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Characterization of processing and formulation parameters of hot-melt extruded polyethylene oxide matrices for extended-release application

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Hot-melt extrusion has been established as suitable processing technique for extended release applications. However, the effect of formulation and processing parameter on processability and release appears to be API and polymer specific. To this end, the aim of this study was to systematically and extensively evaluate the applicability of polyethylene oxide (PEO) as a matrix forming polymer in extended release formulations prepared by HME for diclofenac sodium as a model.Different formulations at 12.5% drug loading of the model drug with various PEO grades comprising PEO 205, PEO N-12K, PEO N-60K and PEO 301 were developed. These formulations were processed at 90 °C \10 rpm, 90 °C\30 rpm, 110°C\10 rpm and 110°C\30 rpm. It was evident that polymer grade had a pronounced influence on modulating the drug dissolution profile. On the other hand, the interplay between formulation variables and the tested temperatures and screw speeds were also found to have a remarkable contribution in modifying the drug dissolution profile. To assign for the drug release mechanism, kinetic modeling of the dissolution profiles applying Korsmeyer-Peppas mathematical model was considered and evaluated. Dissolution testing revealed that extrudates containing PEO (301) at a drug loading percentage of 12.5%, 20% polyethylene glycol and 1% colloidal silicon dioxide had extended the drug release over a period of time of almost (10-12) hours. In conclusion, formulations that contain various grades of PEO own their particular physical properties that could suit different therapeutic compounds. The effects of the selected sets of processing and formulation parameters on the release of diclofenac sodium from extruded PEO matrices have been characterized and identified.

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