Early Input Sought on Proposed <915> Measurement of Structural Strength of Semisolids by Penetrometry

Type of Posting: General Announcement

Posting Date: 01–Feb–2017

Expert Committee: General Chapters—Physical Analysis

Input/Comment Deadline: 31–May–2017 (comment deadline for PF 43(2) [Mar.–Apr. 2017])

Background and objective(s):

USP is requesting early input from stakeholders on a new proposed General Chapter <915> Measurement of Structural Strength of Semisolds by Penetromety, which will be published for comment in Pharmacopeial Forum 43(2) [Mar.–Apr. 2017].

This chapter will describe the empirical methods of measuring the structural strength, or consistency, of a semisolid raw material or dosage form with a penetrometer. Viscosity represents the proportionality of the shear stress to the shear rate for a Newtonian fluid, whereas consistency is the term for this proportionality for semisolids that exhibit non-Newtonian viscoelastic rheological behavior. Because the term consistency may be confused with uniformity or homogeneity, the term structural strength is now the preferred term. In the remainder of this chapter we will use the term structural strength to refer to this property of semisolids. One component of the structural strength of a semisolid is its hardness (yield stress). Penetrometry is one method for quantifying the hardness of semisolid materials.

Penetrometry allows a metal cone with standardized dimensions and weight to penetrate into a semisolid until the buoyancy of the cone and the yield stress of the semisolid exactly balance the gravity-applied force, driving the penetrating object into the semisolid. This observed yield stress of the semisolid is a measure of the semisolid hardness. The yield stress (hardness) of the semisolid will be inversely proportional to the penetration depth of the cone.

This chapter will outline the method for performing the gravity-driven penetrometry measurements of semisolids. Although the results of the

penetrometry measurements may be used to calculate the yield stress of the semisolid (see *Measurement of Hardness of Semisolids* <1912> for more information), the results of the penetrometry experiment are reported as the observed penetration depth in tenths of millimeter (dmm). This chapter also outlines an alternate method for using computer-controlled instruments to perform penetrometry measurements to achieve results that are comparable to the traditional gravity-driven method.

Description of scope and application:

This chapter outlines the method for performing the gravity-driven penetrometry measurements of semisolids, as well as an alternate method for using computer-controlled instruments to perform penetrometry measurements to achieve results that are comparable to the traditional gravity-driven method. This chapter could be considered complementary to the new general informational chapter <1912> *Measurement of Hardness of Semisolids* proposed in the same issue of the PF.

Preliminary outline:

- Introduction
- Apparatus
- Procedure
    - Sample Preparation
    - Determination of Penetration
    - Method I (gravity-driven measurement of structural strength)
    - Method II (constant-speed measurement of structural strength)
- Expression of Results
- Glossary

Estimated proposal Pharmacopeial Forum:

PF 43(2) [Mar.–Apr. 2017]

- View proposed text in advance of its publication in PF

Anticipated implementation timing:

Routine, in-process revision

Contact:

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