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Published

2005

Conference Title

Proceedings of ASCEPT (Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists) and APSA (Australasian Pharmaceutical Science Association), Volume 11, 2005

PHYSICOCHEMICAL STABILITY OF A PARACETAMOL-CONTAINING TABLET REPACKAGED INTO A DAA. A Haywood (1), M Mangan (2) & BD Glass (2), (1) School of Pharmacy, Griffith University, Qld 9726, (2) School of Pharmacy, James Cook University, Qld 4811

Despite the widespread use of Dose Administration Aids (DAAs), pharmacists have limited resources at hand and little available data regarding the stability of drug products during repackaging or storage in these devices. Physicochemical stability studies were performed on a commonly packed paracetamol tablet at ambient (25 ºC; 60 % RH) and accelerated (40 ºC; 75 % RH) conditions and directly after heat-sealing, in a DAA frequently employed in practice. Results at 4 weeks of storage at accelerated conditions showed a slight expected increase in tablet hardness from 146.4 ± 10.0 to 154.0 ± 10.9 N (mean ± SD) (n=20), due to the high relative humidity, with a subsequent increase in disintegration time from 188 to 215 s (n=6), whereas controlled room temperature (ambient) conditions revealed a slight decrease in tablet hardness to 113.6 ± 8.4 N (n=20) with a corresponding decrease in disintegration time to 166 s (n=6). These minor physical changes were not apparent in the dissolution rate profiles (see figure), and were consistent with that of the controls (n=3, P>0.05). Chemical stability was confirmed by HPLC with paracetamol content falling within the required range of 95 – 105 % of the labelled amount, for all experimental conditions. The compendial requirements for physicochemical stability were thus met for both accelerated and ambient conditions. This study provides evidence on stability of drug products in DAAs to support pharmacists in making sound clinical and operational decisions regarding the repackaging of medications in these devices.