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Stability Study Program Management

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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Department: Quality Control Laboratory

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1.0 PURPOSE

This procedure outlines the standardized process for managing stability studies at NovaThera Pharmaceuticals to ensure the quality, safety, and efficacy of pharmaceutical products throughout their shelf life, in accordance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines, thereby supporting pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all drug substances, drug products, and in-process materials manufactured, packaged, and stored at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. It encompasses the procedures for initiating, executing, monitoring, documenting, and reporting stability studies conducted under various storage conditions, ensuring compliance with ICH guidelines Q1A-Q1F and applicable FDA regulations. This SOP is applicable to all personnel involved in the stability study program within the Quality Control Laboratory. It excludes forced degradation studies which are addressed in SOP-QC-011.

3.0 RESPONSIBILITY

QC Inspector: Responsible for performing visual inspections of stability samples, conducting analytical testing as per approved protocols, recording data accurately, and reporting any deviations or out-of-specification (OOS) results to the QA Manager. The QC Inspector is also responsible for maintaining the stability chambers and ensuring their proper functioning.

Production Supervisor: Responsible for providing representative samples of manufactured batches for stability studies according to the approved stability protocol and ensuring proper documentation of batch manufacturing records.

QA Manager: Responsible for reviewing and approving stability protocols and reports, ensuring compliance with GMP and regulatory requirements, investigating OOS results, and implementing corrective and preventive actions (CAPA). The QA Manager is also responsible for the overall management of the stability program and ensuring that it is aligned with the company's quality objectives.

Head of QA: Responsible for the final approval of stability protocols and reports, ensuring adequate resources are available for the stability program, and providing oversight for the overall quality management system. The Head of QA is also responsible for representing the company during regulatory inspections related to stability studies.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coats, nitrile gloves, appropriate respiratory protection where required (e.g., N95 mask for handling potent compounds).

Equipment:

- Stability Chambers (temperature and humidity controlled, with calibrated temperature and humidity sensors): STR-01, STR-02, STR-03, STR-04.
- High-Performance Liquid Chromatography (HPLC) system: HPLC-01, HPLC-02
- Gas Chromatography (GC) system: GC-01
- Dissolution apparatus: DST-01
- UV-Vis Spectrophotometer: UV-01
- Analytical balance (calibrated): BAL-01, BAL-02
- pH meter (calibrated): PHM-01
- Refrigerator (2-8°C): REF-01
- Freezer (-20°C): FRZ-01
- Incubator: INC-01

Documentation:

- Stability Study Protocol (Template: FRM-QC-010-01)
- Stability Sample Submission Form (FRM-QC-010-02)
- Stability Testing Data Sheet (FRM-QC-010-03)
- Stability Chamber Temperature and Humidity Monitoring Log (FRM-QC-010-04)
- Out-of-Specification (OOS) Investigation Report (FRM-QA-005-01)

- Stability Study Report (Template: FRM-QC-010-05)
- Stability Chamber Calibration Records
- Reagent and Standard Logbook
- Equipment Usage Logbook

5.0 PROCEDURE

5.1 Protocol Development and Approval

5.1.1 The QA Manager, in consultation with the relevant departments (e.g., Formulation Development, Production), shall develop a detailed stability study protocol using the approved template (FRM-QC-010-01) for each product or product line.

5.1.2 The protocol shall include the following information:

- Product name and strength
- Batch number(s) of the samples to be tested
- Dosage form and packaging configuration
- Storage conditions (temperature and humidity) to be evaluated (e.g., 25°C/60% RH, 30°C/65% RH, 40°C/75% RH, 5°C, -20°C)
- Testing parameters (e.g., assay, degradation products, dissolution, appearance, pH, moisture content, hardness, disintegration)
- Testing schedule (time points for sample withdrawal)
- Acceptance criteria for each testing parameter based on product specifications.
- Sampling plan, detailing the number of samples to be tested at each time point.
- Reference standards and reagents to be used, including their lot numbers and expiration dates.
- Analytical methods to be employed, including their validation status.
- Details of the stability chambers to be used.
- Any specific instructions or precautions for handling the samples.

5.1.3 The QA Manager shall review the completed protocol to ensure it is complete, accurate, and compliant with GMP and regulatory requirements.

5.1.4 The Head of QA shall approve the stability study protocol prior to commencement of the study. The approval date shall be documented on the protocol.

5.1.5 Any deviations from the approved protocol shall be documented as a protocol deviation and approved by the QA Manager and Head of QA before implementation.

5.2 Sample Submission and Storage

5.2.1 The Production Supervisor shall submit representative samples of the manufactured batches to the Quality Control Laboratory, along with a completed Stability Sample Submission Form (FRM-QC-010-02).

5.2.2 The Stability Sample Submission Form shall include the following information:

- Product name and strength
- Batch number
- Manufacturing date
- Packaging configuration
- Number of samples submitted
- Storage conditions required
- Date of submission
- Signature of the Production Supervisor.

5.2.3 The QC Inspector shall verify the information on the Stability Sample Submission Form and record the date of receipt in the Stability Sample Logbook.

5.2.4 The QC Inspector shall assign a unique identification number to each stability sample.

5.2.5 The QC Inspector shall store the stability samples in the designated stability chambers (STR-01, STR-02, STR-03, STR-04) under the specified storage conditions, ensuring proper temperature and humidity control.

5.2.6 The QC Inspector shall record the location of each sample in the Stability Sample Location Log.

5.2.7 The QC Inspector shall monitor the temperature and humidity of the stability chambers daily using calibrated temperature and humidity sensors and record the data in the Stability Chamber Temperature and Humidity Monitoring Log (FRM-QC-010-04). Any excursions outside the acceptable range shall be reported to the QA Manager immediately.

5.2.8 In case of temperature excursions, the QA Manager shall assess the potential impact on the stability of the products and initiate an investigation, if necessary.

5.3 Sample Withdrawal and Testing

5.3.1 The QC Inspector shall withdraw samples from the stability chambers at the scheduled time points according to the approved stability protocol.

5.3.2 The QC Inspector shall record the date and time of sample withdrawal in the Stability Sample Logbook.

5.3.3 The QC Inspector shall visually inspect the samples for any changes in appearance (e.g., color, clarity, precipitation) and record the observations in the Stability Testing Data Sheet (FRM-QC-010-03).

5.3.4 The QC Inspector shall perform the required analytical testing as per the approved stability protocol, using validated analytical methods.

5.3.5 The QC Inspector shall record all test results accurately and completely in the Stability Testing Data Sheet (FRM-QC-010-03).

5.3.6 All analytical testing shall be performed in accordance with the relevant SOPs for analytical methods.

5.3.7 Reference standards used for testing must be qualified and traceable. Their expiry dates must be checked before use and recorded in the Reagent and Standard Logbook.

5.3.8 If any OOS results are obtained, the QC Inspector shall immediately notify the QA Manager and initiate an OOS investigation according to SOP-QA-005.

5.4 Data Analysis and Reporting

5.4.1 The QA Manager shall review the completed Stability Testing Data Sheets to ensure the accuracy and completeness of the data.

5.4.2 The QA Manager shall analyze the stability data to determine the degradation rate and predict the shelf life of the product.

5.4.3 The QA Manager shall prepare a Stability Study Report (Template: FRM-QC-010-05) summarizing the results of the stability study.

5.4.4 The Stability Study Report shall include the following information:

- Protocol number and title
- Product name and strength
- Batch number(s)
- Storage conditions
- Testing parameters
- Testing schedule

- Summary of test results
- Statistical analysis of the data
- Conclusion regarding the stability of the product
- Recommended shelf life
- Any deviations from the protocol
- Signature of the QA Manager

5.4.5 The Head of QA shall approve the Stability Study Report.

5.4.6 The approved Stability Study Report shall be archived in accordance with the document control SOP.

5.5 Continued Stability Studies

5.5.1 Continued stability studies shall be conducted on production batches to confirm the shelf life assigned to the product.

5.5.2 The frequency and scope of continued stability studies shall be determined by the QA Manager based on the product risk assessment and regulatory requirements.

5.5.3 The procedure for conducting continued stability studies shall be the same as for initial stability studies.

5.6 Stability Chamber Maintenance and Calibration

5.6.1 Stability chambers (STR-01, STR-02, STR-03, STR-04) must be properly maintained and calibrated to ensure accurate temperature and humidity control.

5.6.2 The QC Inspector is responsible for performing routine maintenance of the stability chambers, including cleaning, defrosting, and replacing any worn parts.

5.6.3 The stability chambers shall be calibrated at least annually by a qualified service provider.

5.6.4 Calibration records shall be maintained and reviewed by the QA Manager.

6.0 POST-ACTIVITY ACTIVITIES

6.1 Upon completion of the stability study and approval of the Stability Study Report by the Head of QA, the QA Manager shall update the product specifications and shelf life, as necessary.

6.2 The QA Manager shall communicate the stability study results to the relevant departments (e.g., Regulatory Affairs, Production).

6.3 The QA Manager shall ensure that the stability samples are properly disposed of in accordance with the waste disposal SOP.

6.4 The QC Inspector shall archive all raw data, chromatograms, and other supporting documentation related to the stability study in accordance with the document control SOP.

7.0 SAFETY PRECAUTIONS

7.1 All personnel handling stability samples shall wear appropriate PPE, including safety glasses, laboratory coats, and nitrile gloves.

7.2 When handling potent compounds, appropriate respiratory protection (e.g., N95 mask) shall be worn.

7.3 All chemicals and reagents shall be handled in accordance with their Material Safety Data Sheets (MSDS).

7.4 Stability chambers shall be properly grounded to prevent electrical hazards.

7.5 Any spills or leaks shall be cleaned up immediately in accordance with the spill control SOP.

7.6 Any broken glassware shall be disposed of in designated sharps containers.

7.7 Food and drinks are prohibited in the laboratory area.

7.8 Personnel must be trained on the safe handling of chemicals and equipment before performing any stability testing.

7.9 Always work in a well-ventilated area.

7.10 Do not pipette by mouth.

7.11 Wash hands thoroughly after handling samples and chemicals.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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