# <381> Elastomeric Closure for Injections

**Type of Posting:** General Chapter Prospectus

**Posting Date:** 30–Dec–2016

**Expert Committee:** General Chapters—Packaging and Storage

**Input Deadline**: January 30, 2017

**Suggested audience**: Suppliers of elastomeric materials and components used for packaging systems (primary packaging components) and drug product manufacturers using elastomeric component and system primary containers

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

**Background and objective(s)**: Every elastomeric component used in pharmaceutical packaging and delivery system should be proven safe and compatible for its intended use. It is the purpose of this chapter to provide baseline requirements for the selection of elastomeric components to be further qualified for use in a given system. These same principles can be applied to elastomeric components used in medical devices and combination products, with consideration of the appropriate guidances and regulations.

Establishing the potential safety of a component cannot rely on a single testing strategy, because a single testing strategy cannot cover all of the component's attributes that have a potential safety impact. The chemical testing prescribed is orthogonal in that the Physicochemical Tests provide a general overview of extracted chemical entities and the Extractable Elements Test provides a quantitative assessment of extractable elements of concern. Chemical testing alone may not be adequate to establish a component's safety and compatibility, chemical testing it is augmented by the orthogonal approach of establishing biological reactivity. Determining the suitability of a component to function properly will need consideration of the complete system.Testing must be designed to meet the requirements for intended use as is described in *Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems* <1381>. If components comply with requirements outlined in the chapter, studies should then

be designed to determine safety and compatibility as recommended in *Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems* <1663> and *Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems* <1664>.

Establishing the suitability of packaging systems for pharmaceutical products involves multiple tests and testing procedures, as briefly outlined below:

- Component screening: Baseline requirements in <381> comprise characterization of the elastomer's biological reactivity, physicochemical properties and extractable metals
- Controlled extraction (simulation) study: Worst-case controlled extraction (simulation) study for applicants to determine the extent to which extractables may become probable leachables (for additional information, see *Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems* <1663>).
- Pharmaceutical product assessment: Actual-case measurement of confirmed leachables in the pharmaceutical product in the pharmaceutical packaging/delivery system intended for the commercial market (for additional information, see *Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems* <1664>).

**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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