

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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