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**.

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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).

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