
<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 psychrometry (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
- Application of Water Activity Measurements
- Types of Water Activity Meters
 - Electronic Hygrometer
 - Resistance hygrometer
 - Capacitive hygrometer
 - Psychrometric (wet bulb temperature)
 - Dew Point
 - Chilled-mirror hygrometer
 - Thermocouple
 - Hair hygrometer
 - Freezing-point depression sensor
 - Near infrared spectrometry
- 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).