

CHARACTERISATION AND PREDICTION OF STABILITY OF AMORPHOUS MATERIALS DURING PHARMACEUTICAL DEVELOPMENT: PAIR-WISE DISTRIBUTION FUNCTION

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With the increasing openness to progress with a stabilised amorphous drug formulation due to bioavailability and / or crystallisation issues, a new challenge has arisen in terms of how to rank amorphous samples in terms of predicted physical stability. A new characterisation technique emerging from the literature is the application of Pair-wise Distribution Function (PDF) to organics. PDF extends the use of existing technology (X-ray Powder Diffraction, XRPD) by more detailed data analysis. Analysis times are short and enable physical stability ranking of formulations to be performed within days of manufacture, thus providing the potential to avoid delays in waiting for stability read outs.