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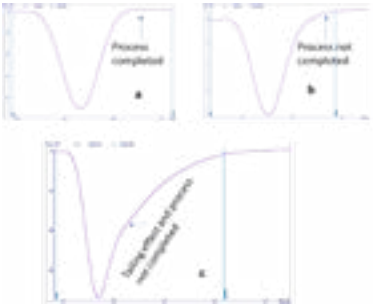
Intentionally made amorphous substance to quantify unintentionally produced amorphous materials: Decades of hands-on experience

Milling induced disordered material, amorphous, is highly energetic and a considerable portion of these particles significantly influence the cohesive and adhesive balance (CAB) of micronised particles. This behaviour results in varying fine particle fraction (FPF) which ultimately affects dry powder inhaler (DPI) performance. There is also an important aspect of milled materials that they are heterogenous in nature. Due to the different particle size, shape, surface area, high energetics, it has been a challenge to produce stable DPI product without a deep understanding of the physical properties of milled and un-milled samples, their behaviour and control over their processing. It is reasonable for the regulatory authorities (e.g. FDA, MHRA) to seek a suitable analytical method to quantify amorphous content, control over amorphous materials, and they may assign limits for amorphous content in batches that are to be used for commercial purposes. There has been extensive work carried out for amorphous content determination using various techniques that has added invaluable insights to fundamental research. However, hands-on experience of handling numerous inhaled APIs and their corresponding products motivated this author to highlight practical approaches required to develop a reliable method (s) for this challenging subject. Research in this field clearly demonstrates that given right skills, knowledge and experience, a suitable method can be developed which ensures reproducible data consistently. There is no standard method to quantify amorphous materials in a crystalline bulk for pharmaceutical solids. As all such particles have different physicochemical properties, it is important that the method is developed as per the sensitivity of the solids to the technique which ensures reproducible data in a robust manner.



Biography

Mridul Majumder is a Founder, Director of M2M Pharmaceuticals Ltd. Before setting up M2M Pharma in 2016, he had worked for a CRO over 12 years in early stage product development especially related to material science for inhalation drug delivery. He is an honorary lecturer at UCL School of Pharmacy, London; Fellow of Royal Society of Chemistry and a Member of Academy of Pharmaceutical Sciences (APS) in the UK. He is a Pharmaceutical scientist with a PhD in pharmaceutics from University of Reading (2013). Before that, he did his MSc drug delivery from UCL School of Pharmacy, London back in 2002 and his MPharm and BPharm were from Jadavpur University (2000) and Bangalore University (1997) respectively.

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