Guidelines to
TECHNICAL INFORMATION REQUIREMENTS
FOR MONOGRAPH REVIEW

Homeopathic Pharmacopoeia Convention of the United States

Monograph Review Committee (MRC)
# Table of Contents

1. **FOREWORD**  
   1.1 Minimum Standards  4  
   1.2 Best Practices  4  

2. **ADMINISTRATIVE**  
   2.1 Cover letters  5  
   2.2 Contact information  5  
   2.3 Presentation Content and Format  5  

3. **GENERAL INFORMATION**  
   3.1 Nomenclature  6  
   3.2 Structure  6  
   3.3 General Properties  7  

4. **MANUFACTURE**  
   4.1 Manufacturer(s)  10  
   4.2 Description of Manufacturing Process and Process  11  
   4.3 Control of Materials  11  

5. **CONTROL OF DRUG SUBSTANCE**  
   5.1 Specification  14  
   5.2 Validation of Analytical Procedures  14  

6. **REFERENCE STANDARDS OR MATERIALS**  
   6.1 Non-official Reference Standards  14  

7. **SPECIAL STORAGE CONDITIONS**  
   7.1 Special Storage Conditions  15  

8. **STABILITY**  
   8.1 Stability of Clinical Batches  15
9. **Toxicology and Safety** 15

9.1 General Toxicological Requirements

10. **Literature References** 17

10.1 Important publications referenced in the report 17

11. **Report Format and Content** 17

11.1 Title Page 17
11.2 Introduction 17
11.3 Table of Contents 17
11.4 List of Abbreviations and Definition of Terms 18
11.3 Content 18

12. **References** 21

12.1 Regulatory References

13. **Appendices** 26

13.1 Consolidated Monograph Review Checklist 26
1. FOREWORD

The following guidelines are presented to help monograph sponsors for homeopathic medicines assemble and present Chemistry, Manufacturing and Controls (CMC) and Safety information in a manner and format consistent with the expectations of the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) Monograph Review Committee (MRC) for approval; and to help guide reviewers who examine monograph submissions to ensure that expected standards of quality are being upheld. These guidelines contain two specific types of criteria: requirements and best practice recommendations. Requirements are recognized by language that is definitive, such as “should” [shall] or “will include”, while best practice recommendations will use qualifiers such as “is recommended”. For monograph approval, the submitted CMC and Safety information must meet all requirements.

Monograph reviewers are instructed to ensure the following criteria are met:

- The definition, description, nomenclature and general properties of the raw material offered for inclusion within the Homeopathic Pharmacopoeia of the United States (HPUS) are adequately described (Section 3).
- The Manufacturing locations, processes and control of materials are identified where appropriate (Section 4).
- The structure elucidation and characterization of the raw material, active principles of complex drug substances and their impurities, are, where appropriate, defined (Section 5).
- The quality, storage conditions and stability of the raw material, are, where needed, clearly stated.
- The safety of the starting material is established on a basis that allows for appropriate calculation of OTC, Rx and, where appropriate, external attenuations levels.

1.1 Requirements  A requirement that must be met for approval of the monograph. Non-compliance with these requirements will likely cause non-approval of a monograph. Requirements will be periodically updated as needed. Requirements contained within these guidelines for monograph submission are recognizable by
language that implies a required element, placement in the left column of the
document, and appearance in the text as regular font.

1.2 Best Practice Recommendation: Suggested method or practices or particular
point that should be considered when conducting development and documentation of
the raw material. Best practices will be updated as standards evolve. Best practice
recommendations contained within these guidelines for monograph submission are
recognizable by language describing the element as “recommended”, placement in the
right column of the document, and appearance in the text as italicized font.

REQUIREMENTS

RECOMMENDED BEST
PRACTICES

2. Administrative

2.1 Cover letters
Cover letters shall be addressed to the
Editor of the HPCUS

Description of what the sponsor is
requesting of the HPCUS and the MRC.

2.2 Contact Information
Corporate name, address, Phone number
Contact/agent, phone number, street and
e-mail addresses.

2.3 Presentation, Content and Format
Proposed monograph shall include both a
descriptive section (Main monograph) and
a Quality section (Standards and Controls
monograph) in the format described by the
Editor.
Documentation supporting the Main and Standards and Controls monographs shall be presented in a format consistent with the Report Format and Content (see Section 11).

Navigation – Submissions shall be in electronic format with an active table of contents

### 3. General Information

#### 3.1 Nomenclature

The drug substance shall be identified using current scientific nomenclature as follows:

Botanical raw materials: Scientific Name: USDA GRIN Taxonomy name. Family, Genus, species, variety and chemo-type.

Zoological raw materials: USDA Taxonomy name, Family, Genus, species, variety, tissue, fluid, part of organ, organ.

Chemical raw materials: International Nonproprietary Name or Official name. IUPAC, CAS.

It is recommended that the sponsor make reasonable attempts to provide other official nomenclature and synonyms:

- Other Pharmacopoeia Names
- Other Homeopathic Names
- Synonyms: English, Latin, French, German, Spanish, Italian, other

It is recommended that any surrogate species within the genus or chemical class used as an active or marker compound reference shall be described according to the guidelines of nomenclature referenced under 3.1.
3.2 Structure

For botanical and zoological raw materials, the chemical class of constituents or characteristic markers, if known, shall be described.

For chemical raw materials, confirmation of the proposed chemical structure based on spectral data (especially 2D NMR and IR) and/or other relevant analytical data shall be provided, if applicable.

Impurities

Information on impurities shall be provided as applicable. Appropriate limits shall be established based on safety considerations and manufacturing experience and stability data.

If applicable, any stereochemistry, including diastereoisomers and enantiomers of chemical starting materials shall be described.

For chemical raw materials, schematic amino acid sequence glycosylation sites or other post-translational modifications and relative molecular weight, if applicable, shall be described.

For peptides, characterization shall include data on the amino acid sequence, and, when relevant, peptide map. For DNA products, characterization shall include nucleic acid sequence, DNA melting point, and side chain modifications when applicable.
3.3 General Properties

For chemical raw materials, a list of physicochemical and other relevant properties of the drug substance shall be provided.

It is recommended that the country of origin be described for botanical and zoological raw materials, and for naturally occurring chemical raw materials if applicable or relevant.

The natural habitat and geographical distribution of the plant, alga, macroscopic fungi, or animal shall be provided.

It is recommended that information be included about the current sources of the substance, including its geographical location and whether it is cultivated or harvested from the wild.

It is recommended that information be included if the critical habitat of the species has been determined to be endangered or threatened.

It is recommended that information be included if the species is an endangered or threatened species under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

It is recommended that information be included if the species is entitled to special

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For botanical raw materials, the part of plant and stage of development shall be provided.

Sponsor shall describe whether fresh or dried Botanical material was used.

The morphological, histological and anatomical description (including gender, if applicable) shall be provided for zoological raw materials.

These guidelines do not address Genetically Modified Organisms (GMO) as starting raw materials. Sponsors are invited to discuss starting raw materials originating from genetically modified organisms directly with the MRC as necessary.

For zoological raw materials, the age, health status, method of breeding and feeding of animals, immunization techniques (immune sera) with description of antigens, culture media (microbial strains) shall be described, if applicable.

For zoological raw materials, the conditions of slaughter and dissection of animals, shall be described, if applicable.

For zoological raw materials, an assessment of the risk of infectivity including viral, bacterial and prionic
diseases, shall be provided.

For raw materials of viral origin: the method of inactivation shall be described.

For chemical raw materials, any biological activity, if applicable, shall be described.

Any Distribution controls on the starting material imposed by any regulatory authority shall be described.

It is recommended that the sponsor make reasonable attempts to identify any addictive properties of the drug substance including literature review and abuse liability studies.

It is recommended that Safe Handling Practices be included when such information can help protect laboratory personnel from unusual or unnecessary danger.

4. MANUFACTURE

4.1 Manufacturer(s)

Sponsor shall provide the name, address, and responsibility of each manufacturer, including contractors, and each production site or facility for batches of homeopathic drug product referenced in the clinical submission.

4.2 Description of Manufacturing
Process and Process Controls

Sponsor shall identify manufacturing methods and processes used to manufacture batches of the homeopathic drug product used in clinical development of the drug substance. If compendial manufacturing methods are used, these shall be referenced. If noncompendial methods or processes are used, these shall be explained and described with the same level of detail as the primary process.

4.3 Control of Materials

It is recommended that information on the quality and control of materials used in the manufacture of the drug substance -be provided and that information demonstrating the materials meet standards appropriate for their intended use should be provided, as appropriate.

For botanical raw materials, a certificate of authenticity signed by a person who is appropriately qualified shall be provided.

For botanical raw materials a macroscopic, and where applicable, a microscopic description of the plant and/or part used for clinical development against a voucher specimen shall be provided.

Sponsor shall provide a photo of the voucher specimen.
For botanical raw materials, a description of the appearance of the resulting tincture shall be provided.

For botanical raw materials, a Chromatographic and or Spectrographic fingerprint is required. For zoological and chemical raw materials, Chromatographic and or Spectrographic fingerprints shall be provided, if applicable.

All publicly available quality standards/methods for the drug substance shall be provided, if available.

It is recommended that any marker compounds used in the suggested analytical methods be described.

It is recommended that heavy metals limits for raw materials be provided and justified.

It is recommended that for Botanical and Zoological raw materials, microbial limits be provided and justified.

It is recommended that residual pesticides, parent, or metabolites for botanical and zoological raw materials be identified.

It is recommended that limits for adventitious toxins (e.g. botanicals: aflatoxins) in botanical and zoological raw materials be provided.
Limits for foreign materials or adulterants shall be provided.

Moisture content limits for chemical starting materials shall be provided.

For chemical raw materials, a chemical or biological quantitative assay shall be provided. For botanical & zoological raw materials, the same shall be provided, if applicable.

For zoological raw materials, a risk analysis or other evaluation of viral security shall be provided.

For zoological raw materials, a risk analysis or other evaluation of TSE security shall be provided.

When considering specifically the risk of transmission of TSE, raw and starting materials, excipients as well as reagents participating in the manufacturing process namely from bovine, ovine and caprine origin, and any other TSE susceptible species, shall comply with FDA guidelines regarding transmission of TSE.

For zoological raw materials intended for manufacturing sarcodes, a Veterinary certificate of wholesomeness shall be

It is recommended that limits for total ash for botanical raw materials be provided.

It is recommended that moisture content limits for botanical and zoological raw materials be provided, if applicable.

Based on risk analysis, it is recommended that appropriate limits for radioactivity be provided.
provided.

For any analytical procedures that are not referenced in an FDA recognized standard reference, a complete description of analytical procedures and appropriate validation data shall be provided.

A Certificate of analysis for the raw material used in clinical batches shall be provided.

5. CONTROL OF DRUG SUBSTANCE

Specifications for the raw material shall be provided.

Analytical procedures for the raw material used for the clinical batches shall be provided.

6. REFERENCE STANDARDS OR MATERIALS

Non-official Reference Standards

It is recommended that when a national or international reference standard is not available, a sponsor's internal reference material that is representative of multiple source points may be used as a reference material, against which batches would be tested prior to their release. If this is the case, it is recommended that the sponsor's internal reference material be described.
7. SPECIAL STORAGE CONDITIONS

Special storage conditions
Any special storage conditions necessary to maintain the stability of the starting materials (and subsequent attenuations, if applicable) shall be described.

8. STABILITY

Stability
Sponsor shall demonstrate that the starting material met specifications at the time the active ingredient was manufactured and the dosage form remained stable throughout the duration of the clinical studies.

9. TOXICOLOGICAL INFORMATION

9.1 General Toxicological Requirements:
Substances currently lawfully marketed as dietary supplements or otherwise without known safety concerns will often not require more than an integrated summary of available medical and toxicological databases.
Substances not otherwise lawfully marketed or with known or potential safety concerns shall require up to a full battery of pharmacology and toxicology information. Sponsors shall provide experimental and or bibliographic evidence of safety within the following areas as necessary: Acute and repeat dose toxicity, genotoxicity, carcinogenicity
reproductive toxicology, local tolerance, antigenicity, immunotoxicity, dependence, metabolites, impurities, other toxicology information

For both risk classifications sponsors are referred to the HPCUS Toxicology and Safety Committee document: Guideline to Toxicological Information Requirements for Admission of a Homeopathic Substance into the HPUS

10. LITERATURE REFERENCES

10.1 Important Publications Referenced in this Report

All publications cited in this submission shall be provided in English or translations upon request. Functioning links to internet sources are acceptable.

11. REPORT FORMAT AND CONTENT

11.1 TITLE PAGE

11.2 INTRODUCTION

11.2.1 Brief introductory statement highlighting the principle Chemical, Physical, Manufacturing and Safety properties of the substance for review.

11.3 TABLE OF CONTENTS

Table of contents shall be provided two steps down from the heading. For example:
11.3 Report Format and Content
11.3.1 Table of Contents
11.3.1.1 Topic of Interest

Additional levels may be added as necessary.

The table of contents shall be in an active format for easy navigation by reviewers.

11.4 List of Abbreviations and Definition of Terms

11.5 General Information

11.5.1 Nomenclature
11.5.1.1 Scientific naming
11.5.1.1 Synonyms

11.5.2 Structure
11.5.2.1 Chemical class
11.5.2.2 Surrogate markers
11.5.2.3 Structural formula
11.5.2.4 Stereochemistry
11.5.2.5 Molecular formula
11.5.2.6 Molecular weight
11.5.2.7 Amino acid sequence

11.5.3 General Properties
11.5.3.1 Physico-chemical properties
11.5.3.2 Country of origin
11.5.3.3 Natural Habitat/Geographical distribution
11.5.3.4 Part of plant/Stage of development
11.5.3.5 Botanical fresh or dry
11.5.3.6 Morphological, histological, anatomical description
11.5.3.7 Current sources of the drug substance
11.5.3.8 Age, health status and cultivation of donor animals
11.5.3.9 Conditions of slaughter
11.5.3.10 Risk assessment of infectivity viral, bacterial, prionic
11.5.3.11 Method of inactivation for drug substances of viral origin
11.5.3.12 Biological activity
11.5.3.13 Any distribution controls imposed by regulatory authorities

Approved by HPCUS Board of Directors for posting April 2014
11.5.3.14 Critical habitat assessment (endangered)
11.5.3.15 Species endangered
11.5.3.16 Safe handling practices

11.6 MANUFACTURE

11.6.1 Manufacturer(s)
11.6.2 Manufacturing process

11.6.3 Control of Materials

11.6.3.1 Quality and control of materials
11.6.3.2 Botanical certificate of authenticity
11.6.3.3 Macroscopic description
11.6.3.4 Microscopic description
11.6.3.5 Photo of voucher specimen
11.6.3.6 Appearance
11.6.3.7 Chromatic or spectrographic fingerprint
11.6.3.8 Publicly available quality methods
11.6.3.9 Heavy metals
11.6.3.10 Microbial limits
11.6.3.11 Residual pesticides
11.6.3.12 Adventitious toxins
11.6.3.13 Foreign material or adulterants
11.6.3.14 Total ash
11.6.3.15 Moisture content
11.6.3.16 Radioisotope contamination
11.6.3.17 Quantitative assay
11.6.3.18 Certification of viral security
11.6.3.19 Certification of TSE security
11.6.3.20 Certificate of wholesomeness
11.6.3.21 Description of analytical procedures
11.6.3.22 Certificate of analysis

11.7 CONTROL OF THE DRUG SUBSTANCE

11.7.1 Specification
11.7.2 Validation of analytical procedures

11.8 REFERENCE STANDARDS

11.8.1 Non-official reference standards
11.9 **Special Storage Conditions**

11.9.1 Special storage conditions

11.10 **Stability**

11.10.1 Stability of clinical batches

11.11 **Toxicology**

11.11.1 Acute toxicity
11.11.2 Repeat dose toxicity
11.11.3 Genotoxicity
11.11.4 Carcinogenicity
11.11.5 Reproductive toxicology
11.11.6 Local tolerance
11.11.7 Antigenicity
11.11.8 Immunotoxicity
11.11.9 Dependence
11.11.10 Metabolites
11.11.11 Impurities
11.11.12 Other toxicology information

11.12 **Literature References**

11.12.1 Literature References used in this report

11.13 **List of Tables and Figures**

12 **References**

Approved by HPCUS Board of Directors for posting April 2014


Approved by HPCUS Board of Directors for posting April 2014 21


Approved by HPCUS Board of Directors for posting April 2014 23
## APPENDIX

### Homeopathic Pharmacopoeia Convention of the United States  Monograph Review Committee Checklist

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**Homeopathic Pharmacopoeia Convention of the United States**

**Monograph Review Committee Checklist**

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<td>Manufacturing Quality</td>
<td>Information on the quality and control of materials used in the manufacture of the drug substance should be provided. Information demonstrating that materials meet standards appropriate for their intended use should be provided, as appropriate.</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Botanical</td>
<td>Botanical certificate of authenticity</td>
<td>YES</td>
<td></td>
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<tr>
<td>Botanical</td>
<td>Microscopic description of the plant/part used against a voucher specimen</td>
<td>YES</td>
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<tr>
<td>Botanical</td>
<td>Photo of the voucher specimen</td>
<td>YES</td>
<td></td>
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<tr>
<td>Botanical</td>
<td>Appearance</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Manufacturing Quality</td>
<td>Chromatographic and/or Spectrographic fingerprint</td>
<td>YES</td>
<td>If Applicable</td>
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<tr>
<td>Manufacturing Quality</td>
<td>Publicly available quality standards/methods</td>
<td>If available</td>
<td>If available</td>
<td>If available</td>
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<table>
<thead>
<tr>
<th>Module</th>
<th>Chemistry, Manf. Quality</th>
<th>Requirement</th>
<th>If Applicable</th>
<th>If Applicable</th>
<th>If Applicable</th>
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<tbody>
<tr>
<td>HMPWG 3</td>
<td>Chemistry, Manf. Quality</td>
<td>Heavy metals</td>
<td>YES</td>
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<td>HMPWG 3</td>
<td>Chemistry, Manf. Quality</td>
<td>Microbial limits</td>
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<td>HMPWG 3</td>
<td>Chemistry, Manf. Quality</td>
<td>Residual pesticides parent or metabolites</td>
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<tr>
<td>HMPWG 3</td>
<td>Chemistry, Manf. Quality</td>
<td>Adventitious toxins (e.g. botanical aflatoxins)</td>
<td>YES</td>
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<tr>
<td>HMPWG 3</td>
<td>Chemistry, Manf. Quality</td>
<td>Foreign materials or adulterants</td>
<td>YES</td>
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<tr>
<td>Chemistry, Manf. Quality</td>
<td>Total ash</td>
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<td>Chemistry, Manf. Quality</td>
<td>Moisture content</td>
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<td>Radioisotope contaminants</td>
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<td>Manufacturing Quality</td>
<td>Quantitative assay chemical or biological</td>
<td>If Applicable</td>
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<td>Manufacturing Quality</td>
<td>Certification of viral security</td>
<td>If applicable</td>
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<tr>
<td>Manufacturing Quality</td>
<td>Certification for TSE security</td>
<td>If applicable</td>
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<tr>
<td>Manufacturing Quality</td>
<td>Veterinary certificate of wholesomeness</td>
<td>If applicable</td>
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<tr>
<td>Chemistry</td>
<td>A complete description of analytical procedures and appropriate validation data should be available for any analytical procedures that are not from an FDA recognized standard reference</td>
<td>YES</td>
<td>YES</td>
<td>YI</td>
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<td>Chemistry, Manf. Quality</td>
<td>Certificate of analysis</td>
<td>YES</td>
<td>YES</td>
<td>YI</td>
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<tr>
<td>Manufacturing Quality</td>
<td>Process Validation and/or Evaluation</td>
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</tbody>
</table>

**Control of Drug Substance**

| Chemistry | Validation of Analytical Procedures | YES | YES | YI |
| Chemistry, Quality, Toxicology | Information on impurities should be provided as applicable. Appropriate limits should be established based on safety considerations and manufacturing | YES | YES | YI |