الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Guideline of Pharmaceutical Products Shelf Life Extension

Version 2.1

Date of issue	06 April 2020
Date of implementation	06 April 2020

The Guideline of Pharmaceutical Products Shelf Life Extension

Version 2.1

Saudi Food & Drug Authority

Drug Sector

For Inquiries *Variation.Drug@sfda.gov.sa*

For Comments *Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1	Executive Directorate of Evaluation	6 April 2020	Final Version
2	Executive Directorate of Evaluation	30 April 2020	Update
2.1	Executive Directorate of Regulatory Affairs	10 November 2021	Update (Next page shows the updated details)

What is New in version no. 2.1?

The following table shows the update to the previous version:

Section	Description of change
2. Scope	**Add:** • This guideline applies to the shelf life extension applications by SFDA and other health authorities of pharmaceutical products that registered by SDFA. • This guideline is not applicable the shelf life extension applications which submitted by the companies. The companies are obligated to follow the extension requirements that mentioned in the variation requirements for the registered products files.
4. REQUIREMENTS	**Delete:** A. Shelf life extension through the manufacturing company
5. The Procedure used to determine the Batches of Health Body's Products that can be Analyzed to Extend their Shelf Life	**Delete:** 4. The product shall not be a biological product.

Table of Content:

1. INTRODUCTION

In view of the role of the SFDA in controlling medicines and their interest in their availability, this guideline was created to establish controls and mechanisms that help and stimulate the availability of necessary pharmaceutical product in the KSA and contribute to ensuring optimal drug security in the Saudi market.

2. Scope

- This guideline applies to the shelf life extension applications by SFDA and other health authorities of pharmaceutical products that registered by SDFA.
- This guideline is not applicable the shelf life extension applications which submitted by the companies, the companies are obligated to follow the extension requirements that mentioned in the variation requirements for the registered products files.

3. APPLICATION PROCEDURES

A request for shelf life extension is through one of the following two mechanisms:

A. The Saudi Food and Drug Authority
B. Shelf life extension requested by health bodies

4. REQUIREMENTS

A. Shelf life extension through SFDA:

The SFDA shall request the analysis of batches which are marketed by the manufacturing company (currently available in the market) in accordance with the following:

1. The analysis of such batches shall take place during a period of not less than six months before the expiry date of the product.
2. The analyses of these batches shall be according to the approved specifications in the pharmacopoeia.
3. Conduct a statistical analysis as defined in ICH Q1E Guideline.

4. The company is required to relabel[1] the batches that their shelf life was extended.
5. The batches that have extended their shelf life are re-analyzed annually or semi-annually in order to verify them or to extend the shelf life again.

B. Shelf life extension requested by health bodies

The SFDA studies requests to extend the shelf life of batches submitted by health bodies in accordance with the mechanism mentioned in this guideline, taking into account the following:

1. The analysis of such batches shall take place during a period of not less than four months before the expiry date of the product.
2. The health body is required to relabel[1] the batches that their shelf life was extended.
3. The batches that have extended their shelf life are re-analyzed annually or semi-annually in order to verify them or to extend the shelf life again.

5. The procedure used to determine the batches of Health Body's products that can be analyzed to extend their shelf life

1. The product shall be registered in the SFDA.
2. Expiry date shall be in no less than four months.
3. The therapeutic importance of the Product.
4. The product should not be of the category of narrow therapeutic index drugs.
5. Product's lack of availability in the local market.
6. The lack of availability for the product alternatives (with the same active ingredient)
7. An adequate quantity of the product batch shall exist in the health body, the batch shall be no less than:
    - 15,000 for tablets and capsules
    - 10,000 for syrups and suspensions
    - 5000 for creams and ointments
    - 3000 for intramuscular and intravenous injections
    - 2000 for intravenous fluids

[1] Relabeling should be done to the inner and outer package with an irremovable sticker indicating the new expiry date

- 2000 for inhalers
- 2000 for drops

And if the quantity is less than what was mentioned above, the price of the quantity must be no less than 200,000 SAR, with a sufficient quantity of the product for analysis (as shown below).

6. Quantities required for each pharmaceutical form for the purpose of analysis

Dosage forms	Volume or Weight	Required quantity
Tablets (Oral, Sublingual, Chewable, etc.)	N/A	100 Tablet
Capsules	N/A	100 Capsules
Syrups/Suspensions/Emulsions/Solutions	Less than or equal 1 L	10 bottles
Eye/Ear/Nasal Drops	All volumes	20 pcs
Creams/Ointments/Gels/Lotions	Less than 15 g	15 tubes
Creams/Ointments/Gels/Lotions	More than 15 g	12 tubes
Ampoules/Vials/Injections	Less than or equal 1 mL	100 pcs
Ampoules/Vials/Injections	2 – 5 mL	30 pcs
Ampoules/Vials/Injections	More than 5 mL	20 pcs
IV Fluids	Less than 500 mL	15 samples
IV Fluids	More than or equal 500 mL	10 samples
Injectable powder	Less than or equal 50 mg	30 pcs
Injectable powder	More than 50 mg	20 pcs
Inhalers	N/A	30 pcs

7. Priority

The SFDA will give priority to the shelf life extension requests in the evaluation.