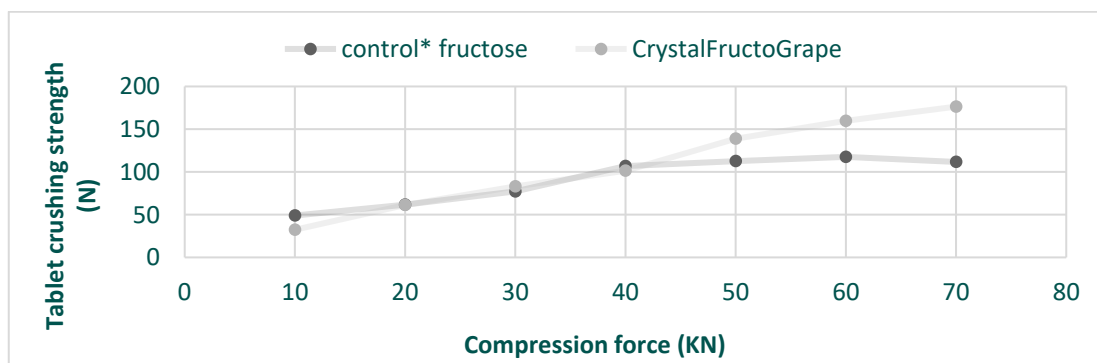- For each compression force, 10 tablets were analyzed

COMPACTION PARAMETERS crystalFRUCTOGRAPE VS. CONTROL* FRUCTOSE

	Compression force (kN)													
	10		20		30		40		50		60		70	
Sugar→	GF	TF	GF	TF	GF	TF	GF	TF	GF	TF	GF	TF	GF	TF
Weight (g)	2,1	2,2	2,08	2,2	2,1	2,2	2,1	2,21	2,09	2,21	2,14	2,21	2,13	2,22
Strength (KP)	3,3	5	6,26	6,3	8,48	8,3	10,35	10,9	14,8	11,5	16,3	12	18,03	11,4
Friability	+	+	+	+	++	++	++	++	++	-	++	--	++	--
Capping	N	N	N	N	N	N	N	N	N	Y	N	Y	N	Y
Lamination	N	N	N	N	N	N	N	N	N	Y	N	Y	N	Y
Other defects	N	N	N	N	N	N	N	N	N	fragility	N	fragility	N	fragility

GF = crystalFructoGrape   TF = control* fructose

+ = good   ++ = very good
- = bad   -- = very bad
N: absent   Y: present

COMPACTION PROFILE crystalFRUCTOGRAPE VS. CONTROL* FRUCTOSE

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SYRUPS

The increased solubility of fructose in comparison to sucrose is advantageous in syrup or solution formulations that must be refrigerated, since settling or crystallization of ingredients is retarded.

Similarly, the greater solubility and hygroscopicity of fructose over sucrose and dextrose helps to avoid 'cap-locking' (sugar crystallization around the bottle cap) in elixir preparations. Fructose has also a greater solubility in ethanol (95%) and is therefore used to sweeten alcoholic formulations.

Fructose has a lower water activity and a higher osmotic pressure than sucrose (which influence microbial stability and freshness). Syrup formulations may be made at lower dry-substance levels than sugar syrups without compromising shelf-life stability.

For phytotherapic preparations (syrups made from plant extracts) one of the more used ingredient is fructose, for its double function of sweetener and preservative. Also, the coprecipitation of fructose with hydrophobic drugs enhances the dissolution profile of such drugs. Fructose apparently acts as a water-soluble carrier upon coprecipitation, thereby allowing hydrophobic drugs to be more readily wetted.

Extracts characterized by the most intense unfavorably organoleptic properties, difficult to mask. (i.e. Valeriana officinalis, Passiflora incarnata, Aloe spp., Camomilla romana) combine very well with crystalFructoGrape, which has proved useful to improve the organoleptic characteristics and quality of the preparations (significant change in the taste).

EXAMPLES OF PHYTOTHERAPIC PREPARATION WITH crystalFRUCTOGRAPE VS. CONTROL* FRUCTOSE

TEST 1	CONTROL	OPTIMIZED
Aloe Vera Juice	nd	nd
control* fructose	35%	/
crystaFructoGrape	/	30% (-12%)
Flavor	0.1%	0.05%

TEST 2	CONTROL	OPTIMIZED
pomegranate juice	nd	nd
control* fructose	70%	/
crystaFructoGrape	/	20% (-70%)

TEST 3	CONTROL	OPTIMIZED
Olea europaea exctract	nd	nd
control* fructose	20%	/
crystaFructoGrape	/	10% (-50%)

CONCLUSIONS

crystalFructoGrape has excellent organoleptic properties to be used as an ingredient in syrup preparations (especially to optimize the taste of phytotherapic extracts difficult to be masked).

In many preparations the use of crystalFructoGrape allows a significant reduction of the content of fructose in the formulation and also of the flavors.

crystalFructoGrape has excellent rheological characteristics to be used as an ingredient / excipient in tableting (ODT and effervescent), even at very high concentrations (up to 100%) and without the need to add additional processing aids. In particular crystalFructoGrape shows tableting performances far better than control* fructose (using which tablets of satisfactory hardness and friability can only be produced by direct compression if tablet presses are operated at relatively slow speeds).

← 3 different types of "commercial" fructose

← 3 different lots of CrystalFructoGrape

Control* fructose = commercial crystalline fructose, from no-fruit sources