General Chapter Prospectus: <1711> Oral Solid Dosage Forms - Dissolution Testing

Type of Posting: General Announcement
Posting Date: 29–Sept–2017
Expert Committee: General Chapters Dosage Forms

Proposed New Title: <1711> Oral Solid Dosage Forms – Dissolution Testing

Input Deadline: 31–Oct–2017

Estimated proposal PF: Pharmacopeial Forum 44(4) [July – Aug 2018]

Description of scope and application: This new informational general chapter will provide approaches for the development of dissolution test procedures for solid oral dosage forms intended for human and veterinary applications, which are not provided by General Chapters <711> *Dissolution*, <724> *Drug Release*, and <1092> *The Dissolution Procedure*: *Development and Validation*. This new chapter will cover sample preparation, sample introduction to the dissolution apparatus, cases where both disintegration and dissolution tests are needed and cases where the dissolution procedure may be replaced with the disintegration test.

Preliminary outline:
1 – Introduction
2 – Dissolution Procedure Development
3 – Solid Oral Dosage Forms
3.1 Tablets
3.1.1 Effervescent Tablets
3.1.2 Chewable Tablets
3.1.3 Sublingual Tablets
3.1.4 Buccal Tablets

3.1.5 Osmotic Pump Tablets
3.1.6 Orally Disintegrating Tablets
3.1.7 Extended-release Tablets
3.1.8 Delayed-release Tablets
3.1.9 Tablets for Oral suspension
3.2 Capsules
3.3 Granules, pellets or sprinkles that are administered with food or beverages
3.4 Buccal Film
3.5 Suspension and Powder or Granulate for Suspension
3.6 Lozenges
3.7 Oral Paste and Oral Gel
3.8 Chewable gel
3.9 Animal Feed and Animal Pre-mix

Anticipated implementation timing: routine

Contact: Margareth R. C. Marques, M.Sc., Principal Scientific Liaison, Ph.D., (301- 816-8106, mrm@usp.org)