Pharmaceutical Dosage Forms and Animal Drugs for Use in Animal Feeds

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Veterinary Drugs Stakeholder Forum
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USP Dosage Forms Taxonomy

- 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>
<1151> Organization

- General Considerations
- General Product Quality Tests
- Dosage Forms
- Glossary
<1151> General Considerations

- Dose Uniformity
- Stability
- Bioavailability
- Manufacture
- Route of Administration
- Packaging and Storage
- Labeling
Follows ICH Q6A

Description (Definition)
Identification
Assay
Impurities
Sterility
Bacterial endotoxins
etc
### Dosage Forms

<table>
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<th>Aerosols</th>
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<td>Systems</td>
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<td>Granules</td>
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<tr>
<td>Gums</td>
<td>Pills</td>
<td>Tapes*</td>
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<td>Implants</td>
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</tbody>
</table>
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
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
Chapter content at a glance

General descriptions and definitions

General principals of preparation

Labeling and packaging

Nomenclature
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
Some requests

<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
- Sterile powders for injection
- Suspensions
- Microparticles
- Stents and Drug Eluting Stents

- Emulsions
- Liposomes
- In situ gels
- Implants
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
Packaging and Storage Requirements

Containers—Glass

Evaluation of Inner Surface Durability of Glass Containers

Plastic Packaging Systems and Their Materials of Construction

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