

UNIVERSITI TEKNOLOGI MARA

**FORMULATION AND EVALUATION
OF KETOCONAZOLE POLYMERIC
FILMS FOR TOPICAL
APPLICATIONS**

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ABSTRACT

The objective of this study is to prepare and evaluate the properties of medicated polymeric films containing ketoconazole, characterising them and *in vitro* testing for topical application and prediction of its *in vivo* release through the results obtained. The polymeric films containing ketoconazole as active pharmaceutical ingredient (API) were prepared with different Eudragit® using solvent casting technique. To evaluate the physico-mechanical properties of medicated polymeric films, the prepared films undergone the tensile strength and extensibility test by using texture analyser. The *in vitro* release of ketoconazole from the prepared films was carried out, in comparison with other topical dosage forms which are ointment, lotion, emulgel and emulsion. The results revealed that film prepared with Eudragit® RL 100 containing propylene glycol as plasticiser produced the highest release of ketoconazole *in vitro* as compared with other topical dosage forms. As a conclusion, ketoconazole incorporated in polymeric films may provide enhancement in the treatment of dermatophytosis.

Keywords: Ketoconazole, polymeric film, Eudragit® RL 100, propylene glycol

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF STUDY

Over the past centuries fungal infections are rising and become one of the most common disease among the population of the world (Payne, 2008). For example, tinea pedis, a fungal infection of the soles of the feet and the interdigital spaces is the most common dermatophytosis that is reported to infect the world population (Robbins, 2014). Although fatality among healthy individual is not common due to these fungal infections, but for immunocompromised patients, such as patient who have Human Immunodeficiency Virus (HIV) infection, diabetes mellitus or cancer patient who received immunosuppressant treatments, a mild fungal infection can worsen their health condition and cause death (Kathiravan et al., 2012).

Azole drug is one of the antifungal drug that has been used for decades. Based on review of antifungal agents by Kathiravan et al. (2012), ketoconazole is one of the azole drug that is still used to treat fungal infection. There are different types of ketoconazole administration forms which are oral and topical dosage form. Ketoconazole topical dosage form is more favourable than oral dosage form now because in year 2013, American Drug and Food Administration and European Medicines Agency issued the concern and warning about ketoconazole oral dosage form which is Nizoral® due to risk of adrenal gland problems and liver damages. However, topical ketoconazole formulations are not included in this FDA warning (Greenblatt & Greenblatt, 2014).