

Metered dose inhaler (MDI) drug delivery system for rats

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Problem Statement: Research is being conducted on the side effects of corticosteroid medications, in particular the effects on the musculature of the tongue and upper airway because atrophy of those muscles can lead to sleep apnea. The goals of this project are to modify the mouthpiece of a metered dose inhaler (MDI) to allow for use by rats in a laboratory setting and develop a way to train the rats to voluntarily and correctly use the mouthpiece. The mouthpiece must be fitted with a custom nozzle sized appropriately for rat usage, as well as account for the fact that the rats will probably not voluntarily put their mouths around the nozzle at first.

1. Client Requirements

- The mouthpiece should be made of a material that can withstand rat bites
- The mouthpiece should be made of a material that propellant medicine will not adhere to
- The nozzle should be detachable and designed in several different sizes
- The material of the mouthpiece should have the capability to be squeezed, similar to the action of getting peanut butter out of a straw
- An automated system should also be designed so that when the rat operates the mouthpiece, a puff is automatically dispensed from the inhaler
- The material needs to be able to undergo sterilization
- The design should cost under \$1000
- Replicates should be made for training purposes
- A way to train the rats to use the nozzle must also be devised and tested

2. Design Requirements

2.1. Physical and Operational Characteristics:

a. Performance Requirements:

The design should consist of a detachable piece that fits on the end of a typical metered dose inhaler with a nozzle on the end that could fit in the mouth of a rat. The nozzle must deliver the drug directly into the rat's oral cavity, allowing the medicine to deposit on the tongue and mouth. In this manner, the method of delivery must be as similar as possible to use of an MDI by a human. The nozzle must be able to withstand multiple uses, including wear and tear from rats who will gnaw on the material. It also must tightly fit to the MDI, allowing little to no medicine to escape.

A training system for use of the nozzle by rats must also be devised. The rats must willingly place their entire mouth over the nozzle with their teeth out of the way when the

medicine is dispensed. It is crucial for the medicine to deposit on the tongue and mouth of the rat(s).

The system should also be automated so that when the rat places its mouth around the nozzle and bites, the drug will be dispensed into the oral cavity.

b. Safety

Since the product will be used with living rats, it must be composed of a material that is non-toxic to rats. The design of the nozzle must also be durable enough as to minimize the risk of a choking hazard to rats, considering that the rats will bite and gnaw on the nozzle. The nozzle also must be made of a material that is compatible with the medicine and sterilization methods, and not cause any toxic by-products.

c. Accuracy and Reliability

The product must be able to withstand multiple uses and accurately deliver the drug. It must fit tightly on the existing mouthpiece of the MDI and be made of a material that particles will not adhere to so that the majority of the drug is deposited in the oral cavity of the rat.

d. Life in Service

The nozzle will be used multiple times with different rats so it must be durable.

e. Operating Environment

The nozzle and MDI system will be placed in a cage, allowing the rats to operate the system themselves. A researcher will be observing the environment, but will not place the nozzle in the rat's mouth or operate the MDI to dispense the drug.

f. Ergonomics

The nozzle must fit comfortably in the oral cavity of a typical lab rat, but also be available in multiple different attachment sizes, as mouth size varies with age.

g. Size

The nozzle must be small enough for the rat to get their mouth around it enough to get a sufficient spray of medicine into its oral cavity. Several sizes should be manufactured to account for differences in rat size as they age.

h. Weight

The product should be lightweight and remain tightly attached to the mouthpiece.

i. Materials

The nozzle should be made of a material that is similar to the plastic of the existing mouthpiece on a traditional MDI. Specifically, it should be made of a material that the medicine will not easily adhere to and can withstand gnawing by rats.

2.2 Production Characteristics

a. Quantity

Multiple nozzles should be designed and manufactured, incorporating different sizes for use on aging rats. Replicates for use in training and testing should also be created.

b. Target Product Cost

The nozzle and automated system should cost under \$1000.