

Compounding for Animal Patients: Background and USP's Role

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Current Environment

Compounding need is great across veterinary medical practice

Interdisciplinary training/resources is lacking or absent

- Veterinarians are not trained in pharmaceutical compounding
- Pharmacists are not trained in veterinary pharmacotherapy

Compounds for animal patients are currently prepared largely from sources using non-standardized methods

- Pharmacy prepared
- Veterinary practice prepared
- Other

Veterinary compounding may be driven by economic factors

Compounds have become commoditized in the veterinary sector

Problems

Therapeutic failure

- Variable compound composition
- Variable compound stability
- Variable compound quality and performance

Toxicity

- Contamination
- Potency
- Suspending vehicle
- Preservatives
- Flavors/sweeteners
- Dyes

Drug Entity “death”

- Compound failure attributed to drug failure or drug resistance

Solutions

Uniform monographs for compounds prepared for animals

- Product monographs for approved veterinary products
- Substance monographs for veterinary API's
- Standardized formula with “vetted”:
 - USP grade API's and NF grade excipients
 - Compounding procedure
 - Stability-indicating assay-determined BUD
 - Packaging, labeling and storage directives

Uniform compounding process and acceptance criteria

- General Chapter guidance

USP's Role

Standard Setting

Product
Monographs

Substance
Monographs

Preparation
Monographs

General
Chapters

Outreach

USP's Role

Product Monographs

- AMDUCA codified compounding for animals utilizing FDA-approved products
- Known potency range for starting ingredients from product monographs
- Known dosing metric (base or salt)
- Need product monographs for all approved veterinary drugs

USP's Role

Substance Monographs

- USP grade API's when approved product inappropriate
- Known identity, purity, strength and quality
- Known potency range of API
 - Compare to Certificate of Analysis
- Known acceptance criteria for quality assurance

USP's Role

Compounded Preparation Monographs

- 5 currently official
- 17 contracted out for assay/BUD determination
- Top 50 veterinary compounds solicited from:
 - American Veterinary Medical Association
 - Society of Veterinary Hospital Pharmacists
 - International Academy of Compounding Pharmacists
- CEC continues to prioritize monograph suitability for remaining 2010-15 and into next Cycle

USP's Role

General Chapters

- Standards to ensure:
 - Consistent preparation and quality control
 - Minimized risk
 - Personnel training
 - Detailed documentation
 - SOP's
 - Training
 - Preparation logs
 - Engineering controls
 - Preparation QA and testing

There is no “veterinary practice exemption” in FD&C Act

USP's Role

Outreach

- Webinars
 - Veterinary community targeted
 - CE for compounding concepts
 - USP standards and the veterinarian
 - Potency vs. stability
 - Stability vs. bioavailability
- Publications
 - *USP on Compounding: A Guide for the Compounding Practitioner*
- Workshops
 - Veterinary community targeted