

TruEase® Soft Gel Capsule

Overview

An accelerated stability study was conducted under the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The study used sealed, high-density polyethylene (HDPE) containers stored at 40°C and 75% relative humidity, and tested at the 0, 1, 2, 3 and 6 month time points. The following were subject to testing: Cannabidiol (CBD) Label Claims, Beta-caryophyllene (BCP) Label Claims, Soft Gel Integrity, and Microbiological Contamination.

Conclusion

At the end of 6 months, the product met (and exceeded) label claims for both Cannabidiol (CBD) and Beta-caryophyllene (BCP). Both compounds were proven to be “very stable” over the six-month period in accelerated conditions, equating to a 24-month real time shelf life stability (according to recognized pharmaceutical standards). Furthermore, there were no issues with soft gel integrity, and microbiological contamination was not observed.

