OROFILM - ORALLY DISSOLVING DRUG DELIVERY SYSTEM

By: Rose Garrett, Maya Miller, Chelsea Lua Hernandez, and Tyson Dougall

OPPORTUNITY

While pills are widely available, some people have difficulty swallowing. Alternatively, syrup delivery methods often have negative feelings, and strong off-putting tastes

In addition to having difficulty swallowing, some patients attempt to avoid taking necessary medications by refusing to swallow

Orofilm is an orally dissolving tab which is placed onto the tongue, and subsequently allows the spread and absorption of medication through the oral submucosa

PROTOTYPING

Prototype 1: Create a film material that dissolved in less than 30 seconds without leaving residue in mouth
Combination of Gelatin, citric acid, glycerol, carrageenan, sorbitol, erythritol, xanthan & locust bean gum
Tested material with wet sponge test

Prototype 2: Altered the design of the film to increase effectiveness and comfortability
Tear strength test
Multiple dimensions and thicknesses

Prototype 3: Test drug loading methods to determine best way to load drug onto film and test flavor profile of the film
Aqueous solution and mint extract were determined to be the best flavor and loading method

Tyson Dougall, Chelsea Lua Hernandez, Maya Miller, and Rose Garrett from left to right.

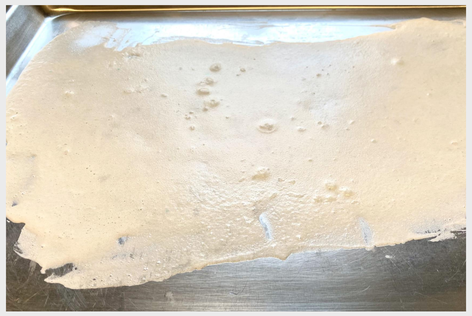

Figure 1: An image of a sheet of initial prototyped Orofilm recipe.

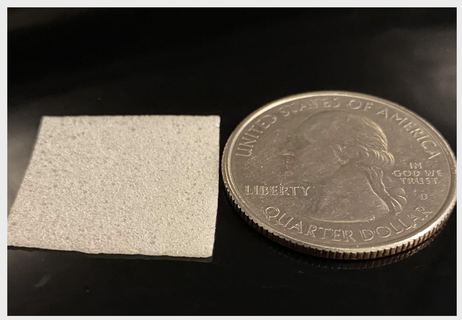

Figure 2: Prototype showing product size. Quarter for reference.

ENGINEERING ANALYSIS

Mathematical models included porosity, tensile strength, and absorption ratio were considered.

The porosity model showed that as porosity increases, so does brittleness and dissolvability. The results of this model showed all disintegrant materials tested had very similar levels of porosity, therefore this did not help narrow down a disintegrant.

The tensile strength model was used to narrow down how much tensile strength and force could be put applied to our product in order to withstand tearing. We decided on a value of 6 Newtons, which is the tearing force of paper. This model, as well as prototype 2, led to a 1.2X batch thickness in the final product.

The absorption ratio model relates dissolvability and the amount of saliva needed. Considering that dry mouth is a side effect of Asenapine, we wanted a small absorption ratio, but not too small that it would dissolve accidentally with wet hands. Citric acid was chosen as our disintegrant which is in the middle range.

FINAL PRODUCT

The team conducted three rounds of testing in order to decide on the parameters that would result in the best final product. The first round of testing resulted in a recipe that includes 19.4 grams of gelatin, 0.6 grams of citric acid, 1 grams of carrageenan, 0.8 grams of sorbitol, 0.3 grams of erythritol, 0.15 grams of both xanthan gum and locust bean gum, 2.5 grams of glycerol, 71 grams of water, and depending on the batch, 2.8 grams of methylene blue or 5 grams of mint extract. The second round of testing revealed that 2x2 centimeter dimensions for the film are most comfortable for placement in the mouth. Finally, testing resulted in two flavor options, strawberry lemonade or mint, and that Asenapine needs to be loaded in liquid form to the batch before the baking process.

These parameters make Orofilm what it is, an orally dissolving film loaded with Asenapine in order to release it for absorption by the lingual artery in less than 30 seconds without leaving any residue in the mouth.

DISCUSSION & CONCLUSION

The team started with an analysis of the healthcare system and the current products available within it. Consideration was given towards the massive number of people who take prescription medications in this country, and how many of these come in a pill form. The lack of variety in options for users to receive the medication they need was alarming, so the team considered what could be done about it.

This process lead the team towards Orofilm. Orofilm is a small, thin film that is placed on the tongue to deliver a drug to the user. This film gives the many people who are not comfortable or able to swallow a pill another way to take their medications. It has the potential to be adapted in order to carry many different types of drugs, positively impacting the lives of millions.

COST ANALYSIS

Current Asenapine products can be very expensive, with price tag upwards of $1200. Our team planned to have our product hit the low end of the spectrum and priced our product at the $200 mark.

With current recipes our total cost for each unit of Orofilm, around 56 doses, comes out to about $60 with a large portion of the cost being the medicine itself. This lends itself to a bright picture where even after transportation, labor, and production costs are incurred, the product will be able to make a reasonable profit. Additionally, with our low base costs for the film itself, any medicine could be swapped in for and sold with a new method of delivery.

FUTURE WORK

Future applications for our film include using the film as an alternative drug delivery method for all prescription drug, as well as further decreasing dissolving time and improving flavor

ACKNOWLEDGMENTS

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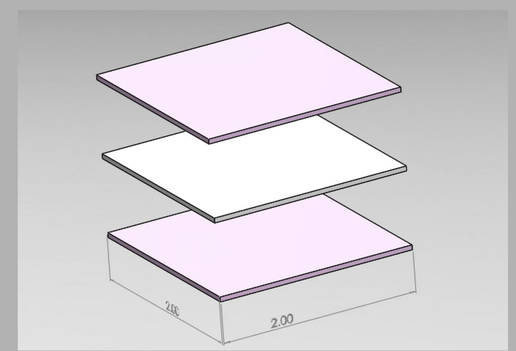

Figure 3: SolidWorks model with disintegrating film shown in white with protective layers shown in color.

Oregon State University