

Stability Study Requirements

➤ **Stability study should include the following information:**

1. Medical device name
2. Code/reference at which study conducted
3. Batch/lot number of samples used in the study
4. Manufacturing/expiry date of batch used
5. Components/raw materials
6. Sterilization method
7. Intended use
8. Required shelf life
9. Required storage conditions.
10. Packaging Material Specifications, including:
 - Material type
 - Dimensions (length, width, welding line width)

1. Scope of the Study

- Clearly define the objective and purpose of the stability study under evaluation and its intended shelf life.

2. Type of Stability Study

- Specify whether the study follows **real-time stability** or **accelerated stability** testing.

3. Accelerated Stability Study (if applicable)

- Provide the **calculation of Accelerated Aging Time (AAT)** using the **Arrhenius equation**:

$$AAT = \text{Desired RT} / AAF$$

Where:

- RT (Real Time Targeted)
- AAF (Accelerated Aging Factor) = $Q_{10}^{[(TAA - TRT)/10]}$
- $Q_{10} = 2$
- TAA (Accelerated Aging Temperature in °C)
- TRT (Ambient Temperature in °C)

4. Real-Time Stability Study (if applicable)

- Document the **storage conditions** under which the study is conducted, including **temperature and humidity**, in accordance with **Zone IVA** requirements for local medical devices.

5. Study Duration

- Indicate the **start and end dates** of the stability study:
 - For **real-time studies**, the duration must match the claimed **shelf life period**.
 - For **accelerated studies**, the duration must align with the **Arrhenius equation results**.

6. Testing Schedule and Parameters

- At the **start, intervals, and end** of the study (the minimum at the end of study), the following should be documented:
 - a) **Test Names:**
 - Performance tests (according to manufacturing standard)
 - Packaging tests according to ISO 11607 (visual inspection, seal strength, and integrity tests)
 - Sterility tests
 - LAL/Endotoxin Pyrogenicity
 - b) **Standards Used:**
 - Reference the **specific standards** followed for each test (a **soft copy** of each standard should be submitted).
 - c) **Test Limits:**
 - Define the **acceptable limits** for each test.
 - d) **Test Results:**
 - Provide **detailed results** for each test performed.

7. Conclusion of the Study

- Summarize the study's findings, including the stability assessment and overall compliance with regulatory requirements.

8. Enclosures

- Submit the following supporting documents:
 - a) A **sample** from the **same batch used in the stability study**, sealed by the inspection department, along with the corresponding Sample Sealing Report. (محضر تحريز العينة)
 - b) A lab **assessment checklist** (for in-house laboratory testing).
 - c) An **accreditation certificate and scope of accreditation** (for external laboratory testing).