
[General Chapter Prospectus: <1567> Pyrrolizidine Alkaloids \(PAs\)](#)

Type of Posting: General Chapter Prospectus

Posting Date: 31-Jul-2020

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

Input Deadline: 30-Aug-2020

Proposed New Title: <1567> *Pyrrolizidine Alkaloids (PAs)*

Suggested audience: Suppliers of Botanical ingredients, Dietary supplement manufacturers of botanical products and testing laboratories.

Estimated Proposal PF: 47(1) [Jan. – Feb. 2021]

Background and objective(s): Pyrrolizidine Alkaloids (PAs) are esters of alkaloids consisting of a necine base moiety, esterified with a necic acid. Currently, more than 660 PAs and their respective N-oxides are known to be hepatotoxic, carcinogenic, and genotoxic. PAs have been identified in more than 6,000 plant species. The worldwide presence of these plants which may be inadvertently co-harvested with desirable plants could lead to contamination of food, food supplements, herbal medicines, and animal feed. USP is proposing the development of a general informational chapter to provide information about the potential for contamination, structures, and toxic characteristics of PAs .

Preliminary outline: The following sections will be included in the proposed General Chapter:

- Introduction
- Structures of PA families
- Review of Toxicological data: This section summarizes the risk associated with acute and chronic exposure to contaminant PAs.
- Limits of PAs:- This section provides information on the limits established by regulatory agencies.
- Recommended PAs for monitoring: This section provides the list of recommended PAs to be monitored.
- Suitable analytical technique: This section summarizes the available literature on the analytical techniques used in the quantification of

contaminant PAs.

Anticipated activities: USP is requesting early input from stakeholders on this informational General Chapter <1567> *Pyrrolizidine Alkaloids (PAs)* which is planned to be published for comment in *Pharmacopeial Forum* 47(1) [Jan.–Feb. 2021].

Contact: Sandeep Putty, Associate Scientific Liaison (301-692-3664, sandeep.putty@usp.org)

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