

## Cured Silicone Elastomers for Pharmaceutical Manufacturing and Packaging Components

**Type of Posting:** General Chapter Prospectus

**Posting Date:** 27-Dec-2019

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

**Input Deadline:** 26-Jan-2020

**Proposed New Title:** <668> Cured Silicone Elastomers for Pharmaceutical Manufacturing and Packaging Components

**Suggested audience:** R&D scientists, contract research organizations, contract manufacturing organizations, Regulatory Affairs, QA/QC specialists

**Estimated proposal PF:** *Pharmacopeial Forum* 46(5) [Sep.–Oct. 2020]

**Background and objective(s):** The General Chapters—Packaging and Distribution Expert Committee will propose a new chapter, <668> *Cured Silicone Elastomers for Pharmaceutical Manufacturing and Packaging Components*, based on comments received from the *Pharmaceutical Forum* 45(2) [Mar.—Apr. 2019] publication of <665> *Plastic Materials, Components, and Systems Used in the Manufacturing of Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products*.

**Description of scope and application:** This chapter would apply to cured silicone components such as tubing, gaskets, and O-rings that are used in manufacturing operations for drug substances and drug products, as well as silicone components for pharmaceutical packaging systems.

Preliminary outline:

- Biological Reactivity
- Identification
- Physicochemical Tests:
  - Appearance
  - Acidity or alkalinity
  - Reducing Substances
  - Substances soluble in hexane
  - Phenylated compounds
  - Mineral Oils
  - Volatile matter
  - Residual peroxides
  - Platinum

**Anticipated implementation timing:** To be determined based on stakeholder feedback.

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