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MONITORING EXTRUSION OF PHARMACEUTICAL POLYMER FORMULATIONS USING NEAR INFRA-RED SPECTROSCOPY

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Melt extrusion of polymer-drug formulations is becoming increasingly used in the pharmaceutical industry. Many new drugs have poor solubility and bioavailability; melt extrusion with a polymer matrix freezes the drugs into an amorphous form and acts to improve these properties. Twin screw extrusion is a continuous and solvent free process which lends itself well to in-line quality control. Process Analytical Techniques (PAT) and Quality by Design (QbD) are being encouraged by bodies such as the FDA. Here we report the use of near infra-red (NIR) spectroscopy to monitor melt extrusion of a range of model drug-polymer systems. A Thermo Fisher Pharmalab 16mm co-rotating twin screw extruder was used, equipped with a Thermo Fisher Antaris II NIR spectrometer with a high temperature probe attached at the extruder die. Polymer and drug systems included glipizide and polyethylene oxide, and ibuprofen and polyvinyl pyrollidone. NIR spectra were taken in real-time during extrusion at a range of drug loadings, set temperatures and screw rotation speeds. Partial least squares analysis was used to correlate the measured spectra to drug loading. The technique was found to be sensitive to drug loading and process induced changes which may affect the drug-polymer miscibility and morphology.