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Natalja Genina, Batol Hadi, Korbinian Löbmann

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Hot melt extrusion (HME) as solvent-free technique for a continuous manufacturing of drug-loaded mesoporous silica

Natalja Genina*[x], Batol Hadi, Korbinian Löbmann[x]

Department of Pharmacy, University of Copenhagen, Universitetsparken 2, DK-2100 Copenhagen, Denmark

*Corresponding author

[x]Contributed equally

ABSTRACT

The aim of the study was to explore hot melt extrusion (HME) as a solvent-free drug loading technique for preparation of stable amorphous solid dispersions (ASD) using mesoporous silica (PSi). Ibuprofen (IBU) and carvedilol (CAR) were used as poorly soluble active pharmaceutical ingredients (APIs). Due to the high friction of a API: PSi mixture below the loading limit of the API, it was necessary to add the polymer Soluplus® (SOL) in order to enable the extrusion process. As a result the APIs distributed between the PSi and SOL phase after HME. Due to its higher affinity to PSi, IBU was mainly adsorbed into the PSi, whereas CAR was mainly found in the SOL phase. Intrinsic dissolution rate (IDR) was highest for HME formulations, containing PSi, compared to pure crystalline (amorphous) APIs and HME formulations without PSi. HME is a feasible solvent free drug loading technique for preparation of PSi-based ASD.