The USP Excipients Stakeholder Forum
Meeting # 2
June 18, 2014

Gelatin, Capsules, Dissolution -
Revisions under Development

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Revisions under Development

- **Gelatin monograph**
  - Harmonized with EP and JP
  - Include requirements for gelatin used in capsules manufacture

- **Hard gelatin capsule shell**
  - New monograph
  - Limit of chromium
  - Limit of melamine
  - Storage conditions
Revisions under Development

- **Pepsin**
  - Activity determination procedure harmonized with FCC
  - Published in PF 39(6) – several comments received
  - New revision in a future issue of Pharm. Forum

- **Simulated Gastric Fluid**
  - Revision to the amount of pepsin

- **Bromelain**
  - Revision to the reagent entry to include additional information and procedure for activity determination
  - Possible development of a reference standard
Revisions under Development

- **<711> Dissolution**
  - Revision to the use of enzymes
  - Stimuli article with rational, calculations and references

- **<1094> Capsules – Dissolution Testing and Related Quality Attributes**
  - 1st Suppl. of USP 37, official on May 1, 2014.
  - Revision in PF 40(4) or 40(5)
Revisions under Development

- **<2040> Disintegration and Dissolution of Dietary Supplements**
  - Revision harmonized with <711>
  - Published in the same issue of PF as <711>

- **<1092> The Dissolution Procedure – Development and Validation**
  - Published in PF 40(1)
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Thank You