Biogel Release to the Ocular Surface of Epithelial Growth Factors (Ocular Biogel)

Project Design Specifications
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Function:

Significant dry eye is an affliction that affects up to four million people in the United States. There are currently options available to treat the symptoms of dry eye, but a way to treat the causes and repair the damage has yet to be found. We aspire to design and fabricate a dissolving biogel that is capable of sustained release of epithelial growth factors that will work to maintain healthy epithelium and restore damaged tissue on the ocular surface.

Client Requirements:

- Design should incorporate a sustained release of growth factor.
- Product should dissolve in lacrimal fluid over 7-14 day period.
- Must be harmless to the ocular surface of eye.
- Must hold up to the standards and regulations of the Food and Drug Administration.

1. Physical and Operational Characteristics

A. **Performance requirements**: The product will only be required to be used once, as it is intended to dissolve during use.
B. **Safety**: The product must not be harmful to the ocular surface of the human eye.
C. **Accuracy and Reliability**: This product must be extremely accurate in its sustained delivery as growth factors facilitate cell proliferation, which may be harmful to a user if the sustained delivery method fails. Along with this accuracy, there is a demand for complete reliability, as failure to function properly could be detrimental to patient's health.
D. **Life in Service**: The ideal length of time that the product should be on the eye while dissolving and delivering medication is 7 to 14 days.
E. **Shelf Life**: The product should be capable of being stored in conditions similar to comparable products. This includes being stored at room temperature in a closed container for up to 24 months.
F. **Operating Environment**: The product design must be made to function on the ocular surface of a human patient. A typical ocular surface contains lacrimal fluid of pH range from 7 to 7.5. The normal temperature range of the eye is 32-34 °C.
G. **Ergonomics**: The final product must be easy to administer by an unqualified user. It must possess the ability to be quickly and efficiently placed, as many of its competing

products are simple in terms of application. The product must also require minimal maintenance or re-application once it is set.

H. **Size**: The product must either fit on the eye, or between the layers of conjunctiva on the surface of the eye and lower eyelid. An estimate of approximately 3-5 mL in volume of biogel is expected to be sufficient for function, while maximizing comfort.
I. **Weight**: The product should be as lightweight as functionally possible, as it will be housed in the eyelid during use. A heavy product would cause discomfort and physical strain to the user.
J. **Materials**: All the materials used in this project must be compliant with the standards of the Food and Drug Administration, as it is designed for use on human subjects. Any materials that fit these criteria may be used.
K. **Aesthetics, Appearance, and Finish**: Aesthetics and appearance are not factors in this design, as the client favors functionality and ease of use.

2. Production Characteristics

A. **Quantity**: One biogel insert will be used per eye being treated at one time.
B. **Target Product Cost**: Similar products available on the market range from $100 to $120 for a one-month supply, so the entire product (biogel and growth factor) should be comparable in price.

3. Miscellaneous

A. **Standards and Specifications**: The final product will require the approval of the Food and Drug Administration.
B. **Customer**: Customers in search of a product to relieve dry eye desire ease of use and application, comfort and effective relief during use, and reasonable cost. All of these factors must be considered when designing a competing product in the market of dry eye relief.
C. **Patient-related Concerns**: As our design may eventually be commercially available for patient use, it must follow all restrictions enforced by the Food and Drug Administration. It must not cause any harm to its user. The final product must also be ergonomically sound to ensure ease of use by an unqualified patient.
D. **Competition**: Restasis® is a prescription drug currently on the market that used to treat chronic dry eye. It reduces inflammation and helps eyes increase tear production. There are also over-the-counter artificial tear lubricating drops, which are highly favorable for mild symptoms because of their price and ease of use.