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Understanding the importance of diversity of particle size methods based on laser diffraction

It is known that particle size can play a significant role on drug substance and product performance (e.g. solubility) and manufacturability (e.g. flowability). Due to low water solubility, in most cases particle-size distribution (PSD) methods intend to measure primary particles in the bulk as there is direct correlation of particle size and kinetics of solubility. For the release methods, the decision on what aspects of particles a given PSD method should measure is ideally based on the Quality Target Product Profile (QTPP) of the drug product. The measurement of agglomerates in the bulk is crucial for formulations where agglomerates remain intact due to their hardness. PSD methods are useful for processes monitoring such as micronization or drying, where secondary agglomeration might happen for controlling process modifications (process improvement) including scale-up processes. PSD methods are sometimes selected as tests involved in stability protocols with reference to the results observed for batches used in bioavailability or clinical studies for drug self-life determination. For more challenging active pharmaceutical ingredients (APIs) regarding bulk properties, a batch-to-batch comparison method might be suitable to distinguish between batches. The different types of PSD methods mentioned above can be applied during different project stages (R&D and GMP) and for different purposes. Such diversity of PSD methods, as well as the fact that there is no general PSD method listed in any pharmacopoeia, might confuse programme leaders and manufacturers. This lecture gives overview on basic principles of PSD methods based on laser diffraction and stress the challenges during method development and method transfers.

Biography

Edislav Lekšić is the Team Leader of Physical Sciences at Almac Sciences. He has worked in the pharmaceutical industry for the past 12 years, with expertise in solid state chemistry related to API selection, crystal surface property, scale-up and production troubleshooting. He has been involved in preformulation work and development of systems such as solid dispersions and cocrystals. He has worked closely with patent law authorities contributing to aspects of IP. He has a strong GMP background and experience in XRPD and PSD method validation and transfers. He received a PhD in supramolecular chemistry from the University of Zagreb.

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