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<1151> Pharmaceutical Dosage Forms and <1152> Animal Drugs for Use in Animal Feeds

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Veterinary Drugs Stakeholder Forum
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- ▶ *Development of a Compendial Taxonomy and Glossary for Pharmaceutical Dosage Forms*, PF 29(5) [Sept, 2003], K Marshall, TS Foster, HS Carlin, RL Williams
- ▶ Organized in three tiers
- ▶ Route of administration,
- ▶ Dosage form
 - ▶ Grouped as solid, liquid, gas, or aerosol with specific form (e.g., tablet, cream, insert) as subordinate categories
- ▶ Type of release: immediate or modified

- ▶ General Information Chapter
- ▶ Longstanding chapter recently revised, USP 35 official May 1, 2012
- ▶ High level information on dosage forms
- ▶ Organized on basis of physical form
 - Route of administration addressed in Chapters <1> to <5>

- ▶ General Considerations
- ▶ General Product Quality Tests
- ▶ Dosage Forms
- ▶ Glossary

- ▶ Dose Uniformity
- ▶ Stability
- ▶ Bioavailability
- ▶ Manufacture
- ▶ Route of Administration
- ▶ Packaging and Storage
- ▶ Labeling

- ▶ Follows ICH Q6A
- ▶ Description (Definition)
- ▶ Identification
- ▶ Assay
- ▶ Impurities
- ▶ Sterility
- ▶ Bacterial endotoxins
- ▶ etc

Aerosols

Capsules

Creams

Emulsions

Films

Foams

Gases

Gels

Granules

Gums

Implants

Injections

Inserts

Irrigations

Liquids

Lotions

Lozenges

Ointments

Pastes

Pellets

Pills

Plasters

Powders

Soaps/Shampoos

Solutions

Sprays

Strips

Suppositories

Suspensions

Systems

Tablets

Tapes*

Dosage Forms:

A combination of drug substance(s) and/or excipient(s) in quantities and physical form designed to allow the accurate and efficient administration of the drug substance to the human or animal patient

Related Terminology

- ▶ Release pattern— Immediate, Extended, Delayed
- ▶ Preferred terminology indicated for entries that represent not preferred terminology

<1152> Animal Drugs for Use in Animal Feeds

Premixes not preferred although a legacy term (e.g., Monensin, Narasin, and Decoquinate)

Not dosage forms by the definition in <1151>

- ▶ Particularly so for drugs given free choice

New general information chapter proposed, PF 40(1) January 2014

General descriptions and definitions

General principals of preparation

Labeling and packaging

Nomenclature

- └ Type A medicated article
 - └ Type A liquid medicated article
- └ Type B medicated feed
 - └ Type B liquid medicated feed
- └ Type C medicated feed
 - | Type C liquid medicated feed
 - | Type C free-choice medicated feed
 - | Type C liquid free-choice medicated feed
 - └ Type C top-dress medicated feed

<1151> addresses dosage forms. Content is intended to apply to animal as well as human dosage forms. The chapter is expected to undergo continuous revision. Please forward any suggestions to me.

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Comment period for PF 40(1) ends March 31

<1> Injections and Implanted Drug Products (Parenterals) - Product Quality Tests

Route of administration(Liaison)

- 1. Injectable / Parenteral(Desmond Hunt)**
2. Oral.....(Antonio Hernandez-Cardoso)
3. Skin surface (Topical, Transdermal).....(Margareth Marques)
4. Mucosal(Will Brown)
5. Lungs, Inhalation (aerosols)(Kahkashan Zaidi)

Team lead: Vinod Shah, USP consultant

- ▶ Original title of a longstanding chapter
- ▶ Title change
- ▶ Content revised to fit into approach taken for the five route chapters
- ▶ Some content moving to other general chapters

Universal product quality tests—Derived from ICH Q6A

Tests for specific parenteral dosage forms—

- | | |
|----------------------------------|--------------|
| ▶ Solutions | Emulsions |
| ▶ Sterile powders for injection | Liposomes |
| ▶ Suspensions | In situ gels |
| ▶ Microparticles | Implants |
| ▶ Stents and Drug Eluting Stents | |

To <7> Labeling

- Labels and Labeling
- Potassium Chloride for Injections Concentrate
- Neuromuscular Blocking and Paralyzing Agents

To <659> Packaging and Storage Requirements

- Containers for Injections
- Containers for Sterile Solids
- Packaging and Storage

To a new chapter, <697> Container Content for Injections

- Container Content

All chapters, <1>, <7>, <659>, and <697> will move to official status at the same time.

USP Packaging Standards

- ▶ <659> Packaging and Storage Requirements
- ▶ <660> Containers—Glass
- ▶ <1660> Evaluation of Inner Surface Durability of Glass Containers
- ▶ <661> Plastic Packaging Systems and Their Materials of Construction
- ▶ <661.1> Plastic Materials of Construction

- ▶ <661.1> Plastic Materials of Construction
- ▶ <661.2> Plastic Packaging Systems for Pharmaceutical Use
- ▶ <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems
- ▶ <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems
- ▶ <1664.1> Orally Inhaled and Nasal Drug Products

Questions

Thank You