THERMOSTABILITY AND POLYMORPHISM OF THEOBROMA OIL AND PALM KERNEL OIL AS SUPPOSITORY BASES

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Thermal stability of pharmaceutical ingredients is an important aspect. In this study, we adopted differential scanning calorimetry (DSC) to investigate thermal stability of suppository bases, theobroma oil (cocoa butter) and a palm kernel oil (PKO) blend. The study shows theobroma oil possesses six polymorphic forms whilst the palm kernel oil blend has three. Upon rescaning, the PKO blend does not show changes in the enthalpy of fusion and the melting point with time, whilst the theobroma oil shows significant reduction, and only regained its thermal stable state after 10 days. This indicates that PKO blend possesses better thermal stability.

Keywords: cocoa butter, DSC, palm kernel oil, pharmaceutical, polymorphism, stability, suppository, theobroma

Introduction

The ability of a molecule to crystallize into more than one arrangement is termed polymorphism and it has profound effect on the shelf life, solubility and formulation [1]. In fat polymorphism, it is the result of different lateral packing of the fatty acid chains and the longitudinal stacking of molecules in the lamellae [2]. Many studies have been conducted to investigate the polymorphism profile of various oil and fats products [3–6]. There are three main polymorphic organizations frequently observed in fat, where the arrangement of their molecules determine the thermal stability of the fat [7, 8].

Polymorphism in a fatty suppository base affects both the manufacturing process and the quality of the finished product, and this has been shown with theobroma as a suppository base [9]. For example, incorrect storage of theobroma (cocoa butter) based suppositories at an elevated temperature, such as above 30°C, causes the suppositories to melt. Upon cooling, the suppositories harden and metastable polymorphic forms appear, and this causes the suppositories to melt at a lower temperature. This problem will be further complicated if the incorporated drug is also prone to polymorphism [10].

The crystallization kinetics of fats including theobroma have been studied, however, the time required for the fats to regain their stable polymorphic forms after melting has not been widely reported [7, 8, 11–13]. In this study, we investigated the recovery time of theobroma and a palm kernel oil blend to their thermostable polymorphic forms. We also determined their suitability as suppository bases using differential scanning calorimetry (DSC), which is an important tool for the study of fat stability [14, 15].

Experimental

Materials

The hydrogenated palm kernel stearin (Batch No. 0091420002), palm kernel stearin (Batch No. 0091420002) and virgin palm kernel oil (Batch No. 0091420002) were obtained from Cargill (M) Sdn. Bhd., Kuala Lumpur, Malaysia. Theobroma (Batch No. BD.80.10HF01.0152) was supplied by KL Kepong, Kuala Lumpur, Malaysia. Other chemicals of analytical grade were obtained from either Sigma Chemical Company or Fisher Scientific, U.S.

Preparation of palm kernel oil suppository base

The palm kernel oil suppository base was prepared by mixing hydrogenated palm kernel stearin (50%), palm kernel stearin (20%) and virgin palm kernel oil (30%) using an Erweka mixer (Model No. AR 402, 45°C, paddle stirrer speed: 100 rpm). The blend was allowed to solidify at 25°C for one week and thereafter kept at 4°C until use.

DSC analysis

The differential scanning calorimeter (DSC 6, PerkinElmer, US) was connected to a chiller (C6, PerkinElmer, US) and a thermal analysis gas station