Naturalia
Fruit natural sugars

NUTRA SHEET

Chemical Name and CAS Registry Number: D-(+)-Glucose monohydrate [5996-10-1]

Empirical Formula: $C_6H_{12}O_6 \cdot H_2O$

Molecular Weight: 198.17

Specifications: crystalDextroGrape complies with specifications of European Pharmacopoeia curr. ed. and US Pharmacopoeia curr. ed. for crystalline dextrose/glucose monohydrate (details in technical sheets)

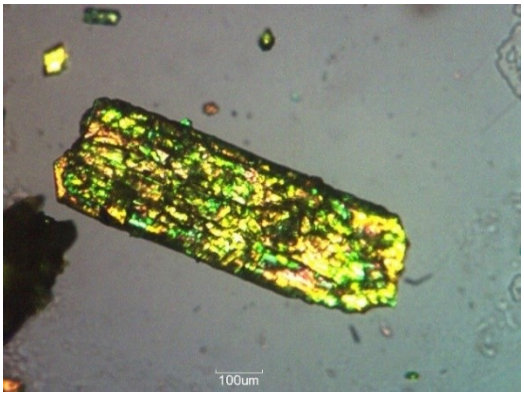
Functional Category: Tablet and capsule diluent; therapeutic agent (referred source of carbohydrate in parenteral nutrition regimens); tonicity agent; sweetening agent

Regulatory Status: Dextrose is Included in the FDA Inactive Ingredients Guide (capsules; inhalations; IM, IV, and SC injections; tablets, oral solutions, and syrups). Included in nonparenteral and parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients

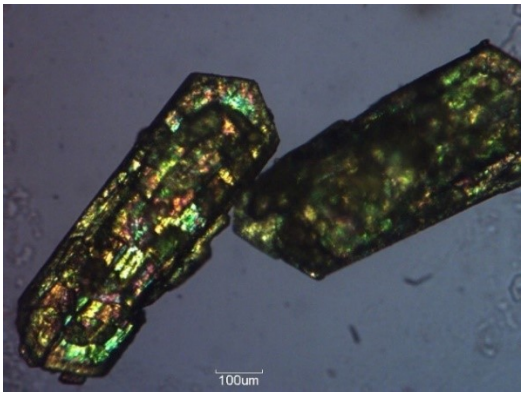
Labelling: Dextrose, Grape dextrose, Dextrose (extracted) from grape

TYPICAL PROPERTIES

- **Description:** Odorless, sweet-tasting, white crystalline powder
- **Purity:** > 99.5%
- **Sweetening power:** lower than sucrose (50-70%)
- **Nutritional properties:** Energy value: 4 kcal/g; high glycemic index (100). Dextrose is an immediate energy source, to restore the energy reserves of the body under stress
- **Stability and Storage Conditions:** Dextrose has good stability under cool dry storage conditions. Aqueous solutions may be sterilized by autoclaving. However, excessive heating can cause a reduction in pH and caramelization of solutions
- **Crystallinity:** There are not significant differences between control* dextrose and crystalDextroGrape



control* dextrose



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- **Acidity/alkalinity:** pH = 4.0 – 6.0 (10% w/v aqueous solution)
- **Melting point:** ≈ 83°C
- **Viscosity (dynamic):** There are not significant differences between control* dextrose and crystalDextroGrape

Dextrose concentration in water	control* dextrose	crystalDEXTROGRAPE (avarage of 3 lots)
% w/w	(cP) 25°C	(cP) 25°C
10	1,70	1,70
20	2,10	2,27
30	3,00	3,07
40	5,00	5,00
50	8,20	8,03
60	18,40	18,20

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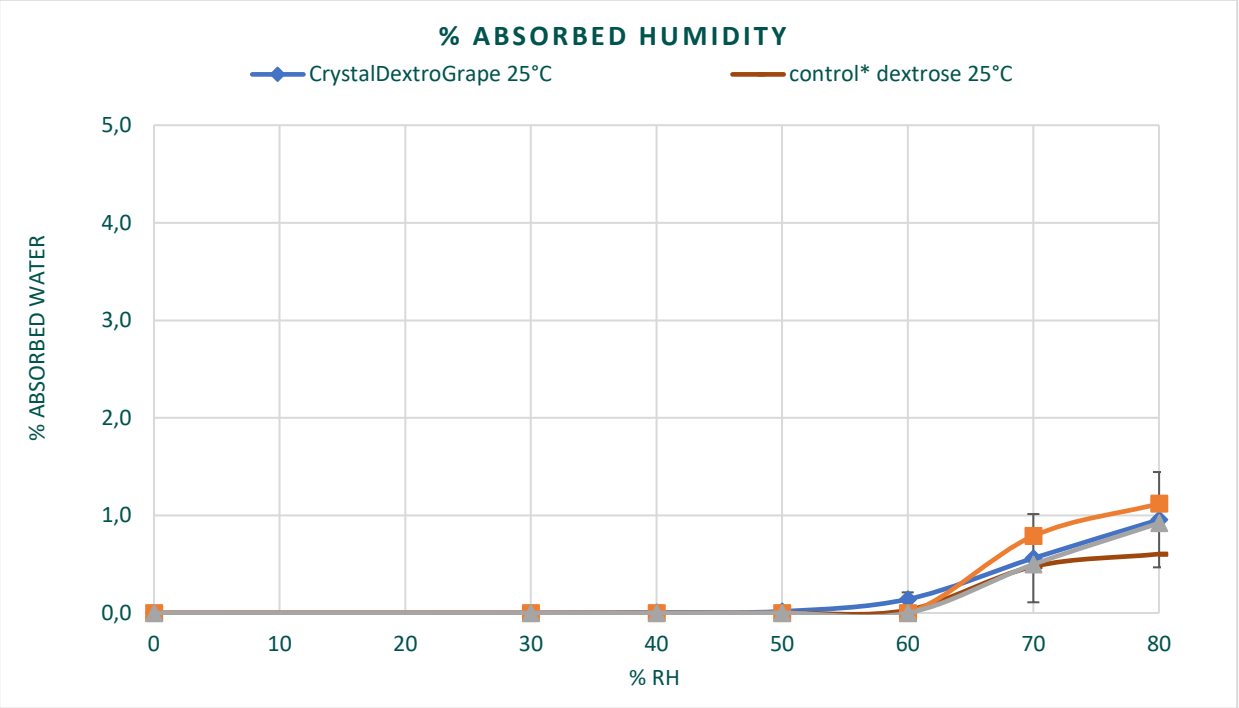
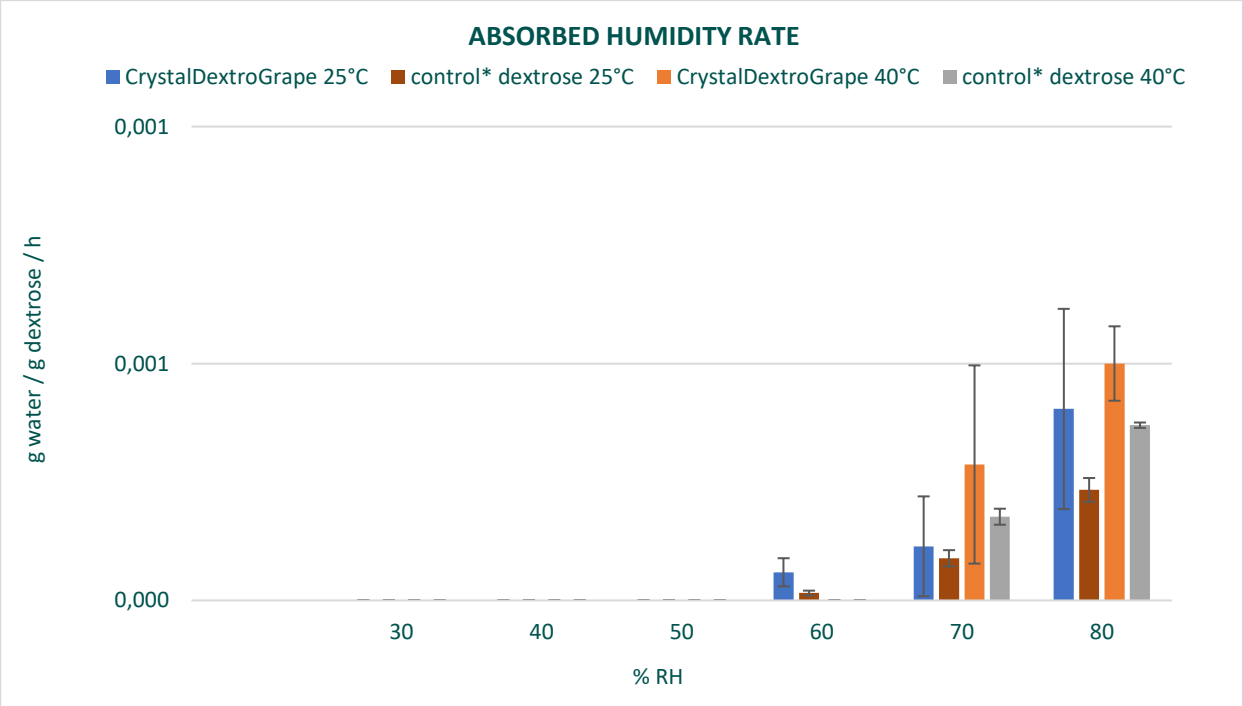
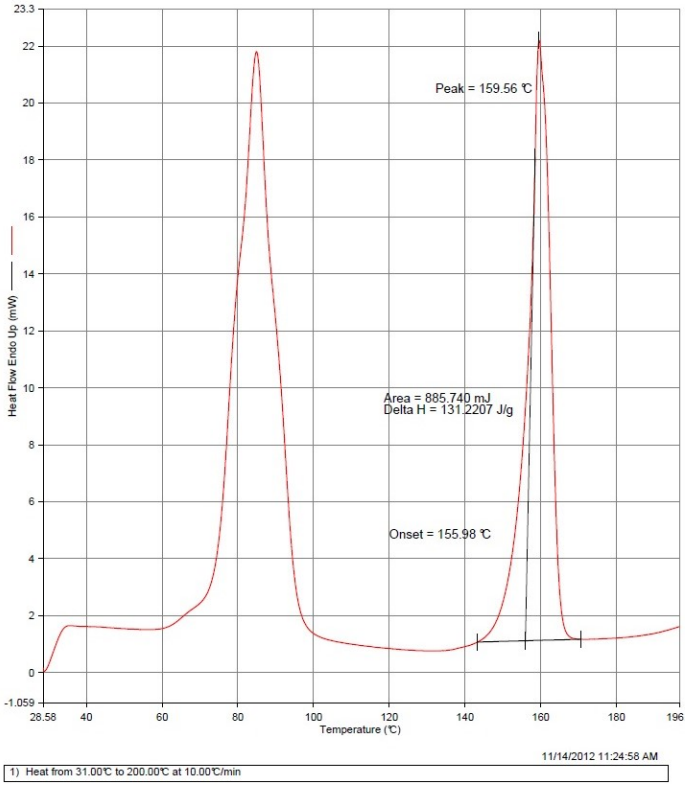
- **Hygroscopicity:** Low. There are not significant differences between control* dextrose and crystalDextroGrape



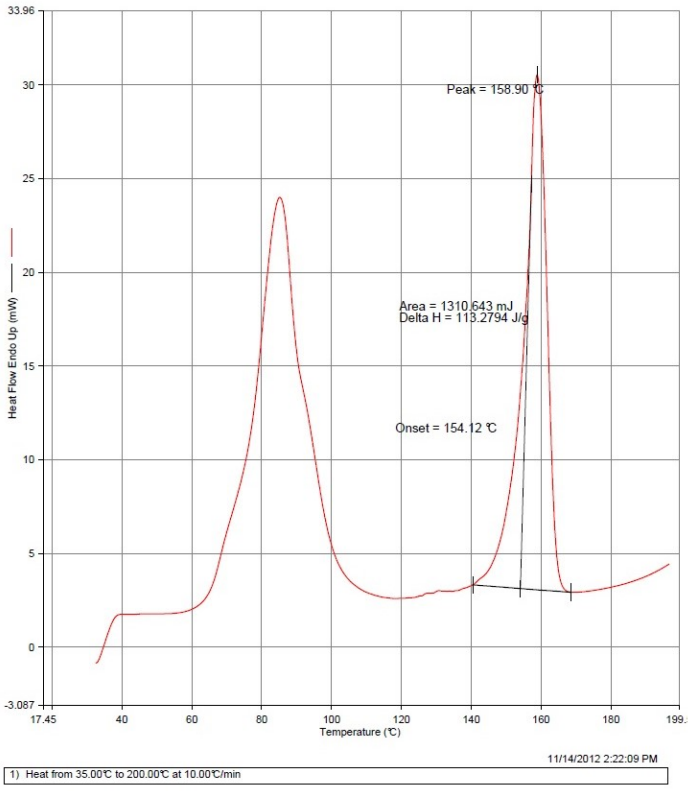


- **Water Activity (Aw):** There are not significant differences between control* dextrose and crystalDextroGrape
  Aw control* dextrose = 0.453 ± 0.11
  Aw crystalDextroGrape = 0.441 ± 0.04

- **Thermodynamic properties:** There are not significant differences between control* dextrose and crystalDextroGrape



control* dextrose



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APPLICATIONS

Dextrose is widely used in solutions to adjust tonicity and as a sweetening agent. Dextrose is also used as a wet granulation diluent and binder, and as a direct-compression tablet diluent and binder, primarily in chewable tablets. The mildly reducing properties of dextrose may be used to improve the stability of active materials that are sensitive to oxidation.

TABLETING

Experimental details:

- Compression tests performed using 5 kg of sugar. No added excipients
- Control: a control* dextrose 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

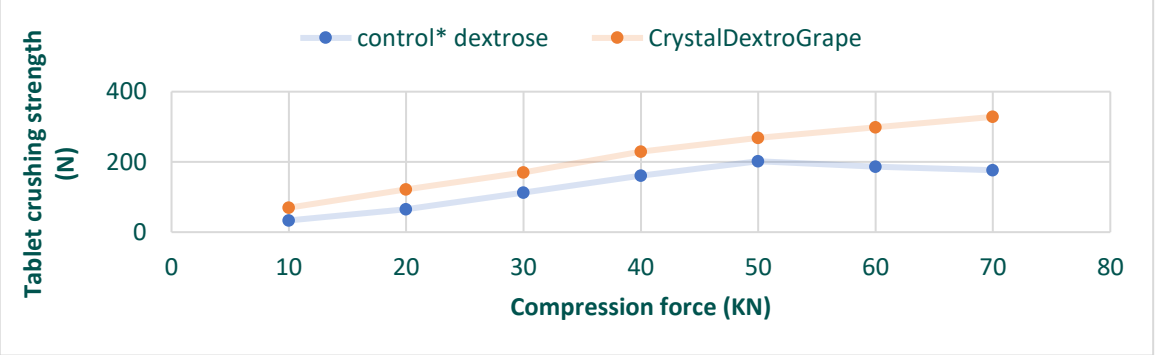
COMPACTION PARAMETERS crystalDEXTROGRAPE *VS.* CONTROL* DEXTROSE

	Compression force (kN)													
	10		20		30		40		50		60		70	
Sugar→	**GD**	**TD**	**GD**	**TD**	**GD**	**TD**	**GD**	**TD**	**GD**	**TD**	**GD**	**TD**	**GD**	**TD**
Weight (g)	1.78	2.17	1.79	2.18	1.8	2.18	1.81	2.18	1.82	2.15	1.82	2.16	1.89	2.15
Strength (KP)	7.1	3.4	12.4	6.9	17.3	12	23.4	16.4	27.4	20.6	30.5	19	33.5	18
Friability	++	++	++	++	++	++	++	++	++	-	++	--	++	--
Capping	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y
Lamination	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y
Other defects	N	N	N	N	N	N	N	N	N	N	N	fragility	N	fragility

GD = crystalDextroGrape TD = control* dextrose

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

COMPACTION PROFILE crystalDEXTROGRAPE *VS.* CONTROL* DEXTROSE



CONCLUSIONS

crystalDextroGrape 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 crystalDextroGrape shows tableting performances far better than control* dextrose (using which tablets of satisfactory hardness and friability can only be produced by direct compression if tablet presses are operated at relatively slow speeds). It should also be pointed out that the increase of the hardness of the tablets made with control* dextrose (dextrose (at the same kN) is always inferior to that of the tablets made with crystalDextroGrape.

Control* dextrose = commercial crystalline dextrose, from no-fruit sources.