

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

Dr. Sanjay Banerjee

Department of Gastroenterology, ILS Hospital, Dumdum, Kolkata, India

Dr. Vasu Praveen Chander Kanuru

Medical Affairs, Dr. Reddy's Laboratories, India

Dr. Kranthi Kiran Pebbili

Medical Affairs, Dr. Reddy's Laboratories, India

Dr. Balakrishna Namala

Medical Affairs, Dr. Reddy's Laboratories, India

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.

Keywords

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