Product Design Specification

Hydrogels for Coating Medical Devices

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Team Members:

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Purpose:

To form PEG macromer-based hydrogels on biomaterial surfaces in an interfacial photopolymerization process and to screen the coatings for interactions with cells and media that mimic physiologic fluids. It is hypothesized that these coatings will resist fouling and may be useful for implantable devices.

Approach:

The biomaterial specimen is stained with an Eosin solution, which is the first component of a 2-part photoinitiator system. The stained specimen is immersed in a macromer solution containing component 2 (triethanolamine) of the photoinitiator system and ferrous and vinyl caprolactam promoters. Visible light energy is applied to the aqueous solution. At the intersection of the stain, the macromer and the light on the surface, an adherent, thin, self-limiting hydrogel forms by polymerization of the macromer. The coated specimen is exposed to cells in culture and ionic (calcium-rich) media to

determine if the cells attach to the coating, and spread relative to controls. Resistance to such fouling is indicative of utility in applications such as catheters, sensors, etc.

Client Requirements:

- Detailed process for applying a hydrogel to surfaces.
- Testing of thickness of hydrogel coatings using a subjective adherence rating system.
- Testing of fouling resistance of hydrogels in various physiologically imitated environments.
- Testing adherence of hydrogels to different materials.
- Resolve logistics of performing experiments.

Design Requirements:

1) Physical and Operational Characteristics

    a. *Performance Requirements:* Testing processes must have universal applications, standardized procedures, and consistent data collection.
    b. *Safety:* The PEG being tested must be non fouling and not negatively affect a physiological environment in any other way. Also, during the creation and application of the hydrogels the team needs to be conscious of the chemicals they are working with and take necessary precautions.

c. *Accuracy and Reliability:* Although some data will be subjectively collected, the same team member will be judging results to ensure consistency.
d. *Life in Service:* Unresolved. The hydrogels will need varying service lives based on where and how they are used.
e. *Shelf Life:* All hydrogel reagents have specific needs as far as temperature during storage. The hydrogel will not be stored once the desired testing of it is complete.
f. *Operating Environment:* The hydrogel could potentially operate in urine in the case of catheters. Possibly blood, or interstitial fluid as well.
g. *Ergonomics:* Not Applicable.
h. *Size:* The testing samples will either be one by one square centimeters or one by two square centimeters and between 25 and 100 microns in thickness.
i. *Weight:* Will be determined once the hydrogel tests samples have been produced.
j. *Materials:*
    i. Eosin Y
    ii. Phosphate Buffered Saline (PBS)
        1. NaCl
        2. Na2HPO4 Anydrous
        3. KH2PO4

4. Distilled Water

iii. Macromer Solution

1. Macromer – 3.35KA2 or 20KA2
2. 10X Buffer
    a. Triehanolamine (TEOA)
    b. Potassium Phosphate, Monobasic (K-Phos)
    c. Water for Injection (WFI)
    d. 2 N Hydrochloric Acid (HCl)
3. N-Vinylcaprolactam (VC)
4. WFI
5. Ferrous Sulfate Heptahydrate
6. D-Fructose

k. *Aesthetics, Appearance, and Finish:* No appearance requirements.

2) Production Characteristics

a. *Quantity*: One application process and multiple experiments with different materials.

b. *Target Product Cost:* No cost restrictions for testing.

3) Miscellaneous

a. *Standards and Specifications:* None

b. Customer: Genzyme Corporation

i. Arthur J. Coury, Ph.D. – Vice President, Biomaterials Research

c. Patient-related concerns: None at this point.

d.*Competition:* Abbott Labs, Amgen, Johnson & Johnson.