



Requirements for stability study for Therapeutic Foods

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1. Scope

This document aims to present the requirement for conducting a stability study. Stability study must be conducted on the final product in primary packaging, for each formula, to confirm the product shelf life and storage conditions.

2. Stability study protocol

Stability studies must be conducted as following, on at least 1 representative batch:

- Long term stability study: $30\pm 2^{\circ}\text{C}$ for the claimed shelf life (real time studies): minimum period requirement for the test of samples is at 0, 3, 6, 9, 12, 18 and 24 months
- The data at 40°C may support extrapolation of shelf life (accelerated data at $40^{\circ}\text{C}\pm 2^{\circ}\text{C}$): test the sample at 0, 1, 3 and 6 months (factor 2)
- Long term stability study at $40\pm 2^{\circ}\text{C}$ for the claimed shelf life (real time studies) can provide useful information in case the product is stored in harsh conditions.

Stability studies must verify:

- Organoleptic stability: taste, odour, product consistency and behaviour: absence of oil separation, absence of oxidation.
- Nutritional value and nutrient stability: product shall be within specifications for all minerals and vitamins during the entire shelf life. The maintenance of a level of vitamin and minerals within specified levels shall be tested for at least one water soluble vitamin and the vitamin A (fat soluble) at every test point. Every vitamin shall be tested at 0 month, 12 months and 24 months.
- Demonstrate absence of microbiological growth
- Stability of oils (peroxide value) and fatty acids
- Integrity of the packing materials and markings

3. Stability study report

The report shall present the entire study, and include:

- An introduction with detailed description of the product and batch used
- The results presented in the form of a summary table, with:
 - The product specifications (acceptance criteria) for all parameters listed above (and for any other parameters deemed necessary by the supplier).
 - The test methods
 - The laboratory(ies) performing the tests (name, city, country) and whether it is accredited or not.
- The conclusion based on the obtained results, including the justification for the shelf life and recommended storage conditions

If stability study is not available or underway (insufficient to cover the proposed shelf life), the manufacturer shall commit to initiate or continue stability studies, and send reports as soon as preliminary results are available and at regular intervals.