Stability of Clozapine Repackaged into Dose Administration Aids

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Objective. Repackaging tablets into dose administration aids (DAA) requires that pharmacists consider stability issues associated with repackaging. Clozapine is an atypical antipsychotic used in the treatment of schizophrenia. Due to the patient profile there is a high rate of repackaging of Clozapine. Because of reports from hospital pharmacy about discoloration of returned Clozapine tablets repackaged into DAAs, the aim of this study was to evaluate the physicochemical stability of these repackaged tablets.

Methods. Clozapine tablets were repackaged into DAAs and evaluated for physicochemical stability over a 6 week period at controlled room temperature (25±1°C; 60±1.5%RH) and accelerated conditions (40±1°C; 75±1.5%RH).

Results. Chemical stability was confirmed for all storage conditions, with clozapine content occurring within the BP range of 90-110%. Although physical stability was confirmed for all tests at room temperature (weight uniformity, hardness, friability, disintegration and dissolution), under accelerated conditions, the disintegration test did not meet BP requirements. However, the dissolution test was successful with 85% of clozapine dissolving in 45 minutes.

Discussion. This study illustrates that clozapine correctly repackaged maintains its physical and chemical stability for 6 weeks. As no discoloration of the tablets was observed, it is assumed that these reports were as a result of improper handling by patients. Based on these findings, it is recommended that patients be advised on the correct handling and storage of their DAAs.