Amorphous Fenofibrate Solid Dispersions Prepared by Thin Film Freezing Combined with Template Emulsion

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Introduction

While DSC (D) has been proposed before as a novel method to prove the amorphous nature of a compound, the XRPD (X-ray powder diffraction) has been successfully used to rule out an amorphous solid dispersion. The present project is based on the combination of these two methods to prove the amorphous nature of the fenofibrate dispersion. The XRPD patterns are used to analyze the crystalline structure of the compounds, while the DSC patterns are used to identify the nature of the compounds.

Hypothesis

A simple, rapid-assay characterization of the presence of solid amorphous drugs can be proposed by the two methods as well as other techniques.

Materials

- Fenofibrate (Sigma-Aldrich, Inc., St. Louis, MO)
- Cremophor RH40 (Sigma-Aldrich, Inc., St. Louis, MO)
- Poloxamer 188 (Sigma-Aldrich, Inc., St. Louis, MO)
- XRPD (X-ray powder diffraction)
- DSC (Differential Scanning Calorimetry)

Methods

Preparation of Co-solvent Solution

- Add the correct amount of polysorbate 80 to make 5 10% solutions at the required concentration to make the dispersion solution.

Preparation of Co-solvent Dispersions

- Add the required amount of solution to be dispersed and stir until the solid is completely dissolved.

Preparation of Solid Co-solvent Dispersions

- Add the required amount of solid to be dispersed to the co-solvent solution.

SEM Micrographs of Fenofibrate Solid Dispersions

- The dispersibility of the solid is increased by the co-solvent solution.

Summary

- The amorphous state of the fenofibrate is confirmed by the DSC patterns.
- The XRPD patterns confirm the amorphous state of the fenofibrate.

Conclusions

- The combination of DSC and XRPD provides a powerful tool for the characterization of amorphous solid dispersions.

References