Naturalia
Fruit natural sugars

NUTRA SHEET

Product description: crystalGrapeSugar consists of a mixture of dextrose (crystalDextroGrape: 50±10%) and fructose (crystalFructoGrape: 50±10%)

Chemical Name and CAS Registry Number: D-(+)-Glucose monohydrate [5996-10-1] and d-Fructose [57-48-7]

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

Functional Category: sweetening agent; tablet diluent

Regulatory Status: Dextrose and fructose are included in the FDA Inactive Ingredients Guide and in the Canadian List of Acceptable Non-medicinal Ingredients

Labelling: Grape sugars (dextrose and fructose); Dextrose and fructose (extracted) from grape; Grape sugar (UE)

TYPICAL PROPERTIES

- **Description:** Odorless, colorless crystals or a white crystalline powder
- **Purity:** > 99.5%
- **Sweetening power:** comparable with sucrose (100-120%)
- **Nutritional properties**: Energy value: 4 kcal/g; low glycemic index (49) [1]
- **Stability and Storage Conditions:** The fructose component makes the product hygroscopic. Store at temperatures below 30°C and a relative humidity of less than 60%. Excessive heating can cause a reduction in pH and caramelization of solutions

APPLICATIONS

crystalGrapeSugar can be used in solutions to adjust tonicity and as a sweetening agent. It can also be used as tablet diluent and binder in direct-compression. The mildly reducing properties of the dextrose component may be usefull 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* mix 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

[1] specific tests carried out by the University of Milan

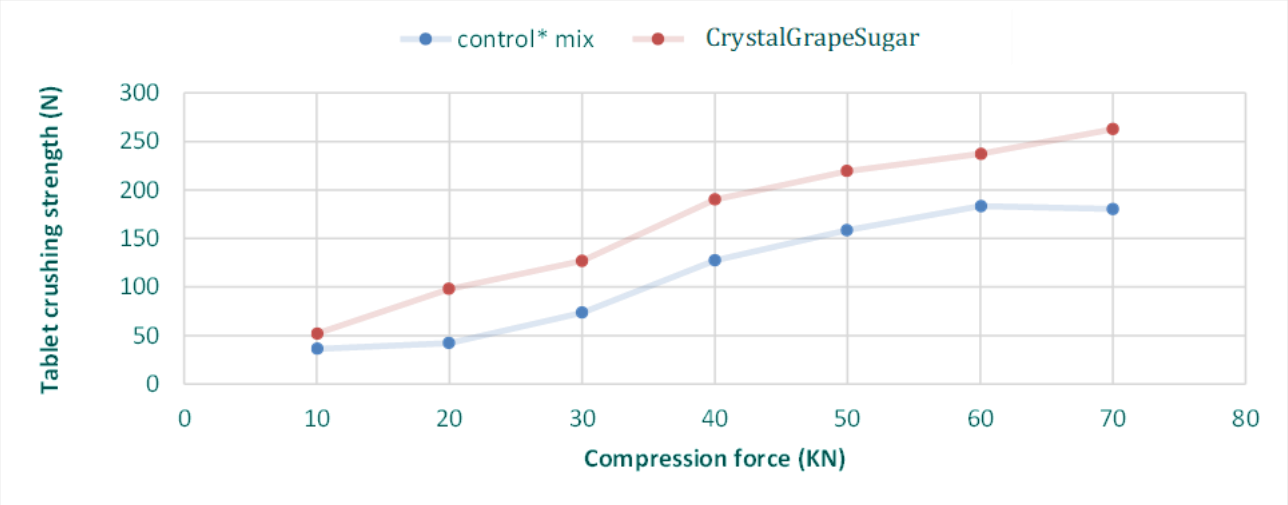
COMPACTION PARAMETERS crystalGRAPESUGAR VS. CONTROL* MIX

	Compression force (kN)													
	10		20		30		40		50		60		70	
Sugar→	**GS**	**TS**	**GS**	**TS**	**GS**	**TS**	**GS**	**TS**	**GS**	**TS**	**GS**	**TS**	**GS**	**TS**
Weight (g)	1.92	2.15	1.93	2.14	1.95	2.14	1.97	2.2	1.96	2.15	1.98	2.16	1.98	2.16
Strength (KP)	5.3	3.7	10	4.3	13.5	7.5	19.4	13	22.4	16.2	24.2	18.7	26.8	18.4
Friability	++	++	++	++	++	++	++	-	++	--	++	--	++	--
Capping	N	N	N	N	N	N	N	Y	N	Y	N	Y	N	Y
Lamination	N	N	N	N	N	N	N	Y	N	Y	N	Y	N	Y
Other defects	N	N	N	N	N	N	N	fragility	N	fragility	N	fragility	N	fragility

GS = crystalGrapeSugar TS = control* mix

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

COMPACTION PROFILE crystalGRAPESUGAR *VS.* CONTROL* MIX



CONCLUSIONS

crystalGrapeSugar 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 crystalGrapeSugar shows tableting performances far better than control* mix (using which tablets of satisfactory hardness and friability can only be produced by direct compression if tablet presses are operated at relatively slow speeds).

Control* mix = commercial crystalline dextrose + fructose, from no-fruit sources (in the same ratio as crystalGrapeSugar)