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The USP Excipients Stakeholder Forum
Meeting # 2
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Gelatin, Capsules, Dissolution - Revisions under Development

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▶ 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

▶ 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

- ▶ **<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)

- ▶ **<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