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 = Desired RT / AAF
     Where:

     - **RT (Real Time Targeted)**
     - **AAF (Accelerated Aging Factor) = Q10^ [(TAA - TRT)/10]**
     - **Q10 = 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, which has been 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).

  N.B " If a sample from the same batch used in the stability study is unavailable, it shall not be subject to quarantine".