Development of controlled drug delivery for animals

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INDUDTRIAL CHALLENGES : –

The production of, controlled release drug delivery technologies are same, both in, humans and animals, but, the reasons for developing them are not same. In humans and animals, the controlled drug delivery permits safe, effective and easy handling for the user. In humans, to develop a drug into long acting one, the reasons to be considered are, less dose frequency, more patient compliance and to improve the well being of the patient. However, in animals to develop a drug into long acting one, the reasons to be considered are, minimum animal handling, low cost of treatment and small time for the administration of the drug. In human field, main focus is on the health of the patient, but, in animal arena, main focus is on the low cost of treatment, easy administration by the farmer and minimum animal handling. In veterinary industry, these reasons challenge the production of controlled drug delivery technologies. (1).

The challenges in a veterinary drug industry, for the development of controlled drug delivery for animals are small commercial market, low profits and money spent on the research is less. The price of the finished product depends on the selection and price of the excipients, polymers, methods used for manufacturing and marketing team responsibilities (1).

The major challenge is cost of the finished product and it depends on the method of design, type of excipient and polymer used and how many excipients used during the formulation (1).

Marketing team responsibilities is another challenge. Poor marketing is responsible for decreased efforts to develop a new product (1).

Another challenge is farmed animals. There are, large number of physiological differences between the species and within the species. One example for physiological difference is body weights, Beef cattle weighs 266-641kg, dairy cows weighs 600-700 kg and sheep weighs 54-66 kg. Animals, throughout their life cycle shows different weights. Due to these differences, dosage forms should be developed with different strengths and volumes. Due to this challenge scientist faces a problem, whether dosage is to be developed per animal or weight of the animal. If the dosing per animal is considered, the challenges are measures of drug safety. If the dosing is as per the body weight, the challenge is design is design of a flexible delivery technology that covers wide range of animals and the animals that are growing. An example is, CIDR® intra vaginal inserts for sheep, pigs and cattle. The intra vaginal inserts for sheep and cattle are having same shape, but, different in size. These inserts for pigs are different in shape compared to sheep and cattle. Basically, same technology is used for the preparation of these three inserts. (1).

Another challenge is, drug or residues exist in the food. To overcome this challenge wide absorption, distribution, metabolism and excretion (ADME) studies are conducted and also characterization techniques are developed.

These studies, depends on the cost of the final product. In veterinary industry, new polymers and excipients for controlled release are rarely used. (1).

Another challenge in the veterinary industry, is administration of dose. In animal field, the dose should be administered manually, for this suitable applicators are to be designed. The designed applicators should facilitate easy use by the end user (1).

The challenges faced by the veterinary industry are many. The developed products must have safety, stability and efficacy. These profiles are built into each product and additional challenges are also to be addressed i. e. the presence of residual drug at the site of administration. Safety profiles are applicable to both animals and users. For efficacy profiles different breeds, different seasons and different geographical locations are considered. Chemical stability of drugs is major challenge. Farms lack areas for the storage of pharmaceuticals. Physical stability of the drug is another challenge. Farmers show less interest towards efficacy profile, how to use, method of administration, residual drug in the tissue etc. scientists should improve the features like method of administration, acceptable safety and efficacy profiles and during the storage drug should not be altered. (1).

Another challenge is influence of delivery technique on the environment. The new delivery technology should not show any impact on the ecosystems. (1).

Major challenge in the near future is reduction of carbon compounds for the development of drug delivery technologies, because, carbon dioxide and

methane are considered as green house gases. In the future, specialized controlled release dosage forms will be developed (1).

Another challenge is market. Identification of need is one and another is identified need that can bring profits that are spent on research. For the well being of animal health, several products are used, they are, feed additives, pharmaceuticals, vaccines and nutraceuticals. The challenges associated with these products are different physicochemical properties and different formulation approaches. In the last decade, less money is spent on the research. In UK, 1986, 70% of veterinary products are introduced into the market for live stock, but, 45% of sales were reported in 2008. However, companion sector had grown to 52% in UK, due to increased use of vaccines and novel medicines. The companion animal industry is employing formulation scientists, those are having experience in human product development rather than formulation scientists, who is a farmed animal specialist (1).

Regulatory needs is the future challenge. Manufacturing GMP requirements are same for the final products, both in, animal and human arenas. (1).

In recent times, the curious challenge is seen in farms of certain species like swine and chickens. If these farms do not buy the new products developed by the pharmaceutical companies, they are showing less interest for the investment. This type of challenge is seen in USA (1).

INDUSTRIAL OPPURTUNITIES :-

Now a days, several opportunities are there for veterinary pharmaceutical industry.

Compared to market of the human pharmaceuticals, veterinary pharmaceutical products is shorter. By taking this advantage, employing an experience team, quickly complete the development activities. Due to the short time for the market, income comes quicker, more profits can be achieved before patent expires (1).

Availability of animals for research, rather than humans is another opportunity. In food producing animals, ADME studies are conducted at early stages, which help in the formulation development. This kind of opportunity favours the experimentation on target species (1).

Human drugs are first tested on animals (dogs), this creates an opportunity for veterinary industry. Due to this, pharmacological data of a particular drug is available. In companion animal market, this data is useful in reformulation of human serotonin selective reuptake inhibitors and monoamine oxidase-B for anxiety and cognitive disorders for dogs (1).

The clinical trials, that are done on animals also provides data of environmental assessment, for the development of formulation. This data helps in understanding of degradation process of the drug due to temperature, pH and light (1).

At present, veterinary market lacks new APIs, however, some reports are showing that new compounds are reaching the market. The existing drugs

life can be increased by developing controlled release drug delivery technologies (1).

Reference

(1) Rathbone M, Brayden D. Controlled release drug delivery in farmed animals: commercial challenges and academic opportunities. Current drug delivery 2009; 6 (4): 383-390.