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VETERINARY DOSAGE FORM: REVIEW

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ABSTRACT

Veterinary medicine is the branch of science that deals with the application of science, public, health, dental, diagnostic and therapeutic principle to nonhuman animal including wildlife and domesticated animal including livestock working animal and companion animals. In this review, is to provide the Classification of animals, Need of Veterinary Dosage Form, Veterinary drugs, Dosage form and route, Stability of Drugs, Evaluation.

INTRODUCTION

Veterinary medicine is the branch of science that deals with the application of medical, surgical, public health, dental, diagnostic and therapeutic principles to nonhuman animal including wildlife and domesticated animal including livestock working animal and companion animals. Just like humans, animals receive medicines to keep them hale and hearty. Drugs have been compounded for veterinary practice for many years but, Regulations and Compliance Policy Guidelines (CPGs) should be recognized. A CPG issued in July 2003 listed the current Food and Drug Administration (FDA) limitations on compounding for veterinary medicine. However, veterinarians and pharmacists must be aware of potential incompatibilities and practices that may interfere with the drugs stability, purity, and potency.

Classification of animals:

1) Classification based upon eating habit:

- Herbivorous genus consist of horse and ruminant animals like cattle, sheep, goat.
- Carnivorous genus consists of dog and cat.
- Omnivorous genus consists of pig.
- The digestive system is the principal distinguishing feature between herbivorous and carnivorous species.
- Humans and animals having distinguishing digestive system main difference in the length of the intestinal tract.

2) Classification based upon the rumen:

Hofmann and Stewart divided ruminants into three major categories based on their feed type and feeding habits:

- Concentrate selectors.
- Intermediate types.
- Grass or roughage eaters.
- Pseudo-ruminants.

3) Canine, Fenine:

They are classified into four types:

- Foxes
- Wolves
- Jackals
- Dogs

Need of veterinary dosage forms:

Veterinary science is vital to the study and protection of animal production practices, herd health and monitoring spread of disease like swine flu, chikengunea etc.

Flavors that animals prefer include:

- **Dog:** Prefers beef, Chicken, Cheddar Cheese, Molasses, Peanut Butter, Liver, Raspberry, and Strawberry.
- **Cat:** Prefers Tuna, Chicken, Beef, Cheddar Cheese, Peanut Butter, Liver, and Butterscotch.
- **Bird:** prefers Grape, Mandarin Orange, Tutti-Frutti, Molasses, and Pina Colada.
- **Horse:** prefers Apple, Creamy Caramel, Molasses, Licorice, and Cherry.
- **Rabbit:** prefers Banana.
- **Ferret:** prefers Bubble Gum, Molasses.
- **Gerbils:** prefers Mandarin Orange, Tutti-Frutti.

Diseases in animals

1) Parasitic diseases:

- Strongyloidea (Swine)
- Ancylostomatoidea (Horse)
- Siphonaptera (cattle's)
- Ascaridoidea (Cats and dogs)

2) Bacterial diseases:

- Yersiniosis (Swine's)
- Salmonellosis (Chickens)
- Q-fever (Cattles)
- Rabies (Dogs)

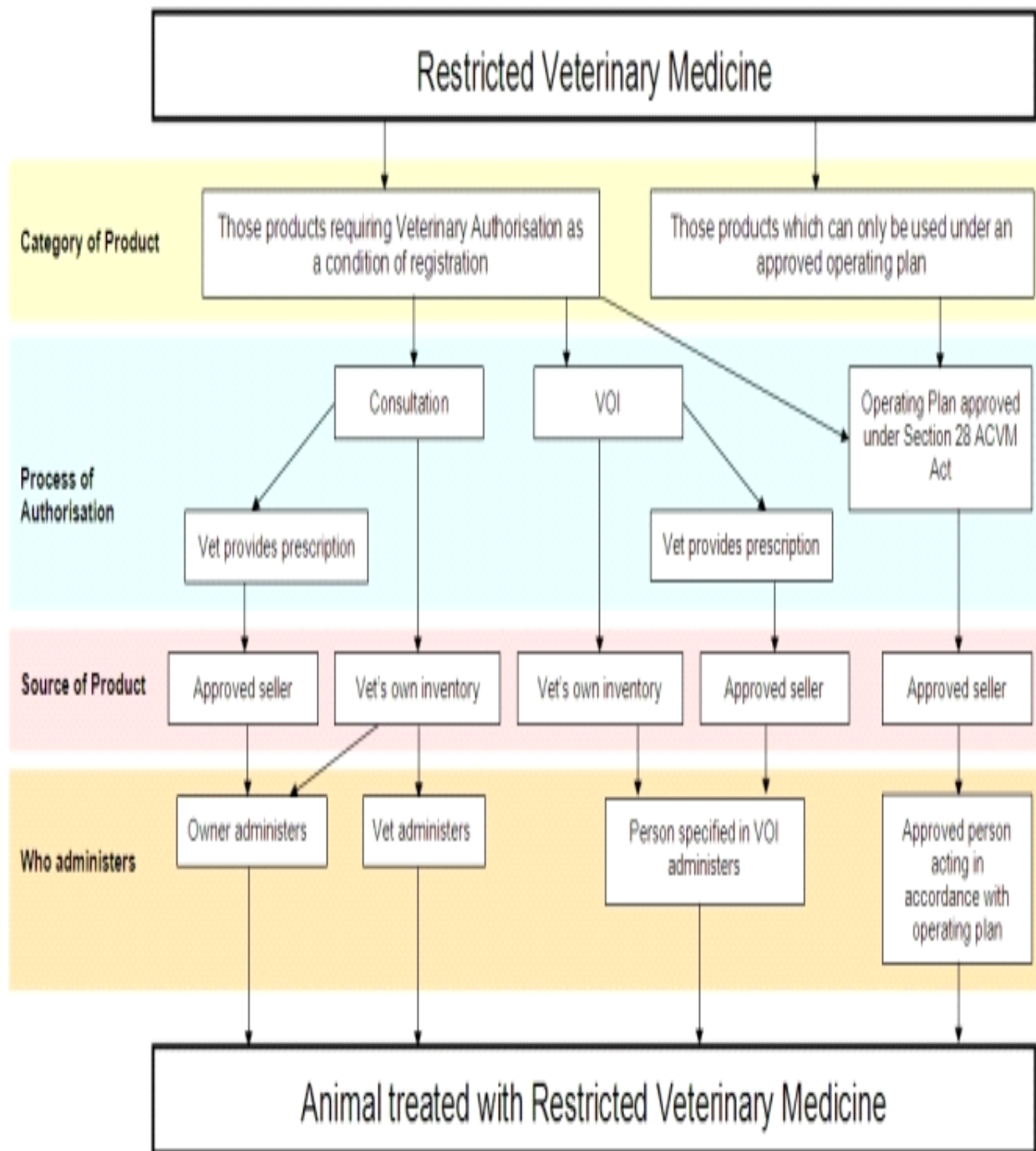
3) Diseases transmitted from animals to human :

These are called as zoonotic diseases. All infectious diseases can transmit from animals. Example of zoonotic diseases includes-Plague, Rabies, Lyme diseases, Ringworm, Tick paralysis, Swine flu, Giardiasis, Chickengunia.

List of Veterinary Medicine:

Acepromazine –	Neuroleptic drug related to chlorpromazine used as a sedative and antiemetic.
Alprazolam –	(Trade name Xanax); used to treat anxiety.
Amantadine –	As an analgesic for chronic pain (this drug is not used in the veterinary field).
Amitraz –	Antiparasitic used to control ticks, mites, lice and other animal pests. Cannot be used on horses.
Amitriptyline –	Tricyclic antidepressant used to treat separation anxiety, excessive grooming and spraying in dogs and cats.
Atipamezole –	Alpha2-adrenergic antagonist used to reverse the sedative and analgesic effects of dexmedetomidine and medetomidine in dogs.
Boldenone –	Anabolic steroid for treatment of horses.
Buprenorphine –	Narcotic for pain relief in cats after surgery.
Butorphanol –	Mu agonist/kappa antagonist, used as a cough suppressant and for a muscle relaxation effect in horses.
Carprofen –	COX-2 selective NSAID used to relieve pain and inflammation in dogs. Anecdotal reports of severe GI effects in cats.
Cefovecin –	Cephalosporin-class antibiotic used to treat skin infections in dogs and cats.
Dichlorophene –	Fungicide, germicide, and antimicrobial agent used for the removal of parasites such as ascarids, hookworms, and tapeworms from cats and dogs.

Restricted Veterinary Medicine:



Classification of Veterinary Delivery Devices:

- 1) Oral Devices:
 - a. Balling gun
 - b. Esophageal delivery devices
 - c. Drench syringes
 - d. Liquid drench guns

- e. Powder drench guns
- f. Paste Dispensers
- g. Water medication metering devices
- h. Rumen lodging devices
- i. Hollow bits
- j. Non pyloric passage devices
- k. Miscellaneous oral dose dispensers

It includes:

- Pump type dispensers
- Nursers
- Droppers
- Mineral dispensers
- Mouthpieces

- l. Buoyant devices
- m. Prolonged release devices
- n. Miscellaneous oral dose dispensers

The main signs of oral disease include:

- Halitosis
- Broken or discolored teeth
- Changes in eating behavior
- Rubbing or pawing at the face
- Ptyalism
- Bleeding from the mouth
- Inability or unwillingness to open or close the mouth
- Change in temperament
- Morbidity
- Weight loss

2. Topical devices:

- a. Pour on, spot on application
- b. Dust bags
- c. Spray race and dip
- d. Teat dip

- e. Aerosol Dispensers
- f. Flea and tick collars
- g. Percutaneous devices

3. Parenteral devices:

- a. Single dose syringe
- b. Multiple dose syringes
- c. Automatic syringes
- d. Multi compartment syringes
- v. Miscellaneous syringes

It includes:

- Gas powdered hypodermic syringe
- Motor actuated syringe
- Flexible needle syringe
- Implanting devices:

Three types of implanting devices are used in veterinary practices:

- Pellet Implanting devices
- Ball Implanting devices
- Molten Implanting devices

Drug Dosage Forms in Veterinary Medicine:

Species code:

Can =	Canine
Fel =	Feline
Bov =	Bovine
Ov =	Ovine
Cap =	Caprine
Por =	Porcine
Rod =	Rodents(individual species listed by name)
Rab =	Rabbit
NHP =	Nonhuman primate
Av =	Avian
Rep =	Reptiles (species listed by name)
Am=	Amphibians (species listed by name)

Oral Drug Dosage Form:

Oral dosage forms comprise liquids (solutions, suspensions, and emulsions), semi-solids (pastes), and solids (tablets, capsules, powders, granules, premixes, and medicated blocks).

- a. **Solution** is a mixture of 2 or more components that form a single phase that is homogeneous down to the molecular level. Solutions offer several advantages over other dosage forms. Compared with solid dosage forms, solutions are absorbed faster and generally cause less irritation of the GI mucosa. The disadvantages of solutions include susceptibility to microbial contamination and the hydrolysis in aqueous solution of susceptible active ingredients. In addition, the taste of some drugs is more unpleasant when in solution. Oral solutions provide a convenient means of drug administration to neonates and young animals.
- b. **Suspension** is a coarse dispersion of insoluble drug particles, generally with a diameter exceeding 1 μm , in a liquid (usually aqueous) medium. Suspensions are useful for administering insoluble or poorly soluble drugs or in situations when the presence of a finely divided form of the material in the GI tract is required.
- c. **Emulsion** is a system consisting of 2 immiscible liquid phases, one of which is dispersed throughout the other in the form of fine droplets; droplet diameter generally ranges from 0.1-100 μm . Creaming, as occurs with milk, also occurs with pharmaceutical emulsions. However, it is not a serious problem because a uniform dispersion returns upon shaking.
- d. **Paste** is a 2-component semi-solid in which drug is dispersed as a powder in an aqueous or fatty base. The particle size of the active ingredient in pastes can be as large as 100 μm . The vehicle containing the drug may be water. Pastes are a popular dosage form for treating cats and horses, and can be easily and safely administered by owners.
- e. **Tablet** consists of one or more active ingredients and numerous excipients and may be a conventional tablet that is swallowed whole, a chewable tablet, or a modified-release tablet (more commonly referred to as a modified-release bolus due to its large unit size). Conventional and chewable tablets are used to administer drugs to dogs and cats, whereas modified-release boluses are administered to cattle, sheep, and goats.
- f. **Capsule** is an oral dosage form usually made from gelatin and filled with an active ingredient and excipients. Two common capsule types are available: hard gelatin capsules for solid-fill formulations, and soft gelatin capsules for liquid-fill or semi-solid-fill formulations.

- g. Powder** is a formulation in which a drug powder is mixed with other powdered excipients to produce a final product for oral administration.
- h. Granule** is a dosage form consisting of powder particles that have been aggregated to form a larger mass, usually 2-4 mm in diameter.
- i. Premix** is a solid dosage form in which an active ingredient, such as a coccidiostat, production enhancer, or nutritional supplement, is formulated with excipients. They are administered to poultry, pigs, and ruminants.
- j. Medicated block** is a compressed feed material that contains an active ingredient, such as a drug, anthelmintic, surfactant (for bloat prevention), or a nutritional supplement, and is commonly packaged in a cardboard box. Ruminants typically have free access to the medicated block over several days, and variable consumption may be problematic.

Parenteral Dosage Forms:

Parenteral dosage forms and delivery systems include injectables (i.e., solutions, suspensions, emulsions, and dry powders for reconstitution), intra-mammary infusions, intra-vaginal delivery systems, and implants.

- a. Solution** for injection is a mixture of 2 or more components that form a single phase that is homogeneous down to the molecular level. “Water for injection” is the most widely used solvent for parenteral formulations.
- b. Suspension** for injection consists of insoluble solid particles dispersed in a liquid medium, with the solid particles accounting for 0.5-30% of the suspension. The vehicle may be aqueous, oil, or both. Injectable suspensions are commonly used.
- c. Emulsion** for injection is a heterogeneous dispersion of one immiscible liquid in another; it relies on an emulsifying agent for stability. Parenteral emulsions are rare because it is seldom necessary to achieve an emulsion for drug administration.
- d. Dry powder** for parenteral administration is reconstituted as a solution or as a suspension immediately prior to injection. The principal advantage of this dosage form is that it overcomes the problem of instability in solution.
- e. Mastitis intra-mammary infusion products** are available for lactating and non-lactating (dry) cows. Lactating cow intra-mammary infusions should demonstrate fast and even distribution of the drug and a low degree of binding to udder tissue. These properties result in lower concentrations of drug residues in the milk.

- f. Intra-vaginal delivery systems** include controlled internal drug release (CIDR) devices, progesterone-releasing intra-vaginal devices (PRID), and vaginal sponges. These systems are used for estrus synchronization in sheep, goats, and cattle.
- g. Implants** used in veterinary medicine are compressed tablets or dispersed matrix systems in which the drug is uniformly dispersed within a non-degradable polymer.

Topical Dosage Forms:

The topical dosage forms available for treating animals include solids (dusting powders), semisolids (creams, ointments, and pastes), and liquids (solutions, suspension concentrates, suspoemulsions, and emulsifiable concentrates). Of special interest are transdermal delivery systems that elicit clinical responses by carrying medications across the skin barrier to the bloodstream. Examples of these are transdermal gels and patches that are used in companion animals. Also of interest are dosage forms that are unique to veterinary medicine, such as spot-on, pour-on, and backliner formulations developed for the control of parasites.

- a. Dusting powder** is a finely divided insoluble powder containing ingredients such as talc, zinc oxide, or starch.
- b. Cream** is a semisolid emulsion formulated for application to the skin or mucous membranes. Droplet diameter in topical emulsions generally ranges from 0.1-100 μm .
- c. Ointment** is a greasy, semisolid preparation that contains dissolved or dispersed drug. Ointments are indicated for chronic, dry lesions and contraindicated in exudative lesions.
- d. Paste** for topical use is a stiff preparation containing a high proportion of finely powdered solids such as starch, zinc oxide, calcium carbonate, and talc. Pastes are less greasy than ointments because much of the fluid hydrocarbon fraction is absorbed onto the solid particles. Pastes are indicated for ulcerated lesions.
- e. Solution** for topical use is a mixture of 2 or more components that form a single phase down to the molecular level. Topical solutions include eye drops, ear drops, and lotions.

Drug Stability in Veterinary Dosage Forms:

The January 1979 issue of this Journal contained an editorial on “Consistency in Stability Testing”. This timely editorial was of great interest to the Review Chemists in the Bureau of Veterinary Medicine of the Food and Drug Administration because they are deeply involved in the review and evaluation of stability testing of drug products.

The Bureau of Veterinary Medicine is a counterpart to the Bureau of Drugs, though with a smaller contingent of Review Chemists. The public only hears about veterinary medicine on

such issues as DES, nitrites, nitrofurazones, and low-level antibiotics. The Bureau, however, has a much larger responsibility in approving drugs for animal use. Such critical areas as animal safety and human safety must be considered in addition to the effectiveness of the drug. The process of approval is just as intense as that for human products. In many cases, the approval is more critical since food products are involved. Veterinary drug products are sold as pharmaceutical dosage forms (identical in many cases to the human dosage forms except for labeling), as medicated feed preparations (premixes, supplements, and complete feeds), and as other forms such as medicated blocks. Bureau Review Chemists are responsible for evaluating the manufacturing operations related to the production of the final products to ensure that they meet the standards they purport to possess.

Stability is an important issue for veterinary products just as it is for human products. In fact, the issue is much more complex because of the variety of products and use patterns. Because of these complexities and often questionable areas of stability testing for veterinary products, the Bureau of Veterinary Medicine developed a set of guidelines for industry and reviewer use. The Bureau issued the Guidelines in July 1976 with a Federal Register² notice of availability in November of the same year. The Guidelines were updated in February 1978.

For veterinary products, stability is probably more critical and harder to focus on. Because of obvious reasons, human drug products enjoy a much higher plateau in the various fields of research and methods development. Human products are often used under controlled situations or conditions—stored in pharmacies and used in clinics, hospitals, and households. Probably the only controlled conditions for veterinary product usage, however, are in veterinary clinics, hospitals, or offices. Use by farmers of drugs purchased by them or dispensed to them leaves much to be desired as far as stability and shelf life are concerned. Many animal drugs are subjected to higher temperatures and abuse than human drug counterparts. However, as provided under our laws, a veterinary drug is a “drug” and must meet the requirements and individual standards of strength, quality, purity, and identity as proclaimed by the Act. The drug must also be manufactured under the cGMPs as published by the FDA. We, in the Bureau of Veterinary Medicine, feel the Guidelines we have issued are meaningful and provide the guidance needed by industry. Many companies concerned with human pharmaceuticals are currently using our Guidelines. The Guidelines represent our best scientific judgment on the topic and should be used as just that—“guidelines.” Our general position is that every product is unique and must “stand on its own” as far as stability is concerned.

Product Quality and Efficacy:

Before they can be put on the market, the efficacy of veterinary products is confirmed by trials under field conditions. High standards of purity and consistency Pharmaceutical quality is an essential ingredient of product safety, and requires the product to be manufactured according to specific standards of purity and consistency. These standards apply throughout the production and formulation process. Stability studies ensure that the product retains its potency, efficacy and safety, for the full duration of the shelf-life.

Testing methods are continuously being improved:

The pharmaceutical manufacturer is required to guarantee that a medicine contains only those ingredients that are specified in the data file - nothing more, nothing less - and in exactly the proportions indicated. Analytical test methods used to achieve this are continuously being improved. The animal health industry has, on own initiative, introduced sterility tests and visual inspection of random samples as additional control measures. As an example of the efforts made to guarantee consistent product quality, water used for dissolving the active substance of a medicine is distilled twice, sterilized and then kept at 85 ° C until used.

The product will live up to its claims:

Data must also be provided to prove that the product meets a specified level of efficacy in treating or preventing a particular medical condition. Thus the customer can be assured that, when used as directed (correct dose-rate, frequency and duration of treatment), a product will meet its label claims. To support this claim, a product is tested extensively in the laboratory, in disease challenge studies and finally in field trials, which must demonstrate that it works under conditions of practical field use.

The leaflet is part of the product:

An animal health product does not consist of the medicine alone. The product name together with its label and leaflet (giving indications, contra-indications, warnings and withdrawal periods) are also essential parts of the product and its registration process. The registration authorities must also approve these and any changes to them. Dosage Forms of Active Pharmaceutical Ingredients apply to all veterinary dosage forms or preparations of the type defined. However, a valid interpretation of the appropriateness of a test or requirement for compliance with the test given under each dosage form.

Dip concentrates:

Dip concentrates are preparations for the prevention and treatment of ectoparasitic infestations of animals. They contain one or more medicaments, usually in the form of wet

table powders, pastes or solutions from which diluted suspensions or emulsions are prepared by appropriate dilution with the recommended liquid. The diluted preparations are applied by complete immersion of the animal or by spraying, as appropriate. They contain suitable antimicrobial preservatives.

Labeling:

The label states (1) the name(s) and proportion(s) of medicament(s); (2) the name and proportion of any added antimicrobial preservative; (3) the name and quantity of the diluent and the manner of preparing the diluted dip solution or spray; (4) any special precautions to be taken for use of the preparation; (5) the storage conditions; (6) the date after which the preparation is not intended to be used. If the preparation contains an organophosphorus compound the label also states (1) that the preparation contains an organophosphorus compound; (2) and special precautions on the use of the preparation.

Premixes:

Premixes are mixtures of one or more active ingredients with suitable bases intended for mixing with feedstuffs before administration to the animals. They are used to dilute medicament(s) with the feed and are usually issued as pellets, granules or powders. If issued as granules, these are free flowing and free from aggregates. Suitable precautions are taken during manufacture for ensuring that the premix is homogeneous. Unless otherwise stated in the individual monograph, the concentration of the premix in medicated feedstuffs is not less than 0.5%.

Tests:

Loss on drying:

Not more than 15.0 per cent, determined on 3 g by drying in an oven at 105o for 2 hours.

Labeling: The label states (1) the strength in terms of the amount of active ingredient(s) as a percentage; (2) the category of animal for which the premix is intended to be used; (3) the directions for the preparation of the medicated feed; (4) where applicable, the minimum interval between the stoppage of feeding of the diluted premix and the slaughter of the animal for human consumption; (5) any special precautions to be taken for use of the premix; (6) the storage conditions; (7) the date after which the preparation is not intended to be used.

Veterinary oral liquids:

Veterinary oral liquids intended for administration in large animals may also be called Drenches.

Veterinary oral powders: Veterinary Oral Powders are intended for oral administration, usually after dilution in drinking water or the feed. They may be in the form of soluble or wettable powders.

Labeling:

The label states that (1) for single dose containers, the name and quantity of active medicament(s) per container; (2) for multiple dose containers, the name and quantity of active medicament(s) by weight; (3) the name of any added antimicrobial preservative(s); (4) the directions for use of the preparation.

Intramammary infusions:

Intramammary Infusions for Veterinary Use; Intramammary Injections. Intramammary Infusions are sterile products intended for injection into the mammary gland through the teat canal. They are solutions, emulsions or suspensions or semi-solid preparations containing one or more active ingredients in a suitable vehicle. They may contain stabilizing, emulsifying, suspending and thickening agents. If sediment is formed in a suspension, it is readily dispersible on shaking. In emulsions, phase separation may occur but this is readily miscible on shaking. There are two main types of Intramammary Infusions. One is intended for administration to lactating animals as qualified by the term Lactating Cow/ Buffalo and the other, qualified as Non-lactating or Dry Cow/ Buffalo, is intended for administration to animals at the end of lactation or during the non-lactating period for the prevention or treatment of infection during the dry period. Intramammary Infusions are prepared by dissolving or suspending the sterile medicaments in the sterilized vehicle using aseptic precautions, unless a process of terminal sterilization is employed.

Container:

Intramammary Infusions are usually supplied in single dose containers for administration into a single teat canal of an animal. If supplied in multiple dose containers, aqueous preparations contain an antimicrobial preservative in adequate concentration except when the preparation itself has antimicrobial properties. The containers are made as far as possible from materials that meet the requirements for Parenteral Preparations intended for use in human beings. The containers are sealed so as to exclude micro-organisms and each container is fitted with a smooth, tapered nozzle to facilitate the introduction of the infusion into the teat canal. The containers are sterilized and filled aseptically unless the preparation is subjected to a process of terminal sterilization.

Tests:

Sterility:

Intramammary Infusions comply with the test for sterility, using Method A or B, as appropriate, using the contents of 10 containers mixed thoroughly before use in the test. Use for each medium 0.5 to 1.0 g or 0.5 to 1.0 ml, as appropriate, of the mixed sample.

Storage:

Store in sterile, single dose or multiple doses, tamper evident containers Labeling: The label states (1) the strength in terms of the weight or the number of Units of activity of the active ingredient(s) or that may be expressed from the container using normal techniques; (2) whether the preparation is intended for use in lactating cow/buffalo or in dry or non-lactating cow/buffalo; (3) for Intramammary Infusions (Non-lactating or Dry Cow/Buffalo), that the preparation is not intended for use in lactating animals; (4) in the case of infusions in multiple dose containers, the name of any added antimicrobial preservative.

Veterinary parenteral preparations:

Veterinary Parenteral Preparations prepared with oily vehicles are not meant for intravenous administration but are suitable for intramuscular or subcutaneous use. Veterinary Parenteral Preparations comply with the appropriate requirements for Parenteral Preparations (Injections) that are given in the chapter on General Monographs on Dosage Forms of Active Pharmaceutical Ingredients.

Veterinary tablets:

Veterinary tablets are usually solid, circular cylinders the end surfaces of which are flat or biconvex and the edges of which are beveled except that those weighing 5 g or more may be elongated or biconical.

Tests:

Disintegration:

The test may have to be suitably modified in the case of large tablets; the discs may have to be omitted because they would otherwise be dislodged from the disintegration tubes. It may also be necessary to adjust the volume of the disintegration medium so that the tablet does not break the surface of the medium at the top of the upstroke, care being taken to apply the minimum practical volume of liquid for this purpose. For certain tablets where the diameter of the tablet may not permit adequate movement of the disintegration medium, the apparatus and the method should be suitably modified.

Veterinary vaccines:

A major cost to farmers results from the morbidity and mortality caused by infectious diseases that can be prevented or improved by vaccination. However, vaccines need to be given at least twice and, depending on the duration of immunity required, booster doses need to be given at intervals as frequently as every 3 months (though more usually 12 months). The high costs associated with treating animals (herding, etc.,) results in the problem of lack of adherence to recommended protocols for vaccination by farmers. Thus farmed animals would benefit immensely from immunization with a single dose vaccine through the use of a controlled release technology. However, the case of controlled release of veterinary vaccines is interesting since, unlike other preventative or therapeutic drugs which may be directed toward a single biological target, the aim is to present to the immune system a package consisting of an immunogen and immune stimulatory molecules in a particular manner that will result in germane and sustained immunity. This requires thoughtful presentation of antigen to the immune system in the context of appropriate immune signals. Many attempts have been made by formulation scientists to achieve this aim using a pulsed delivery system.

Evaluation:

1 Products – All tests of a dosage form up to In vitro evaluation

2 Target Animals

Tolerance Studies

1 General tolerance

2 Local tolerances

- Tolerance testing of Injectables
- Tolerance testing of products intended for Dermal Applications
- Tolerance testing of products intended for Oral administration

Bioequivalence Studies

I. C_{max}

II. T_{max}

III. AUC

Conclusion:

Veterinary pharmaceuticals serve an important role in preserving and restoring animal health, thereby also enhancing human wellbeing. Efficient development of safe and effective new animal drug continued availability of approved products is essential to maintenance of animal health and productivity. For animal companions, veterinary pharmaceuticals are used to treat a range of disease condition similar to those of human patients.

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