الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Top Deficiencies in Validation and Assessment Phases of Herbal and Health Products

Version 1.0

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Drug Sector

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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
1.0	Executive Directorate of Regulatory Affairs	8 December 2020	Final

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1. INTRODUCTION

1.1. Objective

This document is intended to improve the submission quality of herbal and health products application, based on the most common deficiencies observed in submissions to the SFDA.

1.2. Scope

This guidance is valid for the marketing authorization application of herbal and health products.

1.3. Related guidelines

This document should be read in conjunction with the following drug sector documents:

- Data Requirements for Herbal & Health Products Submission.
- Guidance for Presenting PIL and Labeling Information of Herbal and Health Products
- The Guidance of Products Classification.

2. KEY CONSIDERATIONS

- The product must not contain more than five herbs in accordance with the classification guideline.
- If the product contains vitamins or minerals must be within the limits, which stated in "*General rules for products containing vitamins & minerals*".
- The product should not contain any medicinal constituent. E.g. Vasodilators.
- The product should not contain any prohibited constituent. E.g. Hormones.

3. MODULE 1 (ADMINISTRATIVE DATA)

3.1. Cover letter:

- Classification letter is not provided, when available.
- Exemption letter is not provided, when available.
- Third party authorization letter is not provided, when available.

3.2.Application form:

- Ingredients:
    - Active substance unit is not simplified per one unit, (i.e. supposed to be mg/ml not mg/5ml).
    - Alcohol hand sanitizer or throat lozenges does not match with the limits stated in Appendix.1 in "*Data Requirements for Herbal & Health Products Submission*".
- Finished product: Consistent name, address, and role for finished product manufacturer are not stated in each of the following: application form, artwork, CPP, Section 3.2.P.3.1
- Active substance manufacturer: Consistent name, address, and role for active substance manufacturer are not stated in 3.2.S.2.
- Shelf life: Proposed shelf life does not match with SPC, PIL and 3.2.P.8.1.
- In-use instructions if it is a multi-use product (e.g. Syrup and oral drops) are not available.
- The trade name proposed with strength and/or dosage form, it must be filled without any strength and/or dosage form.

3.3. The Labeling: lack of Arabic translation of the information required in *Guidance for Presenting PIL and Labeling Information of Herbal and Health Products* on the label that indicates product name and strength/unit.

3.4. Artwork (Mock-ups)

- Lack of Arabic translation of the artwork including trade name, pharmaceutical form, size, name of the marketing authorization holder, and strength/unit.
- The artwork includes the agent name. In compliance with circulation No. 2701 21/1/1437, artwork must not include the agent name.

3.5. Samples: Absence of sub-product number.

3.6. CPP or Free-Sale certificate is not signed and stamped by the Saudi embassy.

3.7. Certificate of analysis – Drug Substance / Finished Product: Failure to provide the two certificates of analysis of the active substance/s; one from the API supplier and the other from the finished product manufacturer.

4. MODULE 3 (QUALITY DATA)

4.1. Absence or deficient narrative description of the manufacturing process of the API and finished product, and flow chart of manufacturing process and process controls.

4.2. List of residual solvents is not presented, if used.

4.3. Certificate of analysis of residual solvent is not provided, if used.

4.4. Inadequate or missing information on the type and size of batches used in the batch analysis and stability study.

4.5. Lack of or insufficient details regarding validation process of analytical procedures in case of non-pharmacopeial methods.

4.6. Justification for the overage is not available (e.g., to compensate for expected and documented manufacturing losses).

4.7. Information on the fill size of the container is not provided.

4.8. Lack of long-term stability study that covers at least 12 months at submission.

4.9. In-use stability study does not comply with *The GCC Guidelines for Stability Testing for multi-use drug product*.

4.10. A written commitment to continue the submitted studies through the proposed shelf-life period is not provided, if the submission includes data from stability studies on three batches but does not cover the proposed shelf life.

4.11. A written commitment to place the first three production batches on long-term stability studies through the proposed shelf life period is not provided, if the submission does not include stability data on production batches.

4.12. A written commitment to conduct on-going stability studies (at least one batch per year) is not provided.

4.13. An official letter from the company indicating the expected production size range and confirming that this range will not be changed before getting the SFDA approval is not provided.

4.14. Absence or insufficient clarification on the API supplier used in stability study in case there are more than one API manufacturer or API manufacturer site.

4.15. Absence or insufficient clarification of the primary packaging type and pack size used in stability data.