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Effect of storage on the physical stability of thin polymethacrylate-perphenazine films

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We evaluated the physical stability of thin polymethacrylate-drug films under three different storage conditions by X-ray powder diffraction, differential scanning calorimetry, scanning electron microscopy, polarized light microscopy, and Fourier transform infrared spectroscopy. Mechanical properties i.e. elongation, mechanical strength, and in vitro drug release from the thin films were also determined during storage. The films consisted of ammonium methacrylate copolymer (RLPO)/dimethylaminoethyl methacrylate copolymer (EPO), polyvinylpyrroline (PVP)/polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer (Soluplus) and perphenazine (PPZ). PPZ remained fully amorphous in all RLPO- and EPO-films for up to 12 months' storage at 4 °C in dry conditions. Instead, in EPO+PVP+PPZ 15% -films, higher temperature induced recrystallization of PPZ within three months and higher humidity also at six months. Crystallization was also observed in EPO+Soluplus+PPZ 10% -films at high temperature at 12 months. The amount of PPZ released was significantly lower from recrystallized PPZ films than from stable amorphous films. The better stability of RLPO-films was attributed to PPZ being molecularly dispersed and also because of strong drug–polymer interactions in the films, while increasing storage temperatures weakened the hydrogen bonding interactions in the EPO-films. In addition, the presence of hygroscopic PVP facilitated PPZ recrystallization in the EPO-films if they were stored in a highly humid environment.