UNIVERSITI TEKNOLOGI MARA

DEVELOPMENT AND VALIDATION OF THE HPLC ANALYSIS METHOD FOR STABILITY STUDY OF EXTEMPORANEOUS RIFAMPICIN SYRUP PREPARED BY HOSPITAL PUTRAJAYA

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ABSTRACT

Rifampicin has been used widely to treat infection caused by Mycobacterium Tuberculosis. It exhibits its action by inhibiting-dependant RNA polymerase in bacteria. The aim of this study is to develop and validate a high-performance liquid chromatography (HPLC) quantitative analysis method in order to be utilized in the future to assess the stability of rifampicin syrup prepared by Hospital Putrajaya. The HPLC system with UV detector with wavelength 254 nm was used. The column is Eclipse XDB-C18 (4.6 mm × 150 mm, 5μm). The mobile phase is 65% of 0.01 M of potassium phosphate buffer pH 5 and 35% of acetonitrile. The flow rate of mobile phase is 1 mL/min. the volume of sample injection is 20 μL. Six different concentrations of rifampicin solution were used to develop calibration curves. Correlation coefficient that was obtained is greater than 0.99. Therefore, it can be considered that the curves have very good linearity. Furthermore, the accuracy and precision values meet the FDA requirement. So, this method can be utilized in the future to assess the stability of rifampicin syrup prepared by Hospital Putrajaya.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Rifampicin is one of the most widely used antitubercular agents. Pharmacy department in Hospital Putrajaya compounds rifampicin syrup 100 mg/ml. This drug also has been used to treat bacterial meningitis caused by *Staphylococcus aureus* and *Streptococcus pneumonia*, staphylococcal infectious disease, *Mycobacterium avium* complex infection and leprosy. Rifampicin acts by inhibiting DNA-dependant RNA polymerase in bacteria.

Extemporaneous compounding is a type of compounding performed when a desired strength and dosage form are not commercially available for a specific group of patient. Extemporaneously compounded preparations are frequently unstable for physical, chemical and microbiological reasons. Due to the lack of complete control of conditions and inability to perform stability test on extemporaneously compounded preparation, shorter shelf-life must be ascribed.

Stability is the degree to which a preparation remains the same properties and characteristics it carried at the time of its packaging within the established limits, throughout its period of storage and utilization (Bajaj *et al.*, 2012). So, it is important to conduct this study to verify the chemical stability of extemporaneous preparation.

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