UNIVERSITI TEKNOLOGI MARA

STABILITY OF FOLIC ACID IN EXTEMPORANEOUSLY COMPOUNDED SUSPENSIONS

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ABSTRACT

Some drugs required by paediatric patients are not commercially available in those dosage forms appropriate for their use. These drugs may be needed to be prepared extemporaneously for use in each specific patient. Although the suspension is extensively used in hospital and pharmacy, there is still lack of appropriate formulation for extemporaneously preparation. The objective of this study was to assess the stability of extemporaneously compounded folic acid solution based on physical, chemical and microbiological qualities. For physical and chemical study, the sampling time is 60 days and the samples were kept at 25°C and 4°C. There was no notable changes of colour was observed of the suspension. However, the suspension started to demonstrate signs of caking and change of viscosity after 7 days of storage. There was no significance change between the pH at day 0 and day 60 for both conditions ($p > 0.05$). On average, the mean particle size of suspension was found to be stable at 4°C ($p > 0.05$). No significance change of zeta potential and concentration of suspension at day 0 and day 60 ($p > 0.05$). The preparations were also free from *E. coli* and *S. aureus* over 14 days of microbial testing. In conclusion, based on physical, chemical and microbiological study, folic acid suspensions 1 mg/mL are expected to remain stable for 60 days.

CHAPTER 1

INTRODUCTION

1.1 Background of Study

An extemporaneous preparation is defined as the preparation, mixing, assembling, packaging and labeling of a medical product based on the prescription ordered from a licensed practitioner for an individual patient (Shargel L. *et al.*, 1997). Access to a special dosage form of a medication is crucial when it is intended for administration to infants and children. Some drugs required by pediatric patients are not commercially available in those dosage forms appropriate for their use. Pharmaceutical companies would produce special manufactured product for pediatric patients essentially if the products are likely to be remarkable and will generate profit for the manufacturers themselves (Pawar and Kumar, 2002).These drugs may be needed to be prepared extemporaneously for use in each specific patient. Extemporaneous medications can vary from oral formulations such as suspension and solutions, sachets, mouthwashes to the topical formulations such as creams and ointments.

Most of the medications are often commercially available in either tablets or capsules. Solid dosage forms are in fixed doses and do not offer flexibility in dosing. Therefore, oral liquid formulations are preferred due to their flexibility in dosing and increased ease of administration in paediatric patient. Oral liquid medications are usually prepared extemporaneously because of a relative lack of licensed formulations for children who has