

INTERAGENCY REQUIREMENTS FOR STABILITY STUDIES

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Overview

This document aims to present the minimum requirements for stability studies for specialized nutritious foods. It provides guidelines to verify shelf life and storage conditions. Manufacturers must perform stability study in real time storage conditions ($30^{\circ}\text{C}\pm 2^{\circ}\text{C}$ at 65% relative humidity (RH)) and at accelerated storage conditions ($40^{\circ}\text{C}\pm 2^{\circ}\text{C}$ at 75% RH) for the commercial batch. Stability studies must include physical, chemical and microbiological test parameters as well as organoleptic characteristics and packaging integrity. This guidance document can be used to develop stability protocol and later to report the stability study findings. The document also provides a template for summarizing results and establishing organoleptic testing.

Overall, this document is useful for manufacturers looking to understand the minimum stability study criteria for specialized nutritious foods.

Link to Document

<https://www.unicef.org/supply/media/18126/file/IA-stability-study-requirements-nutritional-products.pdf>