Improving Probiotic Stability with Nutracore® Label Friendly Excipients and Molecular Sieve Desiccants

Technical Data

Challenge

Probiotics, particularly strains such as lactobacillus acidophilus, are widely used as supplements for their various gut and immune support health benefits. However, their stability in maintaining the desired viability over the duration of the shelf life is very challenging due to their moisture, oxidation and heat sensitivity. Probiotic formulations require controlled room conditions of low heat and moisture during manufacturing. Moreover, manufacturers often add overage to ensure the label claim is met at the end of shelf life. Formulators face challenges when sourcing excipients that meet performance needs and help minimize environmental stressors (i.e., low water activity) while still being perceived as natural. For instance, microcrystalline cellulose (MCC), though derived from cellulose, undergoes significant chemical processing. Magnesium stearate (Mg St), another commonly used excipient, is chemically derived, prone to over-lubrication and lacks moisture-scavenging or water activity control properties.

Method

Nutracore® Filler and Nutracore® Lubricant were evaluated alongside varying desiccant options (Table 2) to determine the impact of Nutracore in combination with controlled atmosphere packaging on the viability of a lactobacillus acidophilus (200B CFU/g) probiotic formulation. This was compared against a formulation containing MCC and Mg St as a control formulation using Industry-standard excipients (Table 1).

Table 1: Formulation composition

Ingredients	Nutracore-based formulation (%w/w)	MCC-Mg-St based formulation (%w/w)
Lactobacillus Acidophilus	4.1	4.1
Silicon Dioxide	0.5	0.5
Nutracore Filler (NCF)	94.9	-
MCC	-	94.9
Nutracore Lubricant (NCL)	0.5	-
Mg St	-	0.5
Total	100.0	100.0

Table 2: Packaging configurations

Pack conf. #	Bottle type	Bottle size (cc)	Desiccant (Des) type	Des quantity (g)	# of caps per bottle	Induction seal
C1	HDPE	150	None	0	100	Yes
C2	HDPE	150	Silica gel	2	100	Yes
C3	HDPE	150	M.sieves	2	100	Yes
C4	HDPE	150	M.sieves	4	100	Yes
C5	HDPE	60	M.sieves	1	30	Yes
C6	HAT	60	M.sieves	4	30	No

Results

Table 3: Results at 25°C/60%RH

Formulation	Package configuration	Viability AFU (million cells/g)		Water activity (aW)		%Loss on drying (LoD)	
		0M	3M	0M	3M	0M	3M
Nutracore-based	C1	7900	5080	0.27	0.29	8.3	8.7
	C2	7900	6800	0.22	0.26	7.8	7.8
	C3	7900	7980	0.19	0.23	7.4	8.2
	C4	7900	6510	0.16	0.20	7.2	7.1
	C5	7900	6910	0.16	0.20	7.1	7.5
	C6	7900	8260	0.06	0.10	5.8	5.4
MCC-Mg St-based	C1	8070	773	0.35	0.41	5.4	5.8
	C2	8070	1670	0.28	0.34	5.1	5.3
	C3	8070	2020	0.27	0.33	4.6	4.8
	C4	8070	2880	0.23	0.29	4.2	4.4
	C5	8070	3310	0.23	0.28	4.4	5.1
	C6	8070	3610	0.04	0.09	3.2	3.0

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Table 4: Results at 30°C/65%RH

Formulation	Package configuration	Viability AFU (million cells/g)		Water activity (aW)		%LoD	
		0M	3M	0M	3M	0M	3M
Nutracore-based	C1	7900	2080	0.27	0.30	8.3	8.0
	C2	7900	5740	0.22	0.26	7.8	7.5
	C3	7900	5110	0.19	0.25	7.4	7.7
	C4	7900	6510	0.16	0.21	7.2	7.0
	C5	7900	7490	0.16	0.24	7.1	7.3
	C6	7900	8520	0.06	0.12	5.8	5.7
MCC-Mg St-based	C1	8070	598	0.35	0.41	5.4	5.7
	C2	8070	798	0.28	0.36	5.1	5.3
	C3	8070	1120	0.27	0.33	4.6	4.9
	C4	8070	1530	0.23	0.29	4.2	4.4
	C5	8070	1810	0.23	0.29	4.4	4.7
	C6	8070	3830	0.04	0.09	3.2	2.9

Table 5: Results at 40°C/75%RH

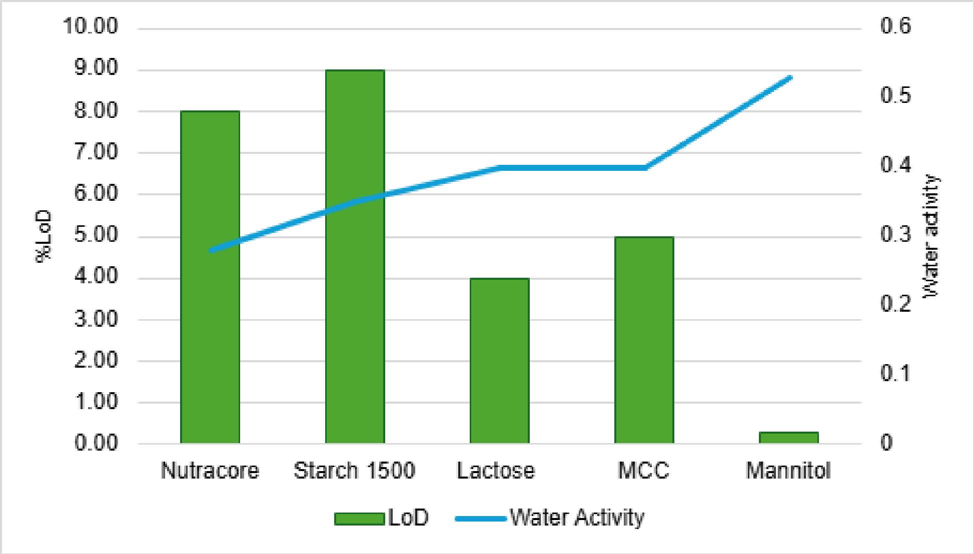
Formulation	Package configuration	Viability AFU (million cells/g)		Water activity (aW)		%LOD	
		0M	3M	0M	3M	0M	3M
Nutracore-based	C1	7900	951	0.27	0.31	8.3	7.9
	C2	7900	363	0.22	0.29	7.8	7.7
	C3	7900	1050	0.19	0.27	7.4	7.5
	C4	7900	3550	0.16	0.24	7.2	7.1
	C5	7900	585	0.16	0.25	7.1	7.0
	C6	7900	8350	0.06	0.16	5.8	6.0
MCC-Mg St-based	C1	8070	314	0.35	0.42	5.4	5.7
	C2	8070	305	0.28	0.39	5.1	5.6
	C3	8070	291	0.27	0.35	4.6	4.9
	C4	8070	449	0.23	0.29	4.2	4.4
	C5	8070	279	0.23	0.31	4.4	4.6
	C6	8070	3940	0.04	0.13	3.2	3.2

All manufactured capsules had comparable viability at 0M as shown in Table 3. In terms of moisture properties, the Nutracore formulation had lower water activity at 0M compared to the MCC-Mg St formulation. After three months storage at 25°C/60%RH, Table 3 shows that the Nutracore formulation resulted in overall higher viability and lowest water activity compared to the MCC-Mg St formulation. The water activity of the Nutracore formulation was significantly lower than the MCC-Mg St formulation despite having lower moisture content.

Among each formulation, molecular sieve desiccants resulted in less water activity and LoD compared to the formulation stored in the HDPE bottle with no desiccants. HAT bottles showed the most significant moisture control, reducing water activity and LoD compared to other packaging configurations. Similar observations were found at 30°C/65%RH (Table 4).

At extreme conditions of 40°C/75%RH, as depicted in Table 5, the Nutracore formulation stored in HAT bottles retained comparable viability and the lowest water activity, even after 3 months. On the other hand, the MCC-Mg-St formulation was observed to lose most of its viability even at 30°C/65%RH. Regardless of excipient type, increased desiccant—especially molecular sieve—and smaller containers improved viability. Even with MCC and Mg. St, which degraded more than Nutracore, higher desiccant levels had a positive effect.

Figure 1. LoD and water activity of Nutracore Filler compared to other filler excipients

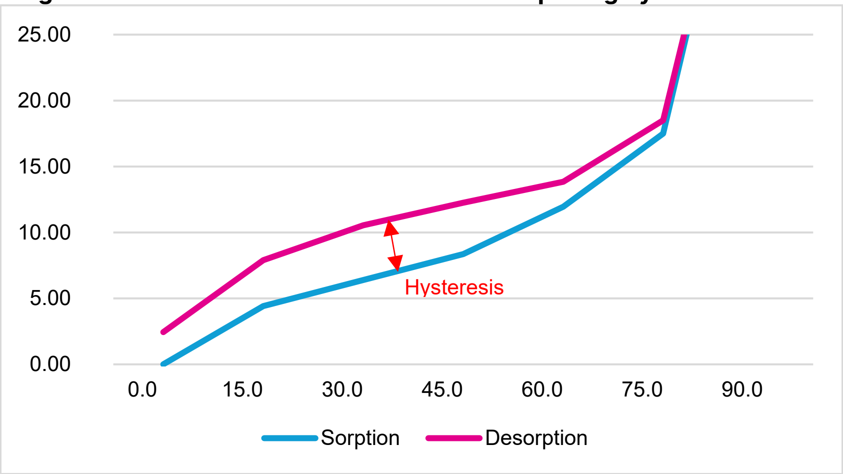


Nutracore Filler demonstrated strong stabilising properties for moisture-sensitive ingredients such as probiotics. This enhanced stability is likely attributed to several factors:

1. Lowest water activity among tested fillers, as illustrated in Figure 1, which reduces the potential for moisture-induced degradation.
2. Moisture scavenging capability, evidenced by the DVS isotherm in Figure 2, where Nutracore Filler effectively captures and retains free moisture in the environment, preventing interaction with active ingredients that could lead to stress and breakdown.
3. Presence of acacia gum, which not only contributes to stability but also offers prebiotic benefits that may further support probiotic viability.

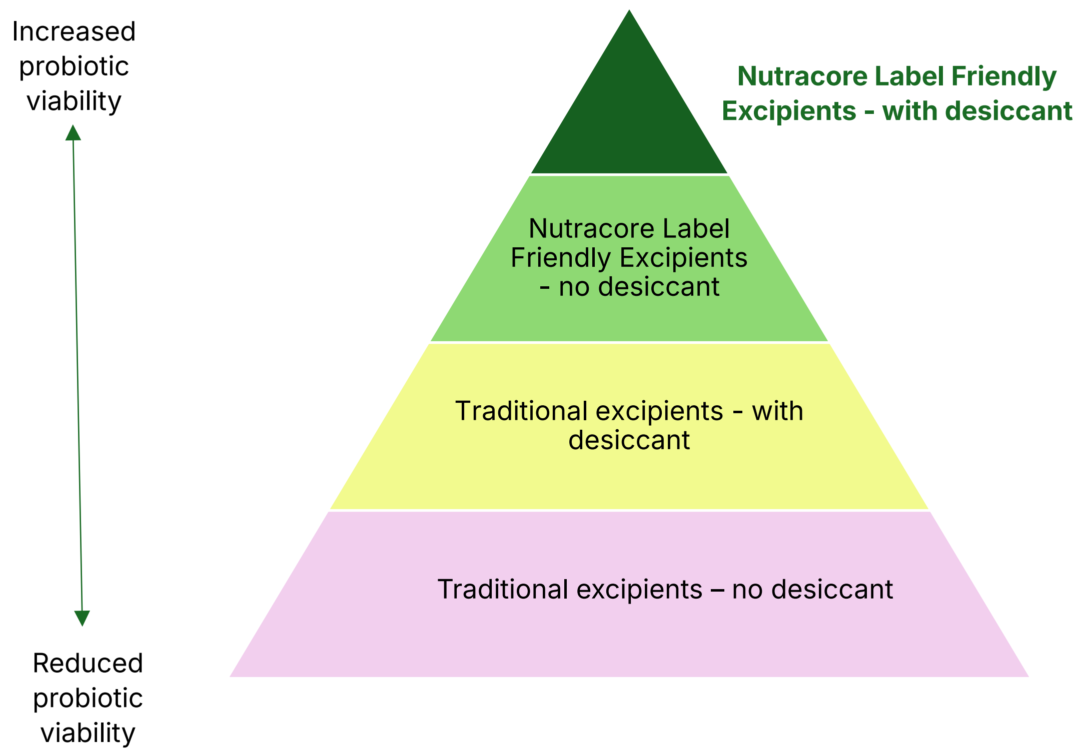
Beyond moisture protection, Nutracore Filler and Nutracore Lubricant also exhibit excellent flowability, compressibility, and lubrication, making them highly suitable for advanced formulation needs.

Figure 2. DVS Isotherm of Nutracore Filler depicting hysteresis



Conclusion

The use of Nutracore Label Friendly Excipients resulted in better moisture control and protection of probiotics such as lactobacillus acidophilus in a capsule formulation. The combination of an appropriate excipient and packaging configuration resulted in protecting lactobacillus acidophilus for 3 months at extreme conditions of 40°C/75%RH. The study shows that the use of Nutracore clean label filler and lubricant, in combination with storage in HAT bottles, resulted in the best probiotic stability, even at extreme conditions of 40°C/75%RH for 3 months; while HDPE bottles which included molecular sieve desiccants provided sufficient protection at 25°C/60%RH and 30°C/65%RH.



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