

**Development and Optimization of Orally Dissolving  
Films Targeting Pediatrics and Patients Suffering from  
Dysphagia**

**By**

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## Dedication

All praise to Allah, today we fold the days' tiredness and the errand summing up between the cover of this humble work.

I dedicate this thesis **to my father**, my character creator, my strong pillar, my source of inspiration, wisdom, knowledge and understanding. He continues to inspire me every day with his determination and affection.

**To my mother**, the words of thanks are not enough to express my love for you, which nourished and prepared the soil in which my proof, sowed the seeds of his knowledge.

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For someone who has always been with me in the most difficult moments. Nadeen, I cannot talk about you so much I just want to tell you something, you cannot stay away from me all the time and thank you for standing by my side always.

To my **family** and all my **friends**, without whom none of my success would be possible. Thank you all for helping to give me the life I love today

# **Development and optimization of Orally Dissolving Films targeting pediatrics and patients suffering from dysphagia**

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## **ABSTRACT**

Orally dissolving films (ODFs) have received much attention as potential drug delivery systems for oral administration of drugs for pediatric patients. With their unique properties and advantages, the technology offers improved patient compliance and wider acceptability, eliminated fear of choking, ease of administration and dosing convenience, without the requirement of water. The aim of this research project was the development of ODF formulations with suitable physicochemical and mechanical properties as a potential dosage form for pediatric use using two model drugs (ibuprofen and topiramate). ODFs were prepared using HPMC (hydroxy propyl methyl cellulose), guar gum, in combination with plasticizers such as glycerin and sorbitol as well as other excipients. Films were prepared via solvent casting method and then produced ODFs were evaluated for mechanical properties, disintegration time, dissolution time and dosage form uniformity. Initial studies focused on screening of different film-forming polymers used for the preparation of orally dissolving films in order to optimize and propose suitable polymers and plasticizers with a suitable manufacturing technique. The work also sought to improve the loading capacity and drug content uniformity of both hydrophilic (topiramate) and hydrophobic (ibuprofen) drugs into

ODFs. Loading capacity varies between the two drugs, where maximum loading capacity of ibuprofen-HPMC ODFs was 54.4% with 20.7 mg ibuprofen per film, whereas topiramate load reached 58.95% with 25 mg topiramate per film (6 cm<sup>2</sup>). Both formulations demonstrated good disintegration time of below 60 seconds and dosage from uniformity which was assessed using weight variation and content uniformity. In conclusion, the ultimate goal of any drug delivery system is successful delivery of the drug to the body; however, patient compliance should not be overlooked. ODFs provide convenient drug delivery systems not only for special populations with swallowing difficulties, such as children and the elderly, but also for all patients. Therefore, the outcome of this research project could be a starting point for further work to optimize and assess ODFs for delivering other drugs via this formulation.

## نموذج تفويض

أنا كيلاني إسماعيل عبد عوده ، أفوض جامعة الاسراء بتزويد نسخة من رسالتي /أطروحتي للمكتبات أو المؤسسات أو الهيئات أو الاشخاص عن طلبها حسب التعليمات النافذة في الجامعة

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## Abbreviation

|                 |   |
|-----------------|---|
| API             | Active pharmaceutical ingredient          |
| °C              | Celsius degree                            |
| cm              | Centimeter                                |
| cm <sup>2</sup> | Square centimeter                         |
| DCP             | Dibasic calcium phosphate                 |
| GIT             | Gastro-Intestinal Tract                   |
| g               | Gram                                      |
| HPLC            | High Performance Liquid Chromatography    |
| HPMC            | Hydroxy propyl methyl cellulose           |
| hr/ hrs         | Hour\ hours                               |
| IBU             | Ibuprofen                                 |
| ICH             | International Conference of Harmonization |
| IU              | International unit                        |
| LOD             | Limit of detection                        |
| LOQ             | Limit of quantification                   |
| µg              | Microgram                                 |
| µl              | Microliter                                |
| mg              | Milligram                                 |
| ml              | Millilitre                                |
| min             | Minute                                    |
| NSAID           | Non-steroidal anti-inflammatory drugs     |
| NO              | Number                                    |
| ODF             | Orally dissolving film                    |
| rpm             | Pound per minute                          |
| RSD             | Relative standard deviation               |
| UV              | Ultra Violet                              |
| UV/Vis          | Ultraviolet-visible Spectroscopy          |
| WHO             | World Health Organization                 |