UNIVERSITI TEKNOLOGI MARA

THERMAL ANALYSIS OF ASCORBIC ACID AND ITS COMPATIBILITY WITH EXCIPIENTS BY USING DSC AND TG/DTG METHODS

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ABSTRACT

The physical-chemical properties and compatibilities of several commonly used pharmaceutical excipients with ascorbic acid were evaluated using thermal method. Differential scanning calorimetry (DSC) was used as a screening technique for assessing the compatibility of ascorbic acid with some currently employed pharmaceutical excipients such as avicel, magnesium stearate and lactose. The influence of different storage temperature on the drug stability in binary mixture after one month was also evaluated. On the basis of DSC result, ascorbic acid was found to be compatible with lactose and PEG 4000. Some drug-excipient interaction was observed with avicel and magnesium stearate. Result shows that, decomposition of ascorbic acid in binary mixtures is higher as the storage temperature is increase except for mixture containing lactose. Thermogravimetry (TG) was of help in interpreting the DSC results.

CHAPTER 1

INTRODUCTION

1.1 Rational of Study

Variety of substances, such as starch, sucrose, talc, which function as a binder, filler, disintegrant, lubricant and preservative are added to tablet formulation in order to obtain an elegant tablet. These substances are known as excipients. Even though excipient is inert, means do not interfere with the active ingredient, the presence of excipients may affect the stability or concentration of the active ingredient in the formulation.

This study is aimed to see drug-excipient interaction between ascorbic acid as an active ingredient and four selected excipients (avicel, lactose, magnesium stearate, and PEG 4000). These excipients are commonly used in the pharmaceutical tablet formulation. Since vitamin C is not a very stable substance, degradation is always occurs and can not be avoided. Degradation may be due various causes, for example, degradation by light, temperature, drug-drug interaction and drug- excipient interaction. The degradation of ascorbic acid in the tablet may be affected by the presence of excipients. By using thermal analysis (e.g.; differential scanning calorimetric, thermogravimetric analysis, and etc), the effect of these excipients on the degradation