

# **A multi-technique characterization of the stability of surfactant containing solid dispersion based buccal patches prepared by hot melt injection moulding**

## **Abstract**

This study investigates the stability of typically complex multi-component hydrophilic solid dispersions that could be used in a clinical application. Felodipine solid dispersions in two types of blends consisting of PEG, PEO and Tween 80 or Vit E TPGS were prepared by hot melt-injection moulding (HMIM) across a range of drug loadings and subjected to a range of storage conditions. Microscopy, thermal analysis, spectroscopy and powder X-ray diffraction were used to characterize the systems. The semi-solid surfactant TPGS showed a better solubilizing effect on the drug than the liquid surfactant Tween 80 in the fresh state and offered some degree of protection over the chemical degradation of PEG/PEO. Better storage stability was observed for the systems with low drug loading. Crystallization of a new metastable polymorphic form of felodipine in the patches with drug loadings at and above the saturation point was observed. Quantitative comparison of the data sets was achieved by a normalisation process and calculation of statistical variance. TPGS containing patches were more sensitive to the aging process than Tween containing patches. For both surfactants, such instability is more responsive to the storage temperature than

humidity. This study established a methodology for probing the complex stabilities of multi-component dispersions.