Developing Solid Dosage Form of Co-precipitation Amorphous Solid Dispersion

Authors: Debbie Wanapun, Cathy Amber, Samir Kulkarni, Efren Alvidrez, Kapil Arora, Aifang Li, Macy Burachio, Jarred Beauchemin, Kelly Field, Chris Chabot, Abigail Gershman, Penny Khamphavong
Presenting Author: Debbie Wanapun
Affiliation: Pfizer Inc
Corresponding Author's email: debbie.wanapun@pfizer.com

Purpose
Co-precipitation (CoPPT) has recently gained interest as an alternative amorphous solid dispersion process due to the potential advantage of combining API isolation and drug product intermediate manufacturing steps. In this work, the author will discuss CoPPT drug product development, challenges, and comparison with spray-dried dispersion drug product.

Methods
The CoPPT of compound A was manufactured using solvent/antisolvent method. Immediate release tablet formulation and process of the compound A CoPPT were developed using a small scale tool, which were subsequently manufactured using roller compaction and rotary tablet compression.

Results
The CoPPT material was confirmed to be amorphous under PXRD and TGA. The comparison of Mechanical and bulk properties of CoPPT versus spray dried dispersion of compound A will be discussed. The manufactured tablets meet target attributes and dissolution profile.

Conclusion
Progress in CoPPT amorphous solid dispersion and CoPPT drug product is reported.

Keywords: Co-precipitation, amorphous solid dispersion, drug product development