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Stability of risperidone in a novel polyol-based low-aqueous *in situ* gelling emulsion

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Introduction. Risperidone is a benzisoxazole atypical antipsychotic used for the treatment of schizophrenia. To maintain therapeutic effects and to prevent rebound symptoms, patients are required to maintain a strict daily treatment regime. Current treatment options include daily tablets or fortnightly injections.
Aims. The aim was to determine the stability of risperidone in a novel *in situ* gelling formulation comprised of a hydrogel-containing polyol-peanut oil emulsion for use as a vehicle for sustained release of risperidone.
Methods. Formulations were prepared to contain 0.05 mg/ml risperidone and tested for stability over an 8-week period at real time (25 ± 1˚C/60% RH), accelerated (40 ± 1˚C/75% RH) and refrigerated (4 ± 1˚C) conditions.
Results. Differential Scanning Calorimetry results showed no changes in physical properties of risperidone within the formulation, however a slight shift in the endothermic peak from 170.6˚C to 166.2˚C was observed when exposed to peanut oil. HPLC results showed no significant loss of drug content over the 8-week study period when stored at room temperature or under refrigerated conditions ($n=3$, $p>0.05$), however a significant decrease in risperidone content was seen after 4 weeks ($n=3$, $p<0.05$) and after 8 weeks ($n=3$, $p<0.05$) when stored under accelerated conditions. There were no changes in physical appearance throughout the study period, with all formulations appearing homogenous, without any apparent change in colour or clarity, and no sign of caking or separation.
Discussion. These results indicate that the risperidone formulation is physically and chemically stable for up to 8 weeks when stored at or below room temperature. Higher temperatures are associated with significant loss in risperidone content, possibly due to physical incompatibility issues with peanut oil at higher temperatures. The physicochemical stability, in addition to the biocompatible excipients and recently demonstrated *in vitro* release capability of the formulation, shows potential for future clinical application in schizophrenia.