



Dossier for Herbal Products

I. Section A

II. Section B

I. Section A: Drug Substance

1. Drug Substance (Name, Manufacturer)

Definition of the herbal product stock(s) and the herb name (s) should be provided.

For herbal stocks of herbal origin for example:

- Binominal scientific name of plant (genus, species, variety and author) and chemotype (where applicable)
- State (fresh or dried) and part(s) of the plant
- Other names (synonyms)/ common names /latin names
- Reference of the herbal product manufacturing procedure
- Description of vehicles used

2. Manufacturer(s) (name and manufacturer)

The name, address, and responsibility of each manufacturer, including manufacturer of stock, dilutions and/or triturations as well as, contractors, and each proposed production site or facility involved in manufacturing/collection and testing should be provided.

3. Description of Manufacturing Process and Process Controls (name and manufacturer)

The description of the herbal product stock(s), intermediate dilutions and/or triturations and final dilution manufacturing process represents the applicant's commitment for the manufacture of the herbal stock(s) and final dilution. Information

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.

Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.

Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404

Email: lab@thscenter.com Website: www.thscenter.com



should be provided to adequately describe the manufacturing process and process controls. For example:

A sequential procedural narrative of the manufacturing process should be submitted. The narrative should include, for example, quantities of raw materials, solvents/vehicles, reagents (if applicable), critical steps and the controls that are intended to result in the routine and consistent production of material(s) of appropriate quality. A flow chart of the manufacturing process should be included. For herbal stock(s) and final dilution reference should be made to the appropriate section of a herbal manufacturing procedure described in an official Pharmacopoeia. The different stages of the preparation of the herbal stock(s) and final dilution or any preliminary treatment or transformation operation must be sufficiently described to allow the assessment of the consistency of the quality. The material, processes and specific precautions (light, moisture, miscellaneous contamination, and temperatures) must be described.

4. Control of Materials (name, manufacture)

The information on the raw material(s) and the solvents/reagents or vehicles used for the Herbal Stock(s) and final dilution preparation should be presented

Nomenclature of the raw materials:

For raw materials of botanical origin, the scientific name -genus, species, variety, chemo type, part employed and other names should be provided.

For raw materials of biological origin, the scientific name (e.g., animal), -genus, species- tissue(s), fluid(s), parts of organ(s) or organ(s) used and other names should be provided.

For minerals or chemicals, the international non-proprietary name (I.N.N), chemical and other names should be provided.

Description of the raw materials

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.
Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.
Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404
Email: lab@thscenter.com Website: www.thscenter.com



For raw materials of botanical origin, the state (e.g. fresh, dried) of the material used and, where applicable, information on pharmacological active, toxic constituents or marker compound(s), if applicable, should be provided. Additionally a macroscopic and microscopic description of the raw material should be presented.

For raw materials of biological origin, information on the physical and/or anatomical and histological state (where applicable) should be provided.

For minerals or chemicals, physical form, structural formula, molecular formula and relative molecular mass, where applicable, should be provided.

Supportive Data

For example, the following data should be presented

- Name and address of the supplier and supplier commitment and/or manufacturer and manufacturer's commitment, if different from the applicant
- Data on the origin/source of the material
- Synthetic or manufacturing route
- Production: (for example)

For raw materials of botanical origin:

- Natural state of plant (wild or cultivated)
- Harvesting location, time of harvesting and, if possible, stage of vegetation
- Conditions of cultivation
- Information on pre or post harvest treatment
- Processing, where applicable
- Duration and conditions of storage

For a mineral or chemical substance:

- Purification stage
- Location of collection (geographical origin)

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.
Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.
Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404
Email: lab@thscenter.com Website: www.thscenter.com

5. Control of Critical Steps and Intermediates (name, manufacture)

6. Process validation and/or Evaluation (name, manufacture)

7. Manufacturing Process Development (name, manufacture)

Reference to the manufacturing method of an official Pharmacopoeia shall be made.

8. Characterization (name, manufacturer)

9. Elucidation of Structure and other Characteristics (name, manufacturer)

Conformation of structure based on e.g., synthetic route, spectral analyses, biological activity, purity and phytochemical characterisation should be provided, where relevant.

10. Impurities (name, manufacturer)

Information on impurities originating from the raw material(s) or arising from the manufacturing process should be provided

For example:

- Potential impurities originating from the route of synthesis
- Potential impurities arising during the production and purification (degradation products)
- Analytical test procedures and their limits of detection
- Test for foreign matters: mineral, biological or botanical other than the herbal active substance defined
- Test for pesticides

11. Control of Drug Substance (name, manufacturer)

12. Specifications (name, manufacturer)

The specifications for raw materials, the herbal stock(s) and final dilutions should be provided.

If the raw material is described in a Pharmacopoeia, the reference to the monograph should be stated and, where applicable, supplementary tests should be described. If

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.

Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.

Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404

Email: lab@thscenter.com Website: www.thscenter.com



the raw material is not described in a Pharmacopoeia, the monograph should be compiled based on scientific data.

13. Analytical Procedures (name, manufacturer)

Analytical procedures used for testing the raw material (s), the herbal stock(s) and final dilution should be provided.

For example for raw materials of botanical origin:

- Various chromatographic techniques best suited to study the composition of the plant
- Test for loss on drying or water content
- If applicable, an assay of the main ingredients
- Test for potential falsification

14. Validation of Analytical Procedures

Analytical validation information, including experimental data for the analytical procedures used for testing the raw material(s), herbal stock(s) and final dilution should be provided.

15. Batch Analysis (name, manufacturer)

16. Justification of Specifications (name, manufacturer)

Justification for the raw material(s), herbal stock(s) and final dilution specifications should be provided.

17. Reference Standards or Materials (name, manufacturer)

Information on the reference standards or reference materials used for testing raw material(s), herbal stock(s) and final dilution should be provided.

18. Container Closure System (name, manufacturer)

Descriptions of container closure system(s) used for storage of the herbal stock(s), final dilution, intermediate dilution/trituration and raw materials (if stored) should be provided. The combination of the container closure specifications and the stock

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.

Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.

Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404

Email: lab@thscenter.com Website: www.thscenter.com



stability data may be sufficient to demonstrate suitability of the container closure system for storage and shipping of the stock.

19. Stability (name, manufacturer)

- **Stability Summary and Conclusions (name, manufacturer)**

Stability data of the herbal stock(s) and final dilution(s) should be provided. Stability data or re-testing may also be required for raw materials that are not processed immediately after testing. Stability data from the herbal stocks are generally transferable to dilution/triturations obtained thereof, if the expiry date of the dilutions/triturations does not exceed the expiry date of the herbal stock.

- **Post-approval Stability Protocol and Stability Commitment**

- **Stability Data**

Stability data or re-testing may also be required for all dilutions or triturations, if the stability is not linked to the expiry date of the stock and that are not processed immediately after testing.

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.

Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.

Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404

Email: lab@thscenter.com Website: www.thscenter.com



II. Section B: Drug Product

- 1. Drug Product (Name, Dosage Form)**
- 2. Description and Composition of the Drug Product (name, dosage form)**
- 3. Pharmaceutical Development (name, dosage form)**
- 4. Components of the Drug Product (name, dosage form)**
- 5. Drug Substance (name, dosage form)**
- 6. Excipients (name, dosage form)**
- 7. Drug Product (name, dosage form)**
- 8. Formulation Development (name, dosage form)**

Where applicable, the differences between clinical formulations and formulation (i.e. composition) described in 3.2.P.1 should be provided.
- 9. Overages (name, dosage form)**
- 10. Physicochemical and Biological Properties (name, dosage form)**
- 11. Manufacturing Process Development (name, dosage form)**

Where applicable, differences with the manufacturing process(es) used to produce pivotal clinical batches clinical should be provided.
- 12. Container Closure Systems**
- 13. Microbiological Attributes (name, dosage form)**
- 14. Compatibility (name, dosage form)**
- 15. Manufacture (name, dosage form)**
- 16. Manufacturer(s) (name, dosage form)**
- 17. Batch Formula (name, dosage form)**
- 18. Description of Manufacturing Process and Process Controls (name, dosage form)**
- 19. Controls of Critical Steps and Intermediates (name, dosage form)**
- 20. Process Validation and/or Evaluation (name, dosage form)**
- 21. Control of Excipients (name, dosage form)**
- 22. Specifications (name, dosage form)**

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.
Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.
Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404
Email: lab@thscenter.com Website: www.thscenter.com

- 23. Analytical Procedures (name, dosage form)**
- 24. Validation of Analytical Procedures (name, dosage form)**
- 25. Justification of Specifications (name, dosage form)**
- 26. Excipients of Human or Animal Origin (name, dosage form)**
- 27. Novel Excipients (name, dosage form)**
- 28. Control of the Drug Product (name, dosage form)**
- 29. Specification(s) (name, dosage form)**
- 30. Analytical Procedures (name, dosage form)**
- 31. Validation of Analytical Procedures (name, dosage form)**
- 32. Batch Analysis (name, dosage form)**
- 33. Characterisation of Impurities (name, dosage form)**
- 34. Justification of Specification(s) (name, dosage form)**
- 35. Reference Standards or Materials (name, dosage form)**
- 36. Container Closure System (name, dosage form)**

The combination of the container closure specifications and the drug product stability data may be sufficient to demonstrate suitability of the container closure system for storage and shipping of the drug product.

37. Stability (name, dosage form)

Herbal medicinal products: if no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered

38. Stability Summary and Conclusions (name, dosage form)

39. Post-approval Stability Protocol and Stability Commitment (name, dosage form)

40. Stability Data (name, dosage form)

41. APPENDICES

- **Facilities and Equipment (name, manufacturer)**
- **Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)**
- **Novel Excipients**

42. Literature references

TOTAL HERB SOLUTIONS PRIVATE LIMITED

Registered Office: 164, Sitaram Poddar Marg, Harlalka Bhavan, Mumbai – 400 002. INDIA.
Corporate Office: A 2 / 4 Prime Showcase, J.V. Patel Compound, Elphinstone Road (West), Mumbai – 400 013. INDIA.
Telephone # (91)(22) 40560400 Facsimile # (91)(22) 40560404
Email: lab@thscenter.com Website: www.thscenter.com