Development of orally dissolving films

Summary

Orally dissolving films (ODF) have become a key part of the medical operations and treatment executions. The project seeks to develop a working and efficient continuous method that will ensure a functional ODFs production. The new method should be explicitly capable of reliably producing uniform thin films that have poor water solubility to enhance drug implementation with the aim of increasing patient compliance. The characteristic will also ensure that the need for continuous productivity is no longer a concern with additional enhancement of poorly water-soluble drugs. The other aims that may be classified as either ripple or secondary include description of the positive outcome of the use of ODFs, outlining the practicality of the process under scrutiny, description of the stems I involved, and exploring the necessary budget of the entire process.

Introduction

Conventional approaches to drug consumption include oral methods such as the use of tablets that have become popular due to the simplicity and reliability regarding the dynamics that revolve around that approach. Moreover, the inherent stability of the platform has also played a massive part in both the production, transportation, and distribution of the medicines. Nonetheless, despite the convenience, the traditional oral dosage forms have their fair share of problems and challenges, especially to the patients. There exist specific challenges and questions that follow within the logical and practicality scope. For instance, the need for liquids to administer drugs, though not applicable to all medicines, remains a key challenge (Dixit and

Puthli 24). Another concern is that oral medicines are usually produced in a batch-wise process. The production is another major reason calling for a complete restructuring. Apart from the production and administration concerns, there exists another bottleneck associated with the method. Some patients are particularly sensitive to solid medication or have developed digestive disturbances. These problems include but are not restricted to pediatrics, geriatrics, and dysphagia (111Zhang et al.). Typical dosage forms present an immensely complicates scenario for these groups of patients. The advancement of technology must hence spread over to the medicine administration methods to better the process and ensure that all patients have a working and convenient platform to make treatment easy and convenient.

Project Description

Oral films focus on poor water solubility and can involve but not limited to preparation through hot melt extrusion (HME), solution, and slurry casting. The films resulting from the HME are subjected to elevated temperatures during the processing. The HME process results in a rich film loaded with amorphous or molecularly spread drug particles (Dixit and Puthli 36). The resulting product allows for an enhanced dissolution rate with poorly-soluble drugs. It is key to note that despite attaining the good composition and convenient structure after processing, recrystallization may be necessary to help with storage. The need for recrystallization is the primary reason for advanced research and optimization in the formulation process. The change in the formulation such as polymer type, drug, excipient the process parameters must be optimized again. In addition to these, the thickness of

most films produced via HME is around 300 µm or thinner (70-120 µm) but has a standard deviation of at least 10 µm. These are not acceptable features since the thickness is the most important parameter regarding patient compliance. Additionally, drug content is strongly dependent on the thickness of the film.

In solution casting, the drug is dissolved in the polymer solution before casting. If the drug is poorly water-soluble, an organic solvent must be used in the polymer solution to dissolve the drug. If the drug is water soluble, there is no need for an organic solvent. Recrystallization is a significant issue when using this method of film creation. In the polymer solution the drug dissolves and becomes amorphous, but as the solvent is evaporated during the drying process, the drug particles tend to recrystallize. However, either case needs process optimization for each drug and other components. If the polymer solution is prepared using water as the solvent, and the poorly water-soluble drug is directly added, it results in a suspension. When this suspension is used to cast film, the method is called slurry casting. Since the drug is not dissolved, formulation optimization doesn’t depend on the drug as much as in HME or solution casting methods.

The Work Plan

1. The schematic plan of the overall process

This method consists of 3 main processes (i) continuous mixing process at room temperature (ii) casting via a sheet die integrated to the co-rotating twin screw extruder (TSE) and (iii) drying in a chamber connected to TSE.

2. The lifespan of the project

The project is supposed to take approximately six weeks and an additional two weeks to cater for any unforeseen setbacks as those are key to any project. The project cycle comprises of four major phases. These include:

1. The building of the drying chamber as it is a key part of the project implementation,
2. managing and observing critical process parameters that affect the product,
3. managing and observing essential material attributes that affect the product, and
4. the product, and comparison of the developed method to the current approach.

The Intended Impacts

The project factors in all the patients, including those that may have different difficulties when it comes to oral medication implementation. As mentioned earlier, this project would greatly benefit many patients across the world because this new technology will reduce the overall cost of therapy and it will make it easier for patients that have difficulties of swallowing traditional oral solid dosage forms.

Conclusion

Overall, the medical field has witnessed tremendous changes in the past. However, there have been minimal improvements in oral medicine implementation. As such, the new proposal, the orally dissolved film’s method will provide an excellent platform to factor in the concern of various patients across the globe. Additionally, ODFs can disintegrate in a few

seconds with no need for water or any administration liquid. This new approach has improved acceptance and patient’s agreement with no risk of choking associated with recovering safety in comparison with classic dosage forms. Another key concern is the factoring in of the patients that may have swallowing complications as they will no longer have key challenges with mediation. Production, storage, and transportation will also benefit immensely from the advancements. The implementation of the ODFs will be a key game changer in the medical platform towards bettering the medical field.

Budget and Timelines

Timelines

According to the research and estimation, the project will cost about $14000. 000. The amount factors in a 10% value for any unforeseen involvements including the need for hiring surveyors and the acquisition of additional materials for the process. The cost also involves the materials for the process as well as the wages for two professionals that will head and manage the process.

1. N

o.	Activity	Timelines	Additional Comments
2.	Construction of the	November 5th,	This phase of the

drying chamber	2018 to December 3d 2018	project will require about $3000. 00 in funding. The funding will allow for purchases of necessary materials such as plexiglass panels, small electric fans, and a conveyor belt. Additionally , $2, 000. 00 will be allocated toward a pump to for

			moving the precursor polymer solution.
3.	Managing and observing critical process parameters that affect the product	Nov 18th, 2018 to Feb 21st, 2019	This step requires about $2500. 00 in funding to purchase raw drugs for testing. Griseofulvin and Fenofibrate are two drugs that will be used throughout the lifecycle of the project and can be bought relatively

			cheaply in powder form from manufacturers.
4.	Managing and observing critical material attributes that affect the product	Feb 23rd, 2019 to April 15th, 2019	This step will continue for two months. For this step needs about $ 1500. 00 in funding. See the previous phase for more information on associated costs.

			This phase will take about a month. This last step will cost $ 50000. 00 in funding to pay two experts that will monitor the developmen t of the comparison
5.	Comparis on of the developed method to the current method	Apr 16th, 2018 to May 15th, 2018	

The Budget per Schedules

Months	Costs ($)	Goals for each month
Nov 5 th to Dec 3th 2018	5000 . 00	Construction of the drying chamber
Nov 18 th to Feb 21	2500	Managing and observing critical

st, 2019	. 00	process parameters.
Feb 23th to Apr 15 th, 2019	1500 . 00	Managing and observing critical material attributes
Apr 16th to May 15 th, 2019	5000 . 00	Comparison of the developed method to the current method

Works Cited

- Dixit, RP, and SP Puthli. " Oral Strip Technology: Overview and Future Potential." *Journal of controlled release* 139. 2 (2009): 94-107. Print.
- Zhang, Lu, et al. " Incorporation of Surface-Modified Dry Micronized Poorly Water-Soluble Drug Powders into Polymer Strip Films." *International journal of Pharmaceutics* 535. 1-2 (2018): 462-72. Print.

Appendix

The key guiding materials for the development of the proposal came from key researches that are listed below.

1. Dixit, R. p., and S. p. Puthli. " Oral Strip Technology: Overview and Future Potential." Journal of Controlled Release139, no. 2 (June 24, 2009): 94-107. doi: 10. 1016/j. jconrel. 2009. 06. 014. The above citation provides information regarding ODFs. It discusses the method in its current capacity as well as offering insight into possible directions for the technology.

2. Zhang, Lu, Yidong Li, Manal Abed, and Rajesh N. Davé. “ Incorporation of Surface-modified Dry Micronized Poorly Water-soluble Drug Powders into Polymer Strip Films.” International Journal of Pharmaceutics535, no. 1-2 (November 21, 2017): 462-72. doi: 10. 1016/j. ijpharm. 2017. 11. 040. The above citation is a journal published following the completion of ODF research done by individuals at NJIT. The paper establishes methods used to alter poorly water-soluble drug particles for implementation in ODFs.