# PHARMACEUTICAL DOSAGE FORMS IN VETERINARY MEDICINE

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Veterinary medicine is the branch of science that deals with the prevention, diagnosis and treatment of disease, disorder and injury in animals.

The scope of veterinary medicine is wide, covering all animal species, both domesticated and wild, with a wide range of conditions which can affect different species. The drug (medical pharmaceutical product) is a finished dosage form containing the active substance (s), usually formulated with one or more excipients, which are used in humans and animals for the prevention, diagnosis, treatment or amelioration of a function or a change in human/animal utility.

- Manufacture of medicines for human use
- Production of veterinary pharmaceuticals
- Production of pharmaceutical raw materials
- Manufacture of diagnostic and other pharmaceutical products

The concept of "veterinary medicine" has come into being as human beings begin to domesticate animals.

- Veterinary pharmacology has a rich history.
- Some estimates base the first evidence of the discipline as originating 7000 years ago in India based on archeological findings of a military hospital for horses and elephants.
- Renaissance Europe saw the flourishing of true efforts in discovery that led to the first printed pharmacopeia, titled the Dispensatorium, published by Valerius Cordus in 1547 in Nuremberg.
- This was followed by the London Pharmacopeia in 1618 and the influential Edinburgh Pharmacopeia in 1699.

- It was some 200 years later that the first truly national pharmacopeias took hold, with the first Pharmacopeia of the United States of America published in 1820 and a British Pharmacopeia in 1864.
- In the 19 th century, the French physiologist-pharmacologists Megendie and Pelletier studied the effects of intravenous injections of some substance such as opiates.

 Some other less obvious similarities include very similar regulatory requirements (e.g., International Conference on Harmonization for Humans and The Veterinary International Conference on

Harmonization for Animal)





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#### VICH Guidances

 07/01/1999 VICH GL1 - Validation of Analytical Procedures: Definition and Terminology (PDF - 118KB)

## In the simplest approach the development of pharmaceuticals for humans and animals are the same.

### The process involves:

1. Selection of the active pharmaceutical ingredient (API) with good physicochemical properties for development and determine that it is efficacious and safe,

2. Design dosage form and packaging,

- 3. Produce clinical supplies for efficacious and safety testing,
- 4. Collect registration stability data on the API and drug product,
- 5. Scale-up and transfer API and drug product methods in to commercial facilities,
- 6. Ensure methods to verify that quality are validated and in place,

7. File for approval with regulatory agencies (Republic of Turkey Ministry of Food, Agriculture and Livestock or Ministry of Health)

The most important difference is the added focus in veterinary medicine with food-producing animals of ensuring no unsafe drug or metabolite residues exist in the food being consumed.

This involves extensive ADME and safety characterization.