



Roquette's Plant-Based Excipients for Probiotic Supplements



Introduction

Probiotic supplements is a fast growing dietary supplement category, especially in the United States. Historically promoted for their digestive health benefits, probiotics are increasingly being researched and marketed for clinical benefits associated with the gut microbiome. Probiotic supplements are mainly formulated as powders in hard shell capsules. However, other dosage forms such as sachets, stick-packs and even tablets, including chewables, are being launched. Dosage forms, especially tablets, require formulation strategies to protect the probiotics during the dosage manufacturing process and thereafter to prolong the shelf-life of the consumer product, ideally preserving stability to achieve a 2 year shelf-life.



Roquette Pharma's Solutions

Roquette's excipients address the key factors needed for dosage form stability of probiotic supplements:

- Inert excipients that won't react with the probiotics
- Low moisture that won't encourage microorganism growth and promote instability
- Powder flow, especially for direct compression tableting and incorporation in powder fills for capsules and sachets
- Excellent compressibility and cushioning of probiotic granules, alleviating the heat generated from using high compression force to form tablets.

Roquette solutions by chemistry and dosage form:

	MICROCEL™ 112 & 112 SD	PEARLITOL® 100SD & 200SD, 300 DC	LYCATAB® C & C-LM	GLUCIDEX® range (IT 12, IT 12P, IT 19P)	NUTRIOSE® FM/FB dextrin
Chemistry	Microcrystalline Cellulose	Mannitol, Spray-Dried (SD), Granulated (DC)	Partially Pregelatinized Starch	Maltodextrins based on corn & potato	Corn & Wheat Dextrin
Functionality	Filler/Binder	Diluent/Filler/Carrier/Stabilizer	Diluent/Filler/Bulking Agent/Disintegrant	Diluent/Carrier Agent	Binder/Bulking Agent
Applications	Tablet, Hard Capsule	Tablet (Chewable), Stick-pack	Hard Capsule, Tablet	Sachet, Stick-pack	Hard Capsule, Tablet, Sachet, Stick-pack
Features	<ul style="list-style-type: none"> • Low moisture content • Excellent compressibility at low force, cushioning actives • Odorless & tasteless 	<ul style="list-style-type: none"> • Low moisture content • Non-hygroscopic • Highest stability excipient for moisture sensitive actives • Can be further dried without compromising properties • Free-flowing, proven for direct compression • Cooling taste effect 	<ul style="list-style-type: none"> • Lower moisture content & higher capacity to adsorb/bind water with C-LM, providing stability for moisture sensitive actives • High bulk density reduces capsule size required • Free-flowing, low dust content • High stability compatibility with gelatin capsule 	<ul style="list-style-type: none"> • Free-flowing & easily dispersible • IT 12 proven for probiotic sachets • Neutral taste 	<ul style="list-style-type: none"> • Low hygroscopicity • Free-flowing • Soluble fiber • Quick dissolution • Neutral taste
Key Properties:					
• Moisture content	1.5% max.	0.5% max.	14% max. for C 7% max. for C-LM	5-6% max.	6% max.
• Average particle size (microns)	100	100, 200 for SD 300 for DC	100	60-100	130
• Bulk density (g/mL)	0.28-0.34	0.5 for SD 0.7 for DC	0.64	0.4-0.5	0.41
• Certifications	Multicompential Non-GMO Kosher, Halal	Multicompential Non-GMO Gluten-free available Kosher, Halal	FCC Multicompential Non-GMO Kosher, Halal	FCC Multicompential Non-GMO Kosher, Halal Organic (select grades)	FCC Non-GMO Kosher, Halal

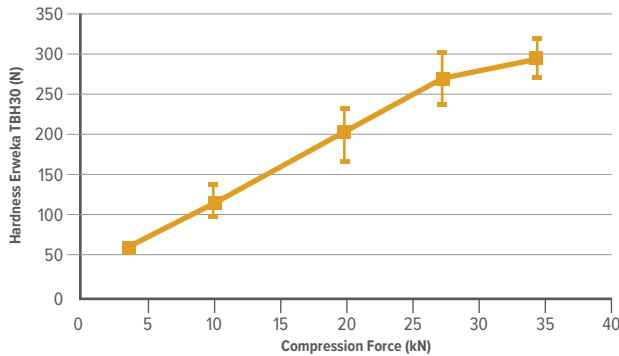
Supporting Performance Data

- High compactability excipients provide tablets of high hardness employing low to medium compression forces, thus minimizing heat generation during the tableting process
- Lower hygroscopicity and non-hygroscopic excipients reduce tablet moisture uptake, thereby providing a stabilizing factor for increased shelf-life

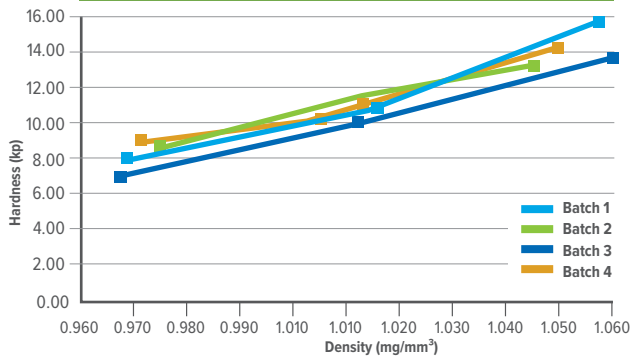


Tablet Compactability

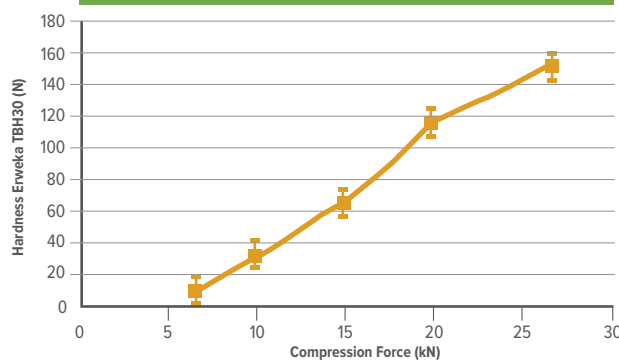
Compression force vs. tablet hardness of PEARLITOL® 200SD



Tablet hardness vs. density of MICROCEL™ 112 MCC batches

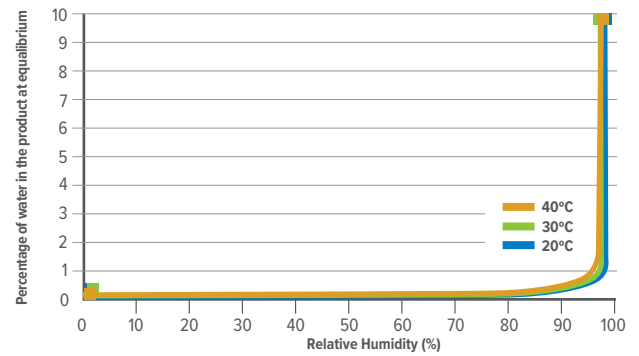


NUTRIOSE®FB 06 compactability

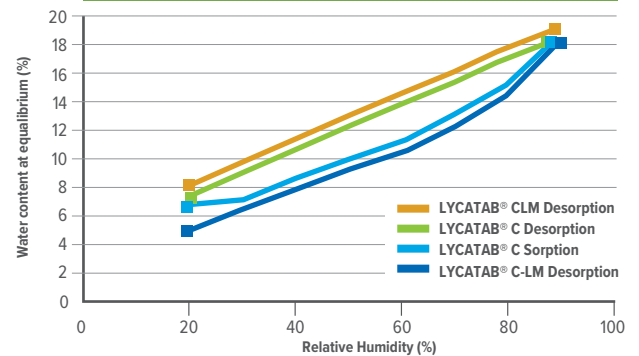


Moisture Uptake

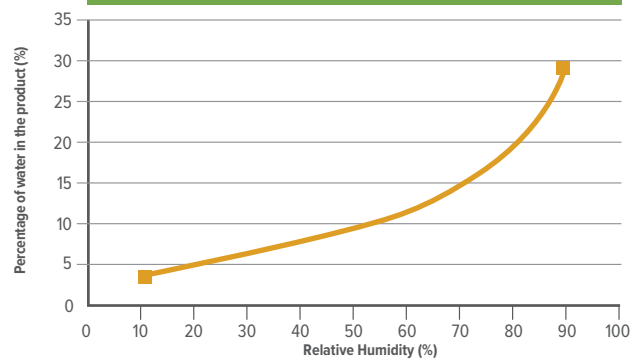
Influence of temperature on hygroscopicity of Mannitol



Sorption and desorption isotherms of LYCATAB® C and LYCATAB® C-LM



Water sorption isotherm of NUTRIOSE®FB 06 at 20°C



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