

**General Chapter Prospectus:** <1114> Ensuring Microbiological Quality of Articles of Botanical Origin

**Type of Posting:** General Chapter Prospectus

**Posting Date:** 29-April-2022

**Expert Committee:** Botanical Dietary Supplements and Herbal Medicines (BDSHM)

**Input Deadline:** 29-May-2022

**Proposed New Title:** <1114> Ensuring Microbiological Quality of Articles of Botanical Origin

**Suggested Audience:** Suppliers of botanical ingredients, dietary supplement manufacturers, and testing laboratories.

**Estimated Proposal PF:** 48(6) [Nov.- Dec. 2022]

**Background and objective(s):** Being of natural origin, botanical ingredients generally have higher bioburden compared to synthetic or purified materials. This presents particular challenges as undesirable microorganisms may be carried over to botanical dietary supplement products. In addition, spores and toxic mycotoxins generated by the micro-organisms may also be present and these are more difficult to eliminate, once they are present in the herbal material. Compliance with current Good Manufacturing Practices (cGMPs) require the control and prevention of microbiological contamination of raw materials and finished products. Raw materials must not contain levels of undesirable microorganisms that would cause the product to be adulterated, or the material must be pasteurized or otherwise treated. Hence, there is a need to control microbial population in the botanical ingredients before they are used in dietary supplement products. Current methods and technologies applied to control the bioburden can have a negative impact on the pharmacopeial quality of botanical materials. This chapter will provide information on 'practices to prevent' as well as 'methods to treat' microbial contamination of articles of botanical origin as well as considerations for maintaining material quality.

**Preliminary outline:** The following sections are proposed to be included in the General Chapter

- Introduction
- Pharmacopeial microbiological quality and regulatory compliance
- Practices for preventing microbial contamination
- Methods for reduction of microbial contamination
- Validation of microbial control measures
- References

**Anticipated activities:** USP is requesting early input from stakeholders on this newly proposed informational General Chapter <1114> *Ensuring Microbiological Quality of Articles of Botanical Origin* which is planned to be published for comments in *Pharmacopeial Forum*.

**Contact:** Binu Koshy, Senior Scientist II (301-692-3672, [binu.koshy@usp.org](mailto:binu.koshy@usp.org))