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| Surface Energy Properties of Polymersby Inverse Gas Chromatography  |
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| **Background:** Soluplus®, a polymeric solubilizer comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate (PEG/PVCp/PVAc), has been designed to enhance the solubility of poorly soluble drugs using the solid solution/dispersion approach. Soluplus is an amorphous graft copolymer with a low glass transition temperature (Tg), low hygroscopicity and high solubility in water and organic solvents, which offers advantages over cellulose based and/or PVP based excipients by increasing the solubility of insoluble drugs in the form of solid solution/dispersion. The solubility/miscibility of polymers with drugs has been investigated by different approaches. Some of these methods require a complete understanding of the chemical structure or composition of the polymer and drug, and often lead to inaccurate results. In contrast, Inverse gas chromatography (IGC) provides accurate values of solubility parameters without requiring the polymer structure or composition. Inverse gas chromatography was used to examine surface energy properties, including dispersive surface energy, specific surface energy, and free energy of desorption for several polar solvents. In addition, solubility parameters of Soluplus and the extrudate with carbamazepine as a model Class II drug were determined. |
| **Methods:** Soluplus extrudate with carbamazepine (CBZ) was prepared on a Polylab co-rotating twin screw extruder. IGC measurements were carried out on a surface energy analyser (SMS-iGC). The measurements were carried out above the Tg of Soluplus and the solid solution.Surface energy experiments were performed at 30°C, 10 ml/minute flow rate, 0% relative humidity, and 0.04 P/Po injection concentration. Dichloromethane and ethyl acetate were used to calculate the specific surface energy using the Good-van Oss approach.Solubility parameter experiments were performed at 60°C, 5 ml/minute flow rate, 0% relative humidity and 0.5 P/Po injection concentrations using undecane, decane, nonane, octane, dichloromethane, acetonitrile, acetone, ethyl acetate, and ethanol.The determination of the solubility parameter is based on the solution theory by Hildebrand and Scatchard and applied to IGC according to the Price and Guillet equation. |
| **Results:** Soluplus and Kollidon VA64 have lower surface energies, whereas, Carbamazepine had the highest dispersive energy, due to strong interactions. Extrudate w/CBZ and Soluplus behaved similarly, indicating that CBZ was completely dispersed in the polymer matrix, leaving no exposed CBZ on the surface of the extrudate.Soluplus and Carbamazepine showed different results in particular with acetonitrile. However, Soluplus and the Extrudate w/CBZ showed similar values for all polar probes. This suggests that the CBZ at 15 wt% in the extrudate is completely dispersed in the polymer matrix. Kollidon VA64 and Soluplus show vastly different behavior, indicating different dominant surface groups for these two samples. |
| **Conclusions:** Inverse gas chromatography is a powerful technique to measure the surface properties of drugs and excipients in the amorphous state. IGC data suggests that CBZ is molecularly dispersed in the extrudate.  |