Ref No	Rev No.	Issue Date

Stability Study Protocol

➢ **Stability study protocol 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)
- Provide a justification for selecting the specific code for study. If this code represents the worst-case scenario, clearly justify the selection criteria.

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.

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5. Study Duration

- Specify the start and end dates of the stability study:

- For real-time studies, ensure the duration corresponds to the claimed shelf-life period.
- For accelerated studies, the duration should be determined based on the results of the Arrhenius equation.

6. Testing Schedule and Parameters

- At the start, at defined intervals, and at the end of the study (at a minimum, at the end of the 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:**

- Provide references for the specific standards followed for each test. Additionally, submit a soft copy of each referenced standard for verification.

c) **Test Limits & specification:**

- Define the **acceptable limits** for each test.

d) **Test methods:**

- Provide **detailed method** 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 **accreditation certificate and scope of accreditation** (for external laboratory testing).

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