

UNIVERSITI TEKNOLOGI MARA

**STABILITY OF EXTEMPORANEOUS
PREPARATION IN HOSPITAL PUTRAJAYA**

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**Dissertation submitted in partial fulfillment of the requirements for the
degree of Bachelor of Pharmacy (Hons)**

Faculty of Pharmacy

November 2009

ACKNOWLEDGEMENT

First of all, Alhamdulillah because of His permission and will, this thesis can be completed in time. This thesis is the results of hard work and also contribution from many people. Here, I want to express my earnest thankfulness to all people who have also work hard to contribute to the completion of this thesis.

I also want to convey unlimited thanks to my supervisors Miss Yap Yen Ling, Mr. Lee Wee Leng and Mr. Meor Mohd Redzuan for all of the supports, guidance, advices and knowledge that they had gave throughout the research period. I am extremely appreciated it.

Also not to forget to Dr. Kalavathy Ramasamy and Miss Ruzianisra as the coordinators for PHR 555 and PHR 556, millions of thank you for their guidance and hard work that leads us to the finishing line of thesis completion. A grateful thanks also to all of the laboratory assistants of Faculty Pharmacy, UiTM Puncak Alam that has spared their time and knowledge during my laboratory work.

Last but not least, I wish to thank to my family and my friends for their support and encouragement. Also to all the people that I may forget to mention here. Thank you very much. For all of them thank you for everything.

TABLE OF CONTENTS

	Page
TITLE PAGE	
APPROVAL	
ACKNOWLEDGEMENT	ii
TABLE OF CONTENTS	iii
LIST OF TABLES	v
LIST OF FIGURES	vi
LIST OF ABBREVIATIONS	vii
ABSTRACT	viii
CHAPTER ONE (INTRODUCTION)	
1.1 Introduction	1
1.2 Significance of study	2
1.3 Objectives	2
1.4 Problem statement	3
1.5 Research questions	3
1.6 Hypothesis	4
CHAPTER TWO (LITERATURE REVIEW)	
2.1 Terms definition	
2.1.1 Stability	5
2.1.2 Extemporaneous preparation	5
2.1.3 Shelf life	6
2.2 Types of stability	7
2.3 Instability in pharmaceutical products	7
2.3.1 Chemical instability	7
2.3.2 Physical instability	8
2.3.3 Microbiological instability	8
2.4 Factors influencing stability of pharmaceutical products	11
CHAPTER THREE (MATERIALS AND METHODS)	
3.1 Materials	
3.1.1 Extemporaneous Preparations	12
3.1.1.1 Chloral Hydrate Elixir 200mg/5ml	12
3.1.1.2 Sodium Bicarbonate 5% Ear Drop	13
3.1.2 Chemicals for Titration and Standard Preparations Of Sodium Bicarbonate	13
3.1.3 Preparation of Solutions	
3.1.3.1 Preparation of 0.1 M Hydrochloric Acid	15
3.1.3.2 Preparation of Sodium Bicarbonate Standard for Calibrations	15

ABSTRACT

The main objective of this study is to determine the expiry date of chloral hydrate elixir 200 mg/ml and sodium bicarbonate 5% ear drop. These are the extemporaneous preparations obtained from Hospital Putrajaya. This is achievable by examining the chemical, microbial and physical stability of the products. In this project, the chemical and microbial stability were examined according to the method described in British Pharmacopoeia (BP) 2007 and United States Pharmacopoeia (USP) 30. The method used to determine the chemical stability of chloral hydrate preparations cannot be performed as it is not suitable to determine the concentration of chloral hydrate in the preparation. The microbial stability testing for chloral hydrate showed that there were numerous microbial growths which may due to contamination of the products and materials.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Stability of drugs can be generally defined as the constancy in the integrity of pharmaceutical products in terms of their active ingredients and physical appearance throughout their shelf life. According to United States Pharmacopoeia (USP 30), other types of stability that can be examined are microbiological, therapeutic and toxicological stability of the pharmaceutical products. For the definition of extemporaneous preparation, it brings the meaning of a pharmaceutical product that is freshly or recently prepared but the actual shelf life is not known, unless it is stated in monographs. However, the shelf life of extemporaneous preparation is usually last within a short period of time and is dependent on various factors including the storage conditions and the way the drug is prepared that may contribute to the degradation of pharmaceutical products. Hospitals usually do extemporaneous preparations because there is lack of commercially available desired dosage form of certain drugs. In this study, drugs that will be examined are Chloral Hydrate elixir and Sodium Bicarbonate ear drops. In British Pharmaceutical Codex, Chloral Hydrate's action is hypnotic and is usually used for children and elderly. The indication of sodium bicarbonate ear drop is ear wax