

Calibrated Eye Dropper Product Design Specifications

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Problem Statement:

A lab in the Department of Ophthalmology and Visual Sciences needs a device to accurately and efficiently deliver 5 μ L drops of experimental drugs into the cornea of the eye for glaucoma therapy testing in animals. Currently, the client uses standard micropipettes which deliver exactly 5 μ L drops, but this method is time consuming, poses a danger to the safety of the animal and makes drop placement difficult. The objective is to optimize accuracy, efficiency, and animal safety in optical drug delivery.

Client Requirements:

- Eye dropper mechanism to deliver 5 μ L of fluid to central cornea
- Minimizes chance of eye damage in case of contact
- Device accommodates different viscosities
- Apparatus should hold 5-15 mL of liquid
- Minimizes time intervals between dispenses
- Device should be small for stabilization of hand
- Device should allow operation with only one hand
- Parts easily sanitized or disposable
- Ergonomically favorable

Design Requirements:

1. Physical and Operational Characteristics
 - a. *Performance requirements:* The device should deliver 5 μ L of liquid to animal eyes with precision and accuracy.
 - b. *Safety:* Must not injure the animal eye if contact should occur.
 - c. *Accuracy and Reliability:* Must deliver same liquid amount repeatedly during each use and must be calibrated to 5 ± 0.05 μ L.
 - d. *Life in Service:* The device will be used about 2000 times per month.
 - e. *Shelf Life:* If it has replaceable tips, then it should be useable for a year without calibration. If solution is put inside the device, then it would be disposed of after each study. Device will be at room temperature. Components must not degrade.
 - f. *Operating Environment:* Used in research laboratory. Chemicals may be spilled on the device in which case, the device should be easily sanitized.
 - g. *Ergonomics:* The device will be hand held so it must be comfortable and easy to operate with minimal effort.
 - h. *Size:* The device should fit in the human hand (The average hand is approximately 3.5 inches in width). The gripping area must be at least 3.5 inches tall.
 - i. *Weight:* The target weight is that of standard pipette which less than 100 grams.
 - j. *Aesthetics, Appearance, and Finish:* The device should be neutral in color with a smooth, cylindrical shape.

2. Product Characteristics:

- a. *Quantity*: One prototype device is required for this semester.
- b. *Target Product Cost*: \$200, which is similar to the cost of a standard pipette.

3. Miscellaneous

- a. *Standards and Specifications*: FDA approval is not required due to the fact that the device will be considered a “custom device” by the FDA. As such, FDA regulations do not require review and approval for the use of the device.
- b. *Customer*: The device will be used by lab technicians.
- c. *Patient (animal)-related concerns*: The device must be sterilized between uses so cross contamination does not occur.
- d. *Competition*:
 - i. The MiniFIX Micropipette is similar to the size constraints desired, but does not have repeated deliveries and the accuracy is 30%.
 - ii. RAININ products makes micropipettes calibrated to 10 μ L with respectable accuracy, but when scaled to 5 μ L the percent accuracy increases past the desirable amount.
 - iii. MicroZippette Handheld Dispensers can be used for volumes of 1mL, but it can be used for repeated deliveries. However, the device cannot deliver the desired volumes.
 - iv. The eye drop dispensing system, US patent number 6610036, allows delivery of a predetermined quantity to the eye. It includes a replaceable cartridge with a collapsible bag for ophthalmic liquid.
 - v. The microdispensing pump, US patent number 7073733, can be used for ophthalmic applications when an accurate dose is necessary.
 - vi. US patent number 5881956 is a microdispensing ophthalmic pump which allows repeated delivery of volumes as small as 5 μ L.