<382> Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems

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Expert Committee: General Chapters—Packaging and Storage

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Suggested audience: Drug product manufacturer using elastomeric component with a packaging system

Estimated proposal Pharmacopeial Forum: *PF* 43(3) [May–Jun. 2017]

Description of scope and application: This chapter will address the functionality requirements of packaging/delivery systems intended for injectable dosage forms that include primary packaging components partially or completely made of elastomeric material. Elastomeric closures when properly fitted with dimensionally compatible packaging/delivery systems are intended to protect and contain the package contents while enabling safe and effective product access at the time of use.

The function being performed by an elastomeric closure is dependent on the packaging/delivery system and may cover more than one functional parameter. In all cases, the elastomeric closure acts as a seal, protecting the drug product from product loss and from contamination by microorganisms and other environmental contaminants, such as gases that pose product quality risk. In the case of dual chamber packaging systems, the elastomeric closure keeps drug product components separate, and limits excessive migration of solvents or gases between chambers. Additional functional requirements depend on the intended use of the individual packaging/delivery system. In pre-filled syringes, cartridges, pens, jet and related injectors, the elastomeric closure (plunger) is required to move in order to empty the container upon demand. The Break Force, Glide Force, and the Plunger Seal Integrity tests are provided to aid the evaluation of these systems. Some elastomeric closures are intended to be singly pierced by a spike, or a needle and others are designed to be repeatedly pierced Here the determination of Penetrability, Fragmentation and Self-

Sealing Capacity are relevant.

The functionality tests outlined in the chapter are intended to evaluate the fitness of a closure as part of its specific final product packaging system

Preliminary outline:

1. Introduction
2. Scope
3. General Test Requirements
4. Assessment of Packaging/Delivery systems Elastomeric Closure Functionality
    - 4.1. Package integrity
    - 4.2. Needle and spike access functionality tests
        - 4.2.1. Fragmentation
        - 4.2.2. Penetration force
        - 4.2.3. Self-sealing capacity
        - 4.2.4. Spike retention and sealability capacity
    - 4.3. Plunger functionality tests
        - 4.3.1. Plunger break force and glide force
        - 4.3.2. Plunger seal integrity
    - 4.4. Tip cap and needle shield functionality tests
        - 4.4.1.Tip cap and needle shield removal force

Anticipated proposed design phase activities (stimuli article, workshop, etc.): To initiate an open dialog with stakeholders regarding this revision, the Expert Committee will host a Workshop at USP Headquarters in Rockville, MD on June 19–20, 2017. The input received during this Workshop will provide input to the revision of the General Chapter.

Anticipated implementation timing (routine, extended, etc.): To be determined

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