

	<b>QA Specialized food</b>  <b>INTERAGENCY REQUIREMENTS FOR STABILITY STUDY</b>	Ref MSF: QA-NFOS-IA-I.1.3-5  <b>Date of issue:</b> 18/11/2011 <b>Revision:</b> 9 03/01/2023
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## 1. Scope

This document aims to present the minimum requirements for stability study report for Specialized Nutritious Foods. Stability study shall be conducted by the manufacturer on at least one representative batch<sup>1</sup> of the finished product in primary packaging, to determine the product shelf life and storage conditions:

- for any **new product development** (or in the absence of shelf-life studies)<sup>2</sup>
- for a change of **production site**
- for a significant change in **production equipment or process** (e.g., packing line, heat treatment...)
- for modification of an existing product:
  - change in **primary packaging material**
  - change of formulation or **major ingredient**, such as but not limited to raw material, vitamins & and minerals premix, additives, e.g., emulsifier
  - change in **supplier for major ingredients**

## 2. Minimum requirements in the protocol

The manufacturer shall demonstrate compliance with the end-product specifications throughout the shelf-life, on at least 1 representative batch<sup>1</sup> (3 batches preferred for UNICEF\*).

Minimum two storage conditions should be followed, with a minimum frequency for the tests: T0, T3, T6, T12, T18 and T25 months and then yearly (when applicable) for both conditions:

- **Recommended conditions: 30 °C±2 °C** with 65% RH<sup>3-4</sup> for the duration of the shelf life
- **Humanitarian supply chain condition: 40 °C±2 °C** with 75%RH<sup>2-3</sup> for the duration of the shelf life. In the absence of complete stability study at 30°C, the data of the stability study at 40 °C±2 °C can be used as **accelerated stability study**, with a minimum frequency for the tests: T0, T3 and T6 and when Q10 factor of 2 is considered, based on most thermosensitive vitamin tracer and organoleptic stability. The shelf life predicted using accelerated stability study must be validated by completing shelf-life study at recommended conditions.

<sup>1</sup> A representative batch is a batch manufactured in the **same conditions as the commercial batch** (same **batch size**), manufactured with the **validated formula and validated process**.

Stability studies performed on pilot scale might be accepted for **preliminary study**, subject to prior approval, and shall be performed on a minimum pilot scale and using a method of manufacture and procedure that simulates the final process to be used for production batches. The representative batch (blend) size must be mentioned on the stability reports both in Kg or Metric tons (e.g. batch/blend of 500kg RUTF per pack of 92 grams). **This shall be completed by a commercial batch size study.**

<sup>2</sup> If stability study is not finalised at the time of initial assessment or submission, the data of a minimum of 6 months of the stability study at 40°C, can be considered. The manufacturer shall continue the real time stability study and send reports when results are available.

<sup>3</sup> Monitoring of relative humidity is not mandatory. If the shelf-life study is performed in an incubator allowing the control of the relative humidity, then relative humidity must be set at 65% and 75%.

<sup>4</sup> Temperature and relative humidity (if applicable) must be regularly controlled and recorded. The record of calibration of incubator(s) shall be available upon request.

\* UNICEF additional requirement

All the tests shall be performed with validated methods, preferably in ISO17025 accredited laboratories. Stability studies must verify the following parameters:

### 2.1. Micronutrient stability

- Minimum one water soluble vitamin (vitamin C mandatory) and minimum one fat soluble vitamin (vitamin A mandatory) shall be tested at every test point: T0, T3, T6, T12, T18, T25 and then yearly if applicable.
- All vitamins shall at least be tested at T0, T6, T12 months, T25 months and yearly (when applicable).

### 2.2. Absence of microbiological growth

- Total plate count shall be tested at T0, T12 and T25 at 30 C
- Aw shall be tested at T0, T3, T6, T12 and T25.

### 2.3. Stability of oils and fatty acids

- Peroxide value should be tested at T0, T3, T6, T12, T18, T25.
- For lipid-based products, fatty acids omega 3 and omega 6 content should be tested at T0, T6, T12, T18, T25 and then yearly if applicable.
- When rancidity is perceived during organoleptic test, anisidine value and free fatty acids shall be tested to get a complete understanding of the rancid notes.

### 2.4. Organoleptic stability

Organoleptic characteristics should be tested at T0, T3, T6, T12, T18, T25 and then yearly if applicable, with product as it is intended for consumption. It is the manufacturer's responsibility to establish quantitative criteria for each organoleptic parameter. The annex I guidance is indicative and can be used for establishing an organoleptic tasting protocol with quantitative scale for each parameter<sup>5</sup>.

### 2.5. Integrity of the packing materials and marking

- Absence of leakage should be tested at T0, T3, T6, T12, T18, T25 and then yearly if applicable:
  - For sachets (e.g., LNS, SC+, HEB): absence of leakage under pressure (recommended 25kPa), by using a quantitative validated method.
- Integrity of markings: The markings should be readable at T0, T3, T6, T12, T18, T25 and then yearly if applicable.

## 3. Stability study report

The report shall include

- Product / Manufacturer details: product name, product description, ingredient list, address of the manufacturing site
- An introduction with the batch used, the manufacturing date and the 'Best Before' date
- The parameters used for the stability study (storage conditions – temperature and RH)

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<sup>5</sup> This is the responsibility of the manufacturer. The annex is only for guidance purposes.

## IA REQUIREMENTS FOR STABILITY STUDY

- The results preferably presented in the form of a summary table, with the specification requirement (acceptance criteria) and time points for all parameters. A reference template is provided in annex II.
- The details on the laboratory(ies) used, its (their) accreditation, and the test methods.
- The conclusion (or the indication based on accelerated studies) based on the obtained results at 30 °C/65% RH, including the justification for the shelf life and recommended storage conditions.
- The stability study protocol shall be sent prior to starting the study for validation and report shall be shared when the results are available at T6 months, T12 months and then yearly until the end of the shelf life or when requested.

Annex I: Guidance for establishing organoleptic testing protocol with suggested attributes & rating

Annex II: Guidance template: Stability study template for Nutritional Products