EMDEX®

Dextrates, NF

100 % Lactose free

- **Multifunctional Excipient**
- **Soluble DC Binder and Filler in One**
- **Excellent Flow and Compaction**
- **Superb Taste and Tablet Appearance**

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EMDEX®

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Introduction

EMDEX® is a directly compressible, water-soluble tablet binder and filler. Its unique composition of 95 % glucose monohydrate and different oligosaccharides derived from starch is monographed under “dextrates” in the NF. With use levels ranging from 1 % to 99 %, **EMDEX®** is designed for a variety of tablet applications.

Physical Properties

- Freely and rapidly water soluble (1000 g/L)
- Natural sweet taste of dextrose
- Spherical, porous particles
- Excellent flowability
- High bulk density
- Calorie content: 4.0 - 4.5 kcal/gram
- Narrow particle size distribution

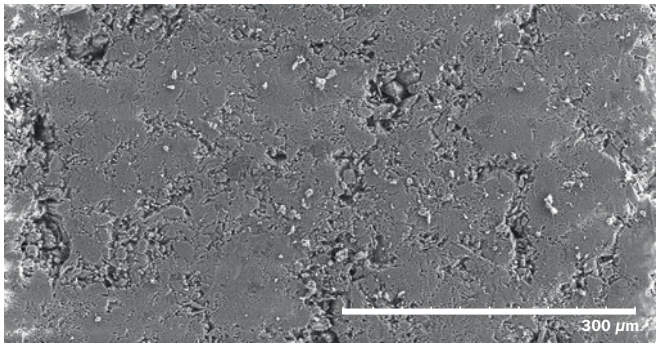
Powder Properties

Bulk Density	0.70 g/m³
Tapped Density	0.75 g/m³
Hausner Ratio	1.07
Angle of Repose	30°
Loss on Drying	7.8 - 9.2 (glucose monohydrate, the assay includes crystal water)
Dextrose Equivalent	93 - 99 %
Heat of Solution	-105 J/g
Medium Particle Size	190 - 220 µm

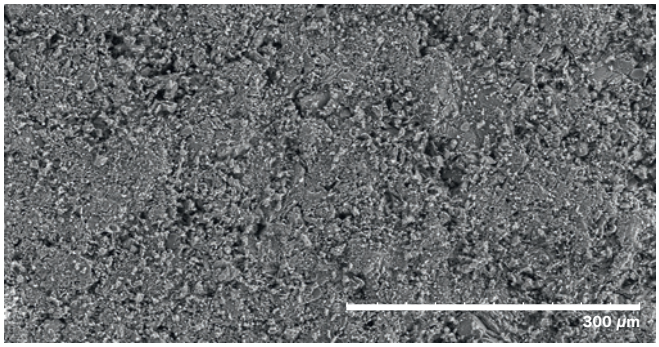
Tab. 1: Powder Properties of **EMDEX®**

Benefits

- Superior flow, compaction, and tablet robustness in direct compression applications
- Does not require a glidant, due to superior flow properties
- Exhibits excellent mixing properties
- Easy to handle – does not stick to punches
- Non-dusting
- Results in smooth, shiny tablets
- Tablets demonstrate very low friability
- Ideally suited for lactose-intolerant patients
- Enables lactose-free line extensions
- Metabolizes fully without osmotic laxative effect
- Provides patients with a pleasant, sweet taste and a cool mouth feel
- Does not cause dry mouth feel when compared to sugar alcohols
- Particle porosity improves **EMDEX®**’s solubility and flavor absorption capacity – a key advantage for tablet taste enhancement
- Compendial (NF), eliminating regulatory hurdles



Micrograph of **EMDEX®** Tablet Surface



Micrograph of Lactose Tablet Surface

Applications

EMDEX® is designed for a variety of tablet types including:

- Chewable tablets
- Ingestible tablets
- Dispersible tablets
- Effervescent tablets
- Soluble tablets
- Veterinary applications
- Stickpacks

Special Applications

- Because **EMDEX®** is 100 % water soluble, it is also perfect for applications in which a good mouth feel or a clear solution are required
- **EMDEX®**'s excellent flowability and non-dustiness makes it appropriate to be used as a flow improvement aid in sachets and stickpacks
- **EMDEX®** is a porous material that absorbs fluids, allowing chewable formulation development and manufacture using liquid APIs
- Highly suited for chewable animal health products, especially for dogs, who are particularly fond of its pleasant taste
- **EMDEX®** should not be used for APIs, which are incompatible with reducing sugars

Functional Aspects

Particle Size and Morphology

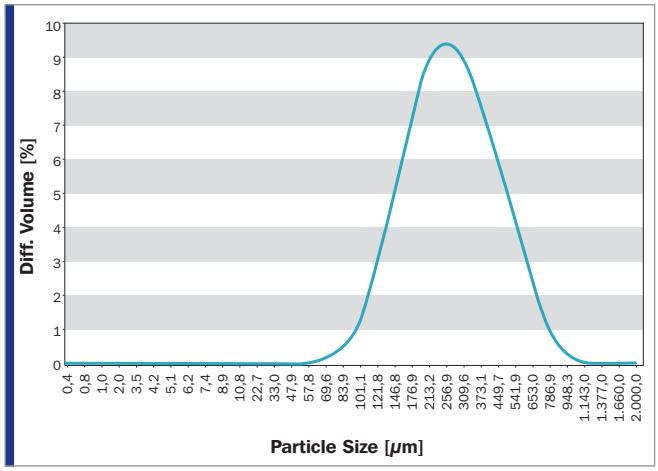
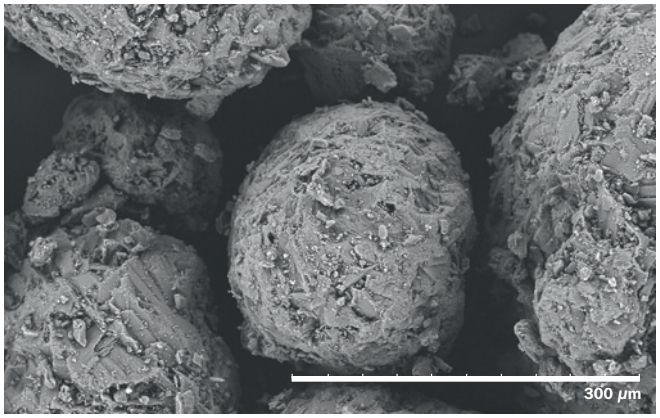
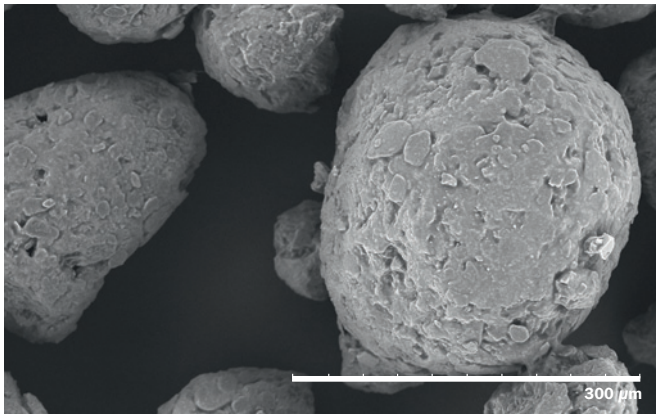


Fig. 1: Particle Size Distribution of **EMDEX®** (Dextrates)

- **EMDEX®** exhibits a narrow particle size distribution with an average particle size of 200 µm. Along with its spherical particle shape and high bulk density, this ensures supreme flow properties
- The porous structure of the spray-dried **EMDEX®** particles enables excellent content uniformity even for low-dose, micronized APIs
- Oily APIs are readily absorbed by the sponge-like structure of **EMDEX®**



Micrograph of **EMDEX®**



Micrograph of Simethicone-loaded **EMDEX®** Particles

EMDEX®

Dextrates, NF

Compactibility

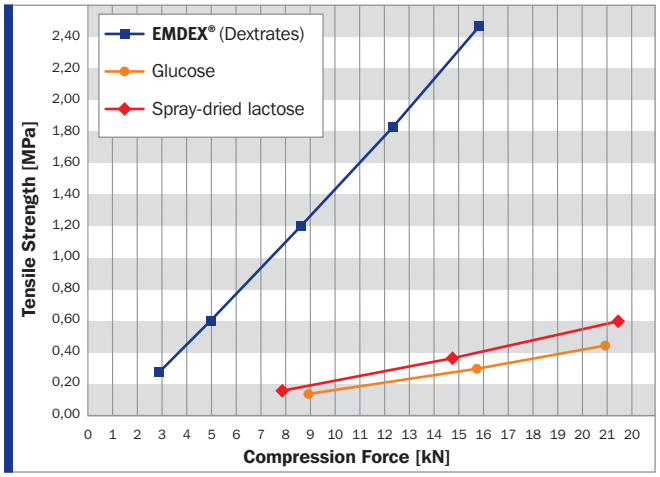


Fig. 2: **EMDEX®** vs. Other Soluble Binders

Lactose is the most widely used water-soluble filler-binder. **EMDEX®** is significantly more compactible than spray-dried lactose, while exhibiting the same (brittle) binding mechanism.

Figure 2 also illustrates the difference in compactibility between **EMDEX®** dextrates and pure glucose mono-hydrate. Spray-drying, as well as the presence of oligo-saccharides in **EMDEX®**, leads to a massive increase in tablet strength.

Flowability

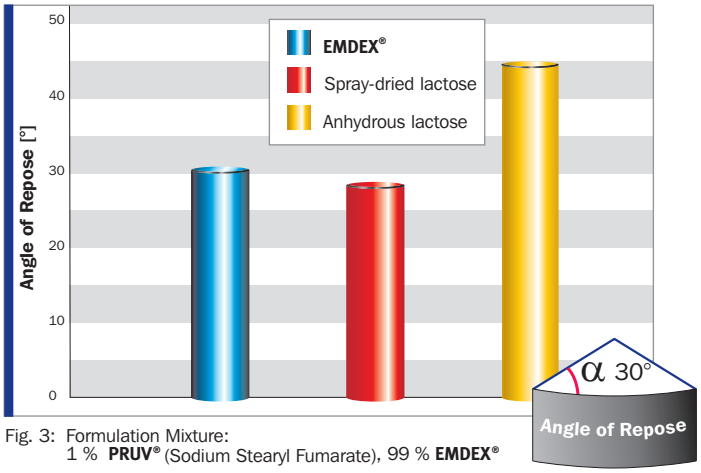


Fig. 3: Formulation Mixture:
1 % **PRUV®** (Sodium Stearyl Fumarate), 99 % **EMDEX®**

Due to its high bulk density and spherical particle shape, **EMDEX®** exhibits excellent flowability. This functional advantage can be utilized in pure form or for flow enhancement in tableting blends and stickpacks.

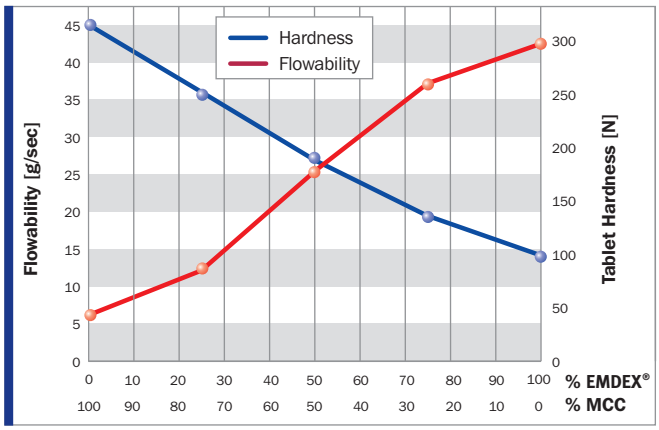


Fig. 4: Crushing Force of Tablets Compressed at 15 kN Force, and Flowability of the Corresponding Tablet Blend.

Figure 4 shows how the flowability of DC-grade micro-crystalline cellulose (**VIVAPUR® 102**) can be further improved by adding increasing amounts of **EMDEX®**.

Case Study: Comparison of Different Water-Soluble Direct Compression Binders with Vitamin C Powder

Formulation

Vitamin C	25.0 %
PRUV® (Sodium Stearyl Fumarate)	0.5 %
Binder	74.5 %

Tab. 2: Different soluble direct compression excipients were formulated with Vitamin C. The excipients and Vitamin C were mixed for 15 minutes and then lubricated for 3 minutes. The resulting formulation mixtures were compressed to yield tablets (13 mm, 500 mg) with a tablet crushing strength of approximately 70 N.

	Angle of Repose (°)	Bulk Density (g/ml)
Glucose Monohydrate	34	0.67
Granulated Lactose	35	0.67
DC Sorbitol	27	0.72
Isomalt	31	**0.52**
Mannitol	34	**0.54**
EMDEX® (Dextrates)	34	**0.79**

Tab. 3: Blend Properties

Results

	Compression Force (kN)	Crushing Strength [N]	Friability (%)	Disintegration (sec)
EMDEX® (Dextrates)	**8.60**	**72**	**0.39**	**34 !**
Isomalt	10.90	72	**1.60**	85
DC Sorbitol	7.50	70	**3.57 !**	**190 !**
Granulated Lactose	40.60	71	**1.65**	60
Glucose Monohydrate	26.00	33	-	-
Mannitol	20.35	35	-	-

Tab. 4: Tabletting Results

As shown in Table 4, the target tablet hardness of 70 N was not reached with the formulations based on mannitol and glucose monohydrate respectively. Granulated lactose required excessive compaction forces to reach the target hardness yet yielded tablets of unacceptable friability.

DC-grade sorbitol and Isomalt resulted in tablets of the desired hardness at reasonably low compaction forces. Their friability values, however, were too high.
Only the **EMDEX®** formulation produced tablets of satisfactory hardness and friability, while also showing outstanding disintegration properties.

EMDEX®

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Model Formulations

Lozenges:

Vitamin C

	mg/tablet
Ascorbic Acid, Granulated	45.0
Sodium Ascorbate	83.0
Orange Flavor	8.5
PRUV® Sodium Stearyl Fumarate	6.4
EMDEX® Dextrates	**607.1**
Total Weight	**750.0**

Tab. 5

Tablet Diameter	16 mm
Compression Force	22 kN
Crushing Strength	160 N

Tab. 6

Multivitamin

	mg/tablet
Multivitamin Mixture	40.0 - 64.0
EMDEX® Dextrates	648.0 - 672.0
Gummi Arabicum	75.0
Xylitol	5.0
Flavor (Orange & Lemon)	4.0
PRUV® Sodium Stearyl Fumarate	4.0
Total Weight	**800.0**

Tab. 7

Compression Force	7 - 8 kN
Crushing Strength	90 - 110 N

Tab. 8

Effervescent Tablets:

Acetylsalicylic Acid

	mg/tablet
Acetylsalicylic Acid	500.0
Natrium Hydrogen Carbonate	400.0
Citric Acid	350.0
PRUV® Sodium Stearyl Fumarate	**20.0**
EMDEX® Dextrates	**800.0**
Total Weight	**2070.0**

Tab. 9

Tablet Diameter	16 mm
Compression Force	15 kN
Crushing Strength	140 N

Tab. 10

Chewable Tablets:

Antacid

	mg/tablet
Aluminium Hydroxide	400.0
Silic Acid	50.0
Flavor	20.0
PRUV® Sodium Stearyl Fumarate	**16.0**
EMDEX® Dextrates	**1014.0**
Total Weight	**1500.0**

Tab. 11

Tablet Diameter	16 mm
Compression Force	28 kN
Crushing Strength	120 N

Tab. 12

Simethicone

	mg/tablet
Simethicone Mix	42.0
PRUV® Sodium Stearyl Fumarate	**10.0**
EMDEX® Dextrates	**440.0**
Total Weight	**492.0**

Tab. 13

Tablet Diameter	13 mm
Compression Force	15 - 17 kN
Crushing Strength	70 - 80 N

Tab. 14

Regulatory Information

EMDEX® meets the following requirements:

- Conforms to NF
- GMO-free grade available
- GMO-free grades fall under food regulations for glucose syrup (dried)
- GRAS (generally regarded as safe) and non-toxic
- Plant-derived
- Kosher
- Halal
- OVI-free (USP <467>)
- Residual Solvents Free (Ph. Eur. 5.4)
- Lactose-free

Packaging, Samples and Storage

Storage
Store in original container at room conditions of <25 °C and 60 % humidity.

Packaging
Available in HDPE-lined paper bags.

Sample Sizes
400 g and 2 kg containers available.

Case Studies
Case studies and formulation examples are available upon request. Please contact your sales rep for more information or visit *www.jrspharma.com.*

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Carriers
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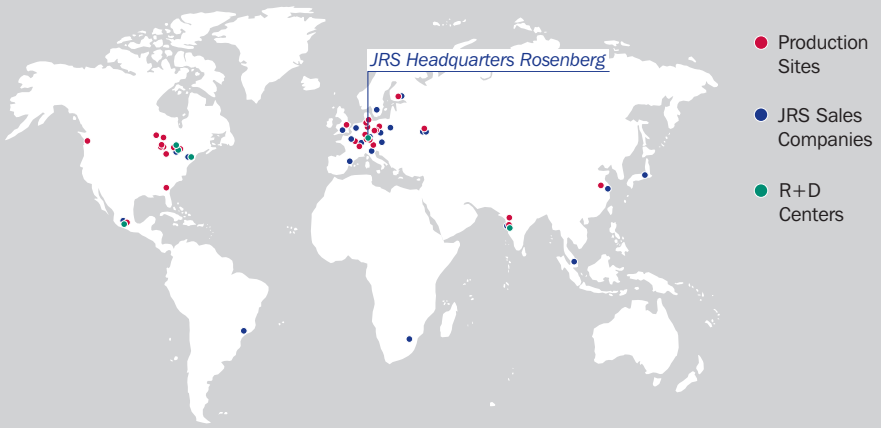

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