A Rapid Micro Quantification Method of Paracetamol in Suppositories Using Differential Scanning Calorimetry

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ABSTRACT

This study adopts Differential Scanning Calorimetry (DSC) to analyze the thermal properties of samples (2.5–4.0 mg) from the tip, middle, and base sections of individual paracetamol suppositories, which were sampled carefully using a stainless steel scalpel. The contents of paracetamol present in the samples obtained from these sections were determined from the enthalpies of fusion of paracetamol and expressed as % w/w paracetamol to allow comparison of the amount of paracetamol found in each section. The tip, middle, and base sections contained 10.1±0.2%, 10.1±0.2%, and 10.3±0.2% w/w paracetamol, and are statistically similar (One-way anova; p>0.05). This indicates that the preparation technique adopted produces high quality suppositories in terms of content uniformity. The contents of paracetamol in the 120-mg paracetamol suppositories determined by DSC and UV spectrophotometry were statistically equivalent (Student’s t-test; p>0.05), 120.8±3.6 mg and 120.8±1.3 mg, respectively, making DSC a clear alternative method for the measurement of content of drug in suppositories. The main advantages of the method are that samples of only 2.5–4.0 mg are required and the procedure does not require an extraction process, which allows for the analysis to be completed rapidly. In addition, it is highly sensitive and reproducible, with the lower detection limit at 4.0% w/w paracetamol, which is about 2.5 times lower than the content of paracetamol (10% w/w) present in our 120-mg paracetamol suppositories and commercial paracetamol suppositories, which contained about 125 mg paracetamol. Therefore, this method is particularly suited for determination of content uniformity in individual suppositories in quality control (QC) and in process quality control (PQC).

Key Words: Content uniformity; DSC; Paracetamol; Suppository; Thermal analysis.

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