

General Chapter Prospectus

Elizabeth Bladen, M.A., M.L.S., M.S.



Background



- ▶ The General Chapter Prospectus is a type of Compendial Notice
- ▶ Prospectus are posted on the Compendial Notices Page under the General Chapter Prospectus Section
 - <https://www.uspnf.com/notices>
- ▶ USP began posting these notices in February 2016
- ▶ 31 notices have been posted
- ▶ SLs are encouraged to post a Prospectus Notice for all new GC or major revisions
- ▶ Designed for use with General Chapters, but we have posted similar “Early Input” notices for other types of standards

- ▶ Solicit preliminary/early input from stakeholders on proposed new standards or major revision
 - Input received is considered for inclusion of PF proposal, but is not included in commentary
- ▶ Increase awareness of USPs planned activities related to standard development prior to their publication in *PF*
- ▶ Help USP identify stakeholders, user needs, and potential risks early in the development process
- ▶ Provide EP/EC with information to direct the development of the standard content
- ▶ Minimize number of times a proposal needs to be published in *PF*

Content



- ▶ Basic Information (Expert Committee, SL contact information)
- ▶ Input Deadline
- ▶ Background and Objections
- ▶ Estimated proposal in PF
- ▶ Preliminary Outline
- ▶ Description of scope and application
- ▶ Suggested audience
- ▶ Anticipated proposed design phase activities
- ▶ Implementation Timeframe

General Chapter Prospectus

As part of a pilot process, USP Expert Committee members will develop a brief prospectus for new general chapters or major general chapter revisions prior to their publication in Pharmacopeial Forum (PF). The purpose of these is to solicit input during the early stages of general chapter development. The input received from the prospectus process will be considered as advisory only. Formal comments on subsequent PF proposals must be submitted separately at the time of publication in PF.

Below is a listing of the currently active general chapter prospectus notices:

- [New Proposed Chapter: <1085> Guidelines on Endotoxins Test](#) (posted 26-Jan-2018)
- [New Proposed Chapter: Evaluating Screening Technologies for Assessing Medicine Quality](#) (posted 29-Dec-2017)
- [New Proposed Chapter: Supplier Qualification by User of Upstream Supply Chain for Pharmaceutical Excipients](#) (posted 30-Mar-2018; deadline 30-Apr-2018)
- [<541> Titimetry](#) (posted 29-Sep-2017)
- [<825> Compounding—Radiopharmaceuticals](#) (posted 01-Jun-2017; deadline 31-Aug-2017)
- [<922> Water Activity](#) (posted 30-Mar-2018; deadline 30-Apr-2018)
- [<1711> Oral Solid Dosage Forms - Dissolution Testing](#) (posted 29-Sep-2017)
- [<1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions](#) (posted 30-Mar-2018; comment deadline 30-Apr-2018)
- [<2740> Manufacturing Practices for Dietary Ingredients](#) (posted 29-Sep-2017)

Screen shot from Compendial Notices webpage

<922> Water Activity

Type of Posting: General Announcement

Posting Date: 30-Mar-2018

Input Deadline: 30-Apr-2018

Expert Committee: General Chapters—Physical Analysis

Proposed new title: <922> *Water Activity*

Suggested audience: Suppliers and manufactures of excipients, drug substances, drug products, veterinary products, regulatory agencies, and manufacturers of water activity instruments

Estimated proposal PF: *Pharmacopeial Forum* 44(6) [Nov.–Dec. 2018]

Background and objective(s):

Water activity (A_w) refers to the effective concentration of pure water in a raw material or product. When water is strongly bound to a solute or surface, it does not contribute to the water activity. Measurements of water activity are made by allowing a sample to equilibrate with the moisture in the headspace above the sample and then measuring the equilibrium relative humidity (ERH) of the headspace. At equilibrium, the ERH is also a measure of the A_w in the formulation. Water activity meters measure the relative humidity with a moisture-dependent resistor or capacitor or may use psychometry (wet bulb temperature) or dew point depression. Regardless of the principle of measurement, water activity meters can be calibrated and qualified using the same saturated salt reference solutions. This chapter will outline the recommended methods to qualify, calibrate, and use water activity meters to accurately measure the water activity of raw materials and products.

Description of scope and application: This new general chapter is intended to provide guidance for performing measurements of water activity (A_w). The general chapter will specify methods for qualification of instruments, calibration of instruments, methods for performing water activity measurements, and reporting of results.

Preliminary outline:

- Introduction
- Background



*Screen shot
from webpage*

Example Continued



- Operation and Calibration of Water Activity Meters
 - Standard Saturated Salt Solutions
 - Calibration of Water Activity Meters
 - Dew Point Hygrometer
 - Electronic Hygrometer
 - Near Infrared spectrometry
 - Precision/Repeatability Assessment (Performance Qualification)
 - Measurement of Water Activity
 - Sample Preparation
 - Calibration Check
 - Measurement Procedure
 - Reporting Results
- Assay Verification and Validation
- Troubleshooting
 - Dew Point Hygrometer
 - Electronic Hygrometer
 - Near Infrared spectrometry
- Glossary
- References

Anticipated proposed design phase activities: The general chapter will be developed by a Joint Subcommittee with representation from General Chapters—Physical Analysis, General Chapters—Microbiology, and the Non-botanical Dietary Supplements Expert Committees. In addition, the Joint Subcommittee will assess the impact of the new general chapter on the existing General Chapter <1112> *Microbiological Attributes Of Nonsterile Pharmaceutical Products—Application Of Water Activity Determination* and work with the General Chapters—Microbiology EC to update <1112> to align with this new general chapter.

Anticipated implementation timing: Routine

Contact: Antonio Hernandez-Cardoso, M.Sc., Senior Scientific Liaison, (301-816-8308), AHC@usp.org.



Next Steps



- ▶ Is there a better location for these types of notices?
- ▶ Is there information that would be more useful to stakeholders?
- ▶ Coordination with other initiatives to improve public input process

Thank You



Empowering a healthy tomorrow