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Comparative Stability and Viability Assessment of Probiotics: A Focus on Saccharomyces boulardii CNCM I-745 (Capsule Econorm®)

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Abstract— Background: *Probiotic efficacy depends on delivery of an adequate viable cell count until the point of consumption. Environmental factors such as temperature and humidity may adversely affect probiotic viability. While several bacterial probiotic formulations utilize substantial overages to compensate for viability loss over time, alignment between labeled and recoverable counts remains an important indicator of formulation quality. This independent comparative study evaluated Capsule Econorm® containing Saccharomyces boulardii CNCM I-745 and selected bacterial probiotic formulations to assess viable count integrity and stability under defined storage conditions.*

Objective: *To perform a comparative in-vitro evaluation of probiotic formulations with respect to viable count accuracy relative to labeled values, stability under ICH-like storage conditions, and practical handling profile under tested environmental conditions.*

Methods: *Products evaluated included Capsule Econorm® (S. boulardii CNCM I-745) and selected bacterial probiotic formulations, including Brand V3. Viability assessment was conducted using strain-specific selective media with aerobic or anaerobic incubation as required. Storage stability was evaluated at 10°C, 25°C/60% relative humidity (RH), and 40°C/75% RH for up to 14 days. Statistical analyses were performed using one-way ANOVA with Tukey's post-hoc test, with statistical significance defined as $p<0.05$.*

Results: *Capsule Econorm® demonstrated baseline viable counts aligned with its labeled value of 2.5 billion CFU, whereas Brand V3 showed an approximately 70% lower recoverable count relative to its labeled value of 112.5 billion CFU.*

Under storage conditions of 25°C/60% RH, Capsule Econorm® retained an absolute viable count of approximately 1.6 billion CFU after 14 days, while Brand V3 demonstrated an approximate 78% reduction relative to its labeled value. At 40°C/75% RH, Capsule Econorm® retained approximately 1.0 billion CFU, whereas Brand V3 showed an approximate 86% reduction from baseline.

At 10°C, Capsule Econorm® exhibited a transient viable-but-non-culturable (VBNC) response, a known physiological adaptation of yeast to cold stress. Viable counts remained above the labeled threshold of approximately 2.5 billion CFU at both 24 and 48 hours. Differential viability patterns were observed among probiotic formulations, supporting the importance of strain-specific and formulation-specific evaluation.

Conclusion: *In this comparative in-vitro study, the yeast probiotic Capsule Econorm® (Saccharomyces boulardii CNCM I-745) demonstrated baseline alignment with labeled potency and maintained meaningful residual viability under tested storage conditions. The findings suggest that probiotic stability should be evaluated not only through absolute viable counts but also through retention relative to baseline and concordance with labeled potency. Within this framework, Capsule Econorm® exhibited a stable and scientifically interpretable viability profile under the evaluated conditions..*

Index Terms: *Saccharomyces boulardii CNCM I-745, probiotics, viability, stability, colony-forming units, storage conditions, label alignment, Capsule Econorm®.*

I. INTRODUCTION

Probiotic efficacy is dependent on the delivery of an adequate viable cell count (CFU) until the point of consumption. Environmental stressors, particularly temperature and humidity, can adversely affect probiotic viability by disrupting cellular integrity and reducing recoverable counts. Although several multi-strain bacterial probiotic formulations incorporate substantial overages to compensate for degradation over time, alignment between labeled and recoverable counts remains an important indicator of formulation quality. In this context, probiotic evaluation should consider not only absolute CFU retention, but also strain identity, baseline alignment with labeled value, and viability behavior under defined storage conditions. Capsule Econorm®, containing the extensively studied yeast probiotic

Saccharomyces boulardii CNCM I-745, represents a formulation with established strain characterization, alignment with label values, and a distinct stability profile under the evaluated environmental conditions. This

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independent comparative study therefore assessed Capsule Econorm® against other bacterial probiotic formulations to examine viable count integrity and stability under defined storage conditions.

A. Objective

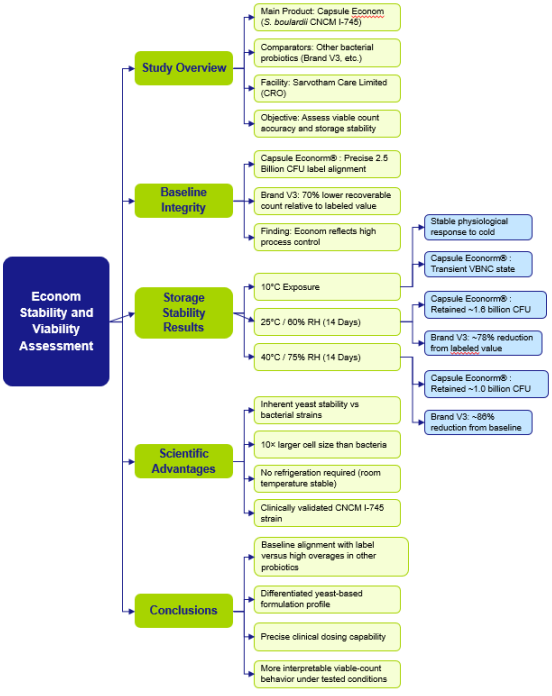
This independent study performs a comparative in-vitro evaluation of Capsule Econorm® against other probiotics to assess:

- Viable count accuracy relative to aligned label values.
- Stability under ICH-like storage conditions (25°C/60% RH and 40°C/75% RH).
- Practical handling profile under tested conditions

II. MATERIALS & METHODS

Products Evaluated: Capsule Econorm® (S. boulardii CNCM I-745) vs. selected bacterial probiotic formulations (Brand V3, Brand D, Brand P, Brand B, Brand S, Brand V and Brand VR)

- Viability Testing: Strain-specific selective media with anaerobic/aerobic incubation as required.
- Storage Stability (ICH-like): 10°C, 25°C/60% RH, and 40°C/75% RH for up to 14 days.
- Statistical Analysis: Data analyzed via GraphPad Prism using one-way ANOVA and Tukey's test



Study Overview and Key Findings

III. RESULTS: DATA-DRIVEN INSIGHTS

A. Baseline Integrity

Capsule Econorm® Precision: Successfully aligned with labeled value of 2.5 Billion CFU, reflecting high process control and formulation integrity.

Other probiotics in the study: Brand V3 showed an approximately 70% lower recoverable count relative to its labeled value of 112.5 billion CFU (analyzed at ~33.2 Billion).

Scientific Insight: Capsule Econorm® demonstrates alignment with labeled value, whereas other probiotics relies on excessive overages that may still fail to meet the therapeutic dose

Comparative Baseline Alignment with Labeled Value (Day 0)

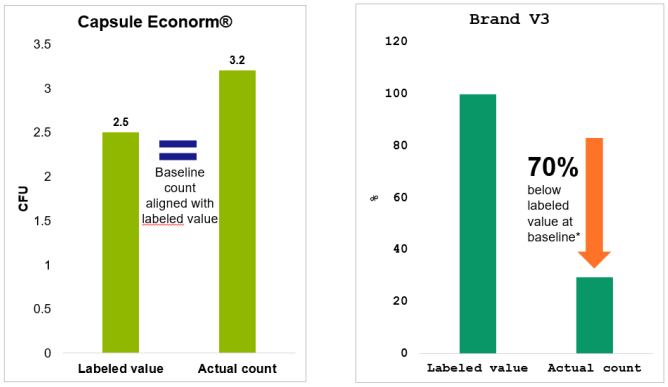


Figure 1. Estimated probiotic viable count of Capsule Econorm® and Brand V3 products along with labeled values. Data are represented as mean (count/%). *p < 0.0001

B. Viability Profile Under Tested Conditions

Differential viability patterns were observed across probiotic formulations under the tested conditions.

- 10°C Exposure: Capsule Econorm® showed a transient reduction to a VBNC (Viable But Non-Culturable) state, a known yeast physiological response to cold stress that does not impact its core viable value.
- Thus, Capsule Econorm® demonstrated a stable and scientifically interpretable viability profile across the evaluated settings.
- These observations support the importance of strain-specific and formulation-specific evaluation rather than assuming equivalent performance across probiotic categories

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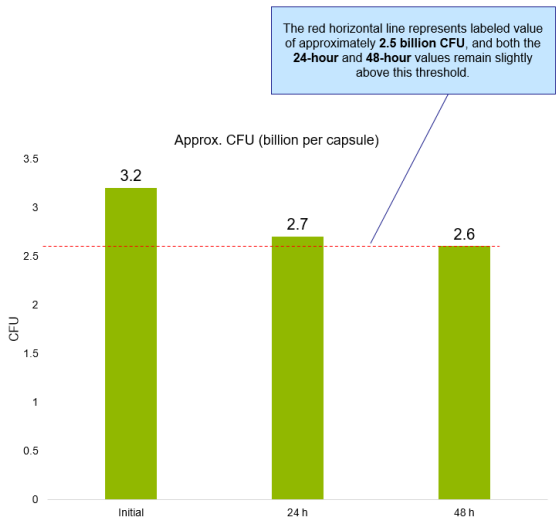


Figure 2. Effect of temperature on Capsule Econorm® viability. (10°C)

C. Storage Stability (ICH Conditions - 14 Days)

Capsule Econorm® vs Brand V3

Declared label value: Capsule Econorm® is labeled to contain 2.5 billion CFU, whereas Brand V3 is labeled to contain 112.5 billion CFU

Baseline: Capsule Econorm® showed baseline counts aligned with its declared label value of 2.5 billion CFU, while Brand V3 showed a recoverable baseline count of approximately 70% below its labeled value.

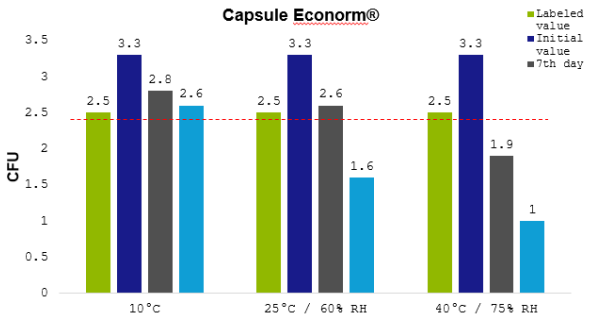
25°C / 60% RH: Capsule Econorm® retained an absolute viable count of ~1.6 billion CFU, whereas Brand V3 showed an approximate 78% reduction relative to its labeled value.

40°C / 75% RH: Capsule Econorm® retained an absolute viable count of ~1.0 billion CFU, whereas Brand V3 showed an approximate 86% reduction from baseline value.

Observation: High overages in other probiotics of the study often mask high environmental sensitivity without improving real-world stability.

These findings suggest that Capsule Econorm®, a yeast-based probiotic containing Saccharomyces boulardii CNCM I-745, offers an advantage in terms of baseline label transparency and meaningful residual viable count under tested conditions, when compared with the bacterial probiotic formulation Brand V3.

(A)



The red line marks the aligned label value, showing that Capsule Econorm® stays close to this value under tested conditions, while Brand V3 remains below its aligned label value and declines further with storage stress.

(B)

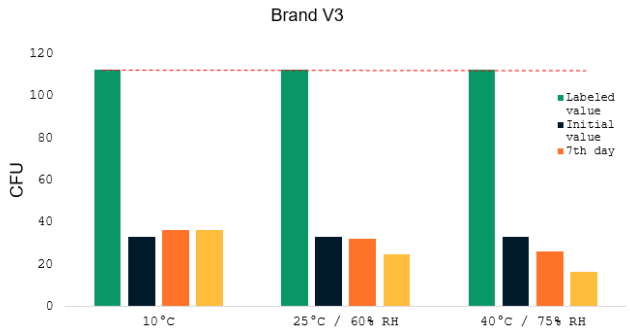


Figure 3. Effect of different storage conditions on probiotic viability,
[A] Capsule Econorm®
B) Brand V3. The red line indicates the declared label value of the product.

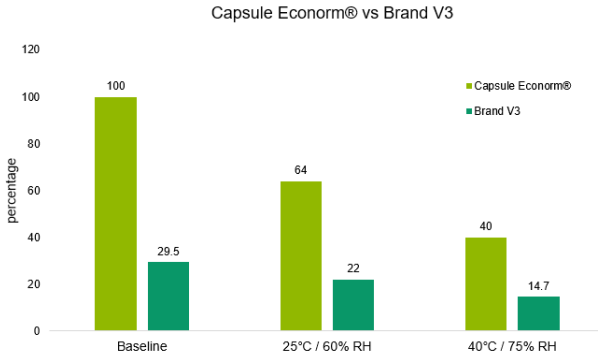


Figure 4. Percentage of labeled value retained by Capsule Econorm® and Brand V3

Table 1: Percentage reduction from relative to labeled value

Product	Baseline alignment with label	Percentage reduction from baseline (25°C / 60% RH)
Capsule Econorm®	2.5 billion CFU	36% reduction
Brand V3	112.5 billion CFU	78% reduction

IV. SCIENTIFIC INTERPRETATION

Compare to alignment with label: Baseline alignment with labeled value: In this comparative in-vitro assessment, Capsule Econorm® demonstrated baseline viable counts aligned with its labeled value, whereas Brand V3 showed a 70% reduction relative to its labeled value at baseline.

- This indicates closer alignment between labeled and recoverable counts for Capsule Econorm® and

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suggests poorer baseline alignment with declared potency for Brand V3.

Viability Profile Under Tested Conditions: The reduction observed for Capsule Econorm® at 10°C remained above the labeled threshold of approximately 2.5 billion CFU at both the 24-hour and 48-hour time points.

- This pattern is consistent with a transient cold-stress response in yeast and suggests that short-term low-temperature exposure did not compromise practical viability relative to the stated labeled value.

Storage Stability: Capsule Econorm® retained measurable viable counts of approximately 1.6 billion CFU at 25°C/60% RH and 1.0 billion CFU at 40°C/75% RH over 14 days, while Brand V3 showed a decline of 86% reduction of CFU from labeled value.

- These data suggest that probiotic stability should be interpreted not only by absolute CFU values, but also by retention relative to baseline and concordance with labeled potency under defined environmental conditions; within this framework, Capsule Econorm® demonstrated a more interpretable stability profile.

V. CONCLUSION

The study showed that yeast probiotics like capsule Econorm® (S. boulardii CNCM I-745) possess better inherent stability than multi-strain lactic acid bacteria (LAB). Capsule Econorm® performance appears to be scientifically interpretable, allowing for precise clinical dosing and better-informed storage guidance. In this study, Capsule Econorm® demonstrated a supportive practical handling profile, with baseline label alignment and meaningful residual viability maintained under the tested storage conditions.

Abbreviation: CFU, Colony-forming units; CNCM, Collection Nationale de Cultures de Microorganismes; CRO, Contract research organization; ICH, International Council for Harmonisation; LAB, Lactic acid bacteria; QA, Quality assurance; RH, Relative humidity; VBNC, Viable but non-culturable.

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