**Preparation and Characterization of Spray-Dried Selumetinib Sulfate Solid Dispersions for Oral Delivery**

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**Background and aims.** Selumetinib sulfate (SEL) is classified as a BCS Class 4, exhibiting both poor aqueous solubility and low permeability, which limit its oral bioavailability. This study aimed to develop a spray‐dried solid dispersion (SD) of SEL that enhanced solubility, inhibits precipitation, improves dissolution rates, and maintains physicochemical stability.

**Methods.** Excess SEL was dispersed in various water-soluble polymers to screening for solubility enhancement and precipitation inhibition. Solubility at pH 1.2 and resistance to precipitation during pH increase were quantified in 1% polymer solutions. The selected polymer was Methylcellulose 4 cP(MC 4 cP) prepared via spray drying to produce SEL-loaded SDs. Characterization of SD morphology, crystallinity, and thermal behavior was performed using scanning electron microscopy (SEM), powder X-ray diffraction (PXRD), and differential scanning calorimetry (DSC). Dissolution profiles of raw SEL and SEL-SDs were evaluated in pH 1.2, 4.0, 6.8 buffers and water. Accelerated stability of the SEL-SD was assessed at 40 °C for one month.

**Results.** In a 1% MC 4 cP solution at pH 1.2, SEL solubility reached 1,584.1 ± 31.6 µg/mL after 3 hours, and no precipitation was observed for at least 24 hours during pH escalation. Among spray-dried formulations, F3 (SEL:MC 4 cP = 1:10) exhibited a dissolution rate more than double that of raw SEL in all media tested. SEM, PXRD, and DSC analysis confirmed amorphous dispersion and drug–polymer interactions. F3 retained its dissolution performance and physicochemical integrity after one month at 40 °C.

**Conclusion/Discussion.** The F3 improves SEL’s solubility, dissolution kinetics, and thermal stability. These attributes suggest that spray-dried SEL-MC 4 cP solid dispersion is a promising formulation strategy for enhancing the oral delivery of BCS Class 4 drugs.

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**References:**

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