Central Administration of Pharmaceutical Products
General Administration of Stability

Submission Guide to the General Administration of Stability
Year 2025

Code: EDREX:NP. CAPP.091
Version No: 2
Issue Date: 21/9/2025
Effective date (if needed): 21/9/2025

Table of Content

1- Introduction:

As part of the efforts of the Egyptian Drug Authority´s continuous efforts-represented by the Central Administration of Pharmaceutical Products – General Administration of Stability, aimed at developing and supporting the pharmaceutical industry and strengthen collaboration with pharmaceutical companies and manufacturers, the General Administration of Stability has, throughout the previous period, worked to overcome the obstacles facing companies in submission processes and requests directed to the General Administration of Stability.

Accordingly, the first edition of this guidance document was issued on 21/08/2024, to facilite and simplify submission procedures, requests, and correspondence.

In continuation of these efforts, this second edition of the guide has been developed as a comprehensive guidance manual for all processes related to:

- the submission of stability studies,
- appeals
- requests
- inquiries
- and complaints

submitted to the General Administration of Stability, and integrated with the unified electronic submission portal of the General Administration of Stability.

2- Purpose:

This guide aims provide comprehensive instructions governing the submission of:

- stability studies,
- appeals, requests,
- Iquiries,
- and complaints addressed to the General Administration of Stability, concerning pharmaceutical products (human, veterinary, and herbal), as well as disinfectants and insecticides, whether locally manufactured or imported.

3- Scope of application:

All stability studies for pharmaceuticals (human, veterinary and herbal), disinfectants, local and imported pesticides submitted to the General Administration of Stability

4- Procedures:

4.1. Submissions Link

- A unified link has been designated as an electronic submission portal, containing all the different submission links for stability studies, requests, and services provided by the General Administration for Stability. This unified link replaces the previously separate electronic submission links of the General Administration for Stability in the windows published on the Egyptian Drug Authority website. To access the unified link, click here

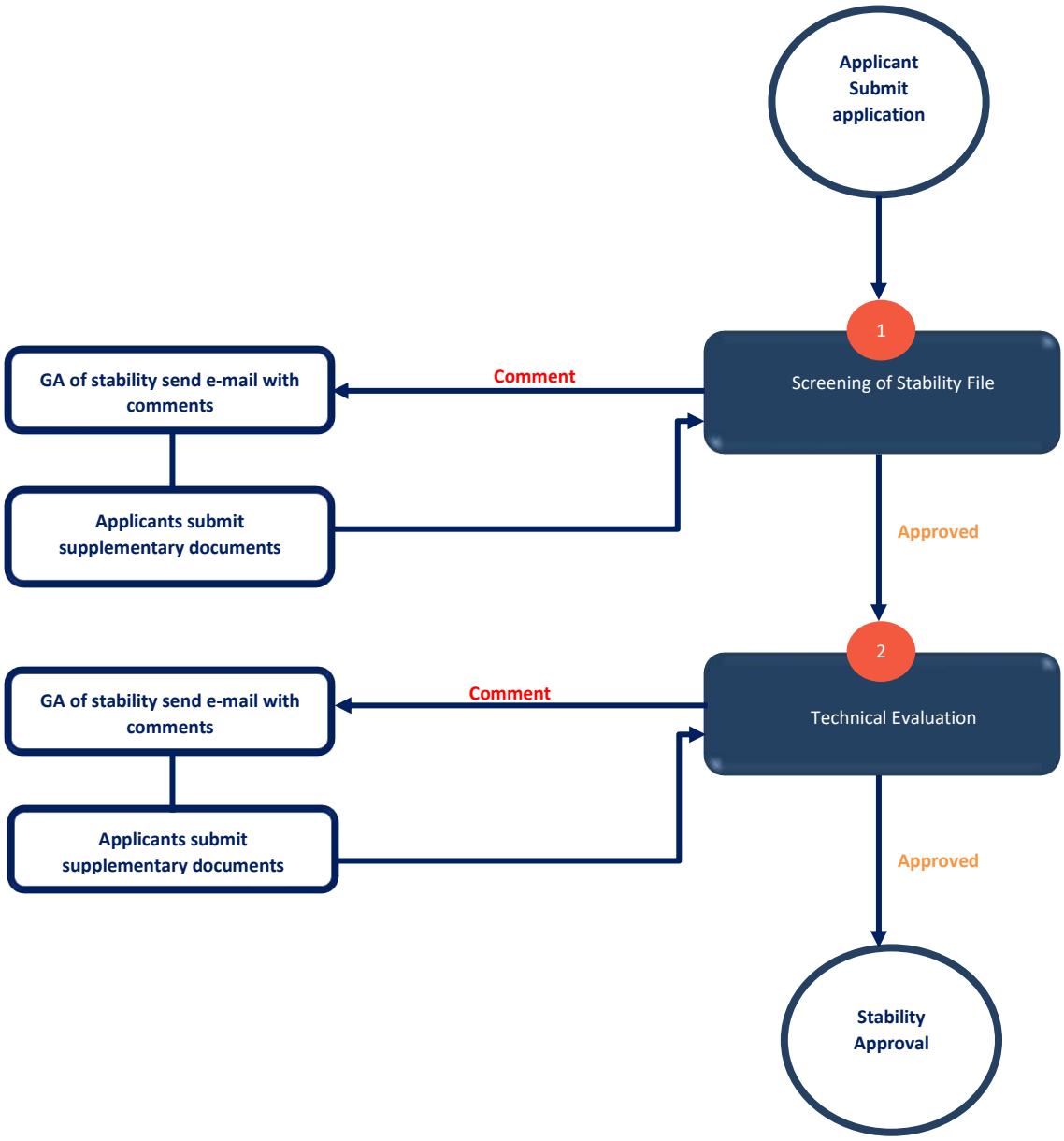
- A web page has also been created that contains all the links to apply in one web page, to enter click here ,

All link timings of the General Administration of Stability These data are subject to modification by the General Administration of Stability, so please view the online version click here			
All stability studies of homemade and imported products			
LinkName	**Opening Timings (9 am - 2 pm)**	**Submission Link**	
Providing stability studies (new/completion of analysis points for a previously approved stability study)	Tuesday & Wednesday	Click Here	
Submission of Phase 1 (Screening) Supplements	Monday	Click Here	
Submission of Phase II (Technical Evaluation) Supplements	All Working Days	For Local Products	Click Here
		For Imported Products	Click Here
General Administration of Stability Services			
Submission of Appeals and Requests for Stability Studies	Thursday	For Local Products	Click Here
		For Imported Products	Click Here
Request for Attendance of Practical Analysis (Injections)	Thursday	Click Here	
Fast track request for in-process submitted stability study (Must pass Screening phase first).	Monday (until the scheduled number is completed)	Click Here	
Inquiries / Complaints / meeting Requests of the General Administration of Stability	Wednesday	Click Here	
Inquire about the status of an inquiry / complaint / meeting request	24/7	Click Here	
Inquire about the status of the submitted stability studies files	24/7	Having Access code or Serial No.	Click Here

		Having Stability tracking ID	Click Here
Notification Tool	24/7	Click Here	

4.2. Submission and evaluation of stability studies:

Figure (1): Flowchart of the Submission and Evaluation Process for Stability Studies



The submission and evaluation mechanism for stability studies comprises only two stages. In the first stage, a preliminary screening of the stability file is conducted, along with a review of the relevant regulatory administrative documents (Screening). Once passed, the file transitions directly to the second phase, which is the technical evaluation, as illustrated in Figure (1). The details of the submission mechanism are outlined below:

4.1.1- Stage One: Screening of Stability File

- Companies submit the complete stability study file, including all required documents and data, via the electronic submission link (click here), the submission form must be accurately and fully completed with all required information related to the submitted stability study.
- **Submission Dates:**
  Tuesday and Wednesday of every week for all stability studies for local and imported products of all kinds

- The General Administration of Stability conducts the initial examination of the Stability Study File, reviews the Screening of Stability File, and ensures that the company submits the complete Stability Study File as stipulated in the Stability File content published on the official website of the Egyptian Drug Authority (EDA website) :
- Outcomes of Phase I (screening):
  - In case of compliance, the General Administration of Stability will transfer the file to the second stage (Technical Evaluation) and send an email to the company containing the following:
    - ✓ Statement of Acceptance of the File in the First Stage (Initial Screening)
    - ✓ The Stability Tracking ID, *which is a number for the submitted stability study that is used to follow up on the status of the stability study and its approval through an updated link for companies (click here)*
  - In case of non-compliance, the General Administration of Stability sends an email to the company containing the following:
    - ✓ Required Updates to the Stability Study File
    - ✓ The Stability Tracking ID, *(click here)*
    - ✓ The company sends the required completions on Monday of every week for all stability studies for the various preparations on the link of the first phase (screening) (click here)

- **Phase 1 Submission Rules & Monthly Quotas:**

The monthly application limits for each applicant are as follows:

Type of product	Monthly Submission Limit per Applicant
Local products (except disinfectants and pesticides)	(6) Stability Studies

Local disinfectants and pesticides	(4) Stability Studies
Imported Products	(6) Stability Studies

- The number of files submitted for each company can be increased: through the mechanism of submitting a fast track request, please refer to (4.5). **Submitting a Fast Track Request)**
- The Bundle Stability Studies Submission System: Introduced to ease the process. Eligibility Criteria for Bundle Submission include: Stability studies of the same pharmaceutical product with different concentrations, volumes, flavors, and/or purpose of stability study. All data is submitted under one request, but each concentration counts as one single stability study regarding limits and service fees.
- Where all the data of stability studies for the same product are presented as a bundle submission in one application, whether in the case of submitting stability studies or supplements, and preparing a single link containing all the stability studies or supplements provided, knowing that each stability study for each concentration is considered as a single stability study in terms of calculating the application limits and the expenses of the various services and mechanisms.
- Time limit: The company is given a period of 3 months to submit the first phase (Screening) supplements, and the companies can extend the deadline for submitting the first phase by clicking the link to submit the supplements with payment for the prescribed service

4.1.2- Phase Two: Technical Evaluation

- The General Administration of Stability conducts a detailed technical evaluation of the stability study provided according to the latest international guidelines (ICH, VICH, WHO, EMEA, FDA, EDA and other relative guidelines as listed in Annex 1).
- Outcomes of Phase 2 (Technical Evaluation):

  - In case of compliance, the General Administration of Stability will issue approval for the submitted stability study
  - In case of non-compliance, the General Administration of Stability sends an email to the company containing the following:
  - ✓ Required Technical Evaluation Updates for the Stability Study File
  - ✓ The Stability Tracking ID, *which is a number for the submitted stability study that is used to follow up on the status of the stability study and its approval through an updated link for companies (click here)*
  - ✓ The company sends the technical evaluation supplements required all official working days for all stability studies for various products on the technical evaluation supplements link (click here).

- **Application Rules:**
  - The Bundle Stability Studies Submission System has been included for stability studies and their various supplements, which facilitates the process of submission and follow-up for companies and the speed of completing their supplements.

Eligibility Criteria for Bundle Submission:

1- Stability studies of the same pharmaceutical product.
2- Different concentration and/or volumes and/or flavors and/or purpose of stability study

- **Key regulation:** Where all the data of stability studies for the same product are presented as a bundle submission in one application, whether submitting new stability studies or supplements, and preparing a single link containing all the stability studies or supplements provided, knowing that each stability study for each concentration is considered as a single stability study regarding submission limits, service fees, and applicable mechanisms..
- **Timeline:** The company is given a period of 3 months to submit the technical evaluation supplements, and the companies can extend the deadline for submitting the technical evaluation supplements by clicking the link to submit the supplements while paying the prescribed service fees.

4.3. Submission of updated analysis time-points for previously approved stability studies

- **Eligibility Criteria for Submission:**
  Completion of Stability Study Data Points for Pharmaceutical Product Variations

- Completion of analytical data points for stability studies of pharmaceutical product variations, including:
- Submission of the 6-month analytical time point after prior approval of accelerated stability studies conducted for 3 months.
- Submission of the 3-month analytical time point after prior approval of accelerated stability studies conducted for 1 month.
- Completion of long-term stability study data points for pharmaceutical product variations.

For stability studies submitted under the CTD (Common Technical Document) pathway:
Submission of the 9- and 12-month analytical time points after prior approval of both accelerated and long-term stability studies conducted for 6 months.

For imported pharmaceutical products with conditional requirements stated in previously issued stability approvals:
Completion of stability studies on three production batches, including submission of stability data on production batches following pilot batches.

- Completion of in-use stability study for a batch approaching the end of its shelf life.
- The application mechanism is as follows:

Case A: In the case of approval of the accelerated stability study for 3 months for the variants or the issuance of the approval of the

accelerated and long-term stability study for 6 months for CTD preparations

- Access the submission link for the new submitted files on Tuesday and Wednesday of every week and fill out the application form click here
- The following field has been designated: (Type of Submission)
- Select the appropriate option according to the type of analytical data point completion:
- 6-month analytical time point after issuance of approval for accelerated stability studies (3-month studies) for product variations.
- -Completion of long-term stability study analytical time points for pharmaceutical product variations.
- 9- and 12-month analytical time points after submission of accelerated and long-term stability studies conducted for 6 months under CTD.
- -Stability studies for imported products subject to conditions stated in previously issued stability approvals.
- Documents to be Uploaded via the Submission Link:

Regulatory Documents Folder

- Approval/validation of Stability Issued for Previous Analysis Points
- Commitment letter confirming no deviation from the previously approved analytical time points.
- Document confirming the product validity for acceptance of stability studies
- Fulfillment of conditions stated in previously issued stability approvals for the relevant analytical time points (if applicable and if the compliance deadline has expired)

Technical Documents Folder

- Updated stability results data (updates, charts, tests.....etc.) for the local products or the stability study of imported products that are conditional on the previous stability approval
- CADC Approval &/or Quality Module File Approval (if applicable)
- Fulfillment of the conditions stated in the previously issued stability approval for the previous analytical time points, if applicable and if the compliance deadline has expired.

Case B: In case the accelerated stability study of 3 months for product variations, or the combined accelerated and long-term stability study of 6 months for CTD products, is still under evaluation by the General Administration for Stability and has not yet been approved or granted stability approval:

For the stability study under evaluation and to which evaluation comments have been sent and waiting for the response of the applicant:
Process: the updated stability results data (updates stability results tables, charts, tests, ...etc.) are sent along with the rest of the updates required by the applicant and attach a letter explaining that the results of the analysis points have been finalized and attached to the required completion to issue the stability approval including the analysis points that have been submitted.

4.4. Submission of Appeals and Requests:

- Companies can submit the following appeals and requests on the Appeals and Requests link (click here) on Thursday of each week and choose the type of appeal or request, after paying the prescribed service fees for each type of appeal or request:

Type of appeal or request	Selection from the application type
➢ Technical Appeals	Appeal
➢ Amendment of Stability Studies Approvals (Technical or Written Amendment)	Approval letter adjustment
➢ Request to Issue a Replacement for a Lost Study Approved	Replacement for missed approval
➢ Special Case Appeal • Re-registration of disinfectants and pesticides on R&D batches • Submission of 6-month accelerated stability studies and 6-month long-term stability studies for the relevant registration decisions	Certain Cases Appeal (as in submission guidance)

- The General Administration for Stability conducts the technical evaluation and final decision on the submitted appeal:
  - ➢ The General Administration for Stability issues an approval letter for the submitted appeal, or sends an email to the company indicating the status of the Administration, or sends an email requesting the company to collect the amended stability approval, depending on each case individually.
  - ➢ The General Administration for Stability issues a rejection letter for the submitted appeal, or sends an email to the company indicating the status of the Administration, depending on each case individually.
  - ➢ In case of incomplete submission, The General Administration for Stability sends an email to the company specifying the required deficiencies for the appeal. The company shall resubmit the complete appeal every Thursday of each week via the same electronic appeal submission link.

- **Application Rules:**
  - ➢ The monthly application limits for each applicant are as follows:

Type of product	Weekly application limit for each company
Appeals for Stability Studies for Homemade or Imported Products	One order **per week** for the company

  - ➢ The number of appeals and applications submitted to each company can be increased: Through the mechanism of submitting a fast track request, please refer to (4.5. **Submitting a Fast Track Request)**

4.5. Submit a Fast Track Request

- All Fast Track pathways and their payment codes are fully integrated into the same submission links used by the General Administration of Stability, without the need to submit a separate request or for company representatives to attend in person to deliver applications or paper payment receipts.
- The Fast Track system includes three pathways designed to accelerate the submission and assessment of stability studies.
- The details of each pathway are as follows:

- **First Pathway: Fast Track System for Stability Study File Review and Assessment**

- **Companies may choose this pathway through one of two methods:**
  - 1. **Pre-process:**
    At the time of initial submission of the stability study through the same submission link, the link includes an option for the company to select either the Regular Track or the Fast Track (click here),
    The electronic payment code is entered directly into the designated field without the need to submit a separate request or for company representatives to attend in person to deliver applications or paper payment receipts.
  - 2. **In-process**
  - ➢ This pathway may be requested after the stability study has been submitted and while it is under assessment. Acceptance of the request is conditional upon successful completion of the first stage, namely the Screening of the Stability File (Click here) Monday of every week
    The electronic payment code is entered directly into the designated field without the need to submit a separate request or for company representatives to attend in person to deliver applications or paper payment receipts.

- **Submission Rules**
  - ➢ Each company is allowed to submit one application per week for this pathway. Applications will be accepted until the weekly quota is reached.
  - ➢ The review, assessment, and approval period for a stability study file under the Fast Track pathway is 10 working days, calculated from the date on which the technical assessment of the stability study file begins.

Type of product	Monthly application limit for each company	Increasing the number of submissions above the monthly limit for each company (Unlimited Quota)
All Locally manufactured pharmaceutical Stability Studies	(4) Stability studies according to the local fast track service fee	Unlimited according to the fast track service fee above the number allowed
All stability studies of imported pharmaceutical products	(4) Stability studies according to the imported fast track service fee	

- **Second Pathway: Exceeding the Monthly Limit of First-Time Stability Submissions**

  Companies may select this pathway through the same Stability Study Submission Link (up to one stability study per week per company). The submission link includes the option "Exceed the Monthly Submission Limit."

  The electronic payment code is entered directly into the designated field without the need to submit a separate request or for company representatives to attend in person to deliver applications or paper payment receipts.

Product Type	Monthly Submission Limit per Company (Normal Quota)	Additional Stability Studies Beyond the Monthly Limit (Extra Quota)	Additional Stability Studies Beyond the Monthly Limit (Unlimited Quota)
Locally Manufactured Pharmaceutical Products (excluding disinfectants and insecticides)	(6) Stability Studies	(4) Stability studies according to the local fast track service fee	Unlimited, subject to the Fast Track service fee for submissions exceeding the permitted limit
Locally Manufactured Disinfectants and Insecticides	(4) Stability Studies	(4) Stability studies according to the local fast track service fee	
Imported Products	(6) Stability Studies	(4) Stability studies according to the importer's fast track service fee	

- **Third Pathway: Increasing the Number of Appeals Beyond the Weekly Limit Allowed per Company**

  Companies may select this pathway through the same Appeals Submission Link, which includes the option "Exceed the Weekly Submission Limit."

  The electronic payment code is entered directly into the designated field without the need to

submit a separate request or for company representatives to attend in person to deliver applications or paper payment receipts.
Product Type

Product Type	Weekly Submission Limit per Company	Additional Appeals (Technical Appeals / Approval Amendments) Beyond the Allowed Limit
Stability Study Appeals for Locally Manufactured Products	One request per company per week, subject to the applicable service fee according to the type of appeal	According to the Fast Track service fee for local products
Stability Study Appeals for Imported Products	One order per week for the company According to the prescribed service fee according to the type of petition	According to the Fast Track service fee for imported products

General Guidelines:

- All Fast Track pathways described above are incorporated into the corresponding submission links for each case individually, except for **Pathway One – Method Two (In-process)**, for which a dedicated submission link has been created.
- This allows companies to opt for the Fast Track review and assessment timeline if it was not selected at the time of the initial stability study submission. Companies may combine more than one Fast Track pathway whenever applicable
  -

4.6 Submit a request to attend the practical analysis

- **Eligibility Criteria for Submission:**

- **Submission Rule:** The request to attend is submitted on Thursday of every week on the following link, click here, one month prior to the scheduled practical analysis of the required stability study time point. This allows the General Administration of Stability sufficient time to review and assess the submitted file and for the company to address any required deficiencies.
- **Required Files:** The complete stability study file must be uploaded in accordance with the Stability File Content requirements published on the official website of the Egyptian Drug Authority. The file should include the analytical results of the latest tested stability time point and be accompanied by proof of payment of the applicable service fee.
- The submitted request will be reviewed to determine the feasibility of applying the practical analysis mechanism, assess the submitted file, and communicate any required deficiencies to the company for completion prior to the scheduled analysis date.

- On the date coordinated with the applicant company, all stages of the practical analysis shall be attended, starting from the withdrawal of stability study samples from the stability chambers. An attendance report shall be prepared and supported by the analytical results and all relevant documentation.
- On the day following the practical analysis, if the results of the practical analysis comply with the accepted limits for physical, chemical, and microbiological tests, the Pharmaceutical Inspection Department of the Central Administration of Operations will be notified to approve the required stability study time point for product release. The company will also be informed of the assessment outcome via email.
- If the practical analysis results fall outside the acceptable limits, or if additional information or documents are required, the company will be notified via email of the necessary actions to be taken.
- **General Guidelines and Requirements:**
  - For products listed as drug shortages, provided that supporting documentation from the competent authority is attached upon submission, the request for attendance of the monthly stability study time point analysis for the purpose of partial release may be submitted on the first Thursday following completion of the initial time point analysis.
  - The applicable service fee covers attendance of the practical analysis procedures for one analysis day.
  - The stability study file submitted with the analysis request must be complete and include all documents and data specified in the Stability File Content published on the Egyptian Drug Authority website, including the analytical results of the latest tested stability time point and proof of payment of the applicable service fee.

4.7. Tracking the Status of Submitted Stability Studies

- The company tracking system has been updated to enable companies to monitor the status of submitted stability studies, as well as the delivery status of the corresponding approvals, through the Stability Tracking ID assigned to each stability study upon submission (click here).

- **How to Inquire About and Track the Status of Submitted Stability Studies and Their Approvals:**

1	Inquiry about the status of stability study files submitted before 27 August 2024 using the Access Code or the Old Serial Number	Click Here
2	Inquiry about the status of the stability studies files submitted for the first time after 27/8/2024 using the Stability Tracking ID	Click Here

4.8. Submission of Inquiries, Complaints, and Meeting Requests

- Access the updated link for inquiries, complaints, and meeting requests related to the General Administration of Stability Click Here every Wednesday from 9:00 AM to 2:00 PM.
- Fill out the Inquiry/Complaint/Interview Request Form.
- Company representatives may view the response of the General Administration of Stability to their submitted request by accessing the following link: Click here.

4.9. Exceptional Registration Pathway for Human Emergency Use Products

- **Mechanism:** Companies shall submit the complete stability study file, including all required documents and data, through the electronic submission link (Click here).
- The submission form must be completed with accurate and complete information related to the submitted stability study.
- In the designated field "Submission Type", select: "Exceptional Registration Mechanism for Obtaining a Registration Notification for a Human Pharmaceutical Product Intended for Emergency Use."
- Core Technical Requirements: The complete stability study file shall be uploaded in accordance with the Stability File Content requirements published on the official website of the Egyptian Drug Authority and shall include the analytical data from the latest tested stability time point, taking into consideration the following:

-Attach the laboratory compliance report/certificate for the finished product.
-Attach the approval of the Human Pharmaceutical Products Technical Affairs Administration for the product composition statement.
-Provide the relevant reference product data, including (SmPC, Package Leaflet and PAR/CMC documentation)

- Process Outcome: **A- If the submitted data are complete and satisfactory:**

-The initial shelf life and storage conditions shall be approved. These may subsequently be amended based on the completed stability study data.
-The approval shall be accompanied by all observations and recommendations that must be considered at future stability study time points.

B. If the submitted data are incomplete:

-The General Administration of Stability shall send an email to the company containing:
All required deficiencies and additional information needed to complete the stability study file.
-The Stability Tracking ID, which is a unique identifier assigned to the submitted stability study and used to track the status of the study and its approval through the updated company tracking link

- Submission of Updated Stability Data: Upon completion of the analysis of each required stability study time point necessary for product registration, the company shall re-submit the updated stability study file containing the newly generated analytical data.

5- Versions:

Issue Number	Release Date	Modifications
First Edition	**21/8/2024**	**Initial release of the integrated guideline.**
Second Edition	**21/9/2025**	• Integrating all the methods of providing stability studies and the different services provided by the General Administration of Stability into a single guide • Adding the method of submitting stability studies for the study of the stability of human pharmaceutical products according to the exceptional registration mechanism to obtain the notification of the registration of a human pharmaceutical product for emergency use • Review the methods of providing stability studies and the various services provided by the General Administration of Stability • Clarification of the conditions for submitting the bundle submission • Adding a fast track service above the scheduled number of unlimited quotas • Add all the dates and links of the submission of the windows and services provided by the General Administration of Stability within the application guide

6- Definitions:

Bundle Submission: submission of stability studies of the same pharmaceutical product with different concentration and/or volumes and/or flavors and/or purpose of stability study

7-References

References for technical assessment of stability studies of products submitted to General Administration of Stability:

1- WHO TRS 1010 annex 10
2- ICH Q1A (R2) Stability Testing of New Drug Substances and Products
3- ICH Q1B Stability Testing : Photostability Testing of New Drug Substances and Products
4- ICH Q1C Stability Testing for New Dosage Forms
5- ICH Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
6- ICH Q1E Evaluation of Stability
7- ICH Q2(R2) Analytical Validation
8- ICH Q3A (R2) impurities in new drug substances
9- ICH Q3B (R2) impurities in new drug products
10- VICH GL58: Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV
11- VICH GL51: Statistical evaluation of stability data
12- VICH GL45: Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
13- VICH GL5: Stability Testing: Photostability Testing of New Drug Substances and Products
14- VICH GL3(R): Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)
15- VICH GL4: Stability Testing: Requirements for New Dosage Forms
16- VICH GL8: Stability Testing for Medicated Premixes
17- VICH GL11(R): Impurities in New Veterinary Medicinal Products (Revision)
18- VICH GL10(R): Impurities in New Veterinary Drug Substances (Revision)
19- VICH GL39: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances + Decision Trees
20- VICH GL1: Validation of analytical procedures : Definition and Terminology
21- VICH GL2: Validation of analytical procedures : Methodology
22- Officially recognized pharmacopeias (USP, BP, Ep, IP, JP)
23- FAO Specifications and Evaluations for Agricultural Pesticides
24- EMEA: Specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products - Scientific guideline
25- European Agency for the Evaluation of Medicinal Products (EMA). Note for guidance on in-use stability testing of human medicinal products
26- European Agency for The Evaluation of Medicinal Product (EMA). Guideline on Stability Testing: Stability testing of existing active substances and related finished products
27- (ICH) guideline Q8 (R2) on pharmaceutical development- Step 5
28- Australian regulatory guideline for over-the-counter medicines Appendix 2: Guidelines on quality aspects of OTC applications
29- Stability by Daan Touw, Judith Thiesen, Jean Vigneron. 2023, Practical Pharmaceutics, p. 809-837

30- FDA Guidance for Industry Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation
31- WHO guidelines on variations to a prequalified product TRS 981 annex 3-2013
32- EDA Guidelines for Human Pharmaceuticals Variations, Updated Version
33- EMA Note for Guidance on In-use Stability Testing of Human Medicinal Products 2001