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Multiparticulate SR Formulation of Dexketoprofen Trometamol by Wurster Coating Technique

Authors : Bhupendra G. Prajapati, Alpesh R. Patel

Abstract : The aim of this research work is to develop sustained release multi-particulates dosage form of Dexketoprofen trometamol, which is the pharmacologically active isomer of ketoprofen. The objective is to utilization of active enantiomer with minimal dose and administration frequency, extended release multi-particulates dosage form development for better patience compliance was explored. Drug loaded and sustained release coated pellets were prepared by fluidized bed coating principle by wurster coater. Microcrystalline cellulose as core pellets, povidone as binder and talc as anti-tacking agents were selected during drug loading while Kollicoat SR 30D as sustained release polymer, triethyl citrate as plasticizer and micronized talc as an anti-adherent were used in sustained release coating. Binder optimization trial in drug loading showed that there was increase in process efficiency with increase in the binder concentration. 5 and 7.5%w/w concentration of Povidone K30 with respect to drug amount gave more than 90% process efficiency while higher amount of rejects (agglomerates) were observed for drug layering trial batch taken with 7.5% binder. So for drug loading, optimum Povidone concentration was selected as 5% of drug substance quantity since this trial had good process feasibility and good adhesion of the drug onto the MCC pellets. 2% w/w concentration of talc with respect to total drug layering solid mass shows better anti-tacking property to remove unnecessary static charge as well as agglomeration generation during spraying process. Optimized drug loaded pellets were coated for sustained release coating from 16 to 28% w/w coating to get desired drug release profile and results suggested that 22% w/w coating weight gain is necessary to get the required drug release profile. Three critical process parameters of Wurster coating for sustained release were further statistically optimized for desired quality target product profile attributes like agglomerates formation, process efficiency, and drug release profile using central composite design (CCD) by Minitab software. Results show that derived design space consisting 1.0 to 1.2 bar atomization air pressure, 7.8 to 10.0 gm/min spray rate and 29-34°C product bed temperature gave pre-defined drug product quality attributes. Scanning Image microscopy study results were also dictate that optimized batch pellets had very narrow particle size distribution and smooth surface which were ideal properties for reproducible drug release profile. The study also focused on optimized dexketoprofen trometamol pellets formulation retain its quality attributes while administering with common vehicle, a liquid (water) or semisolid food (apple sauce). Conclusion: Sustained release multi-particulates were successfully developed for dexketoprofen trometamol which may be useful to improve acceptability and palatability of a dosage form for better patient compliance.

Keywords : dexketoprofen trometamol, pellets, fluid bed technology, central composite design
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