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Study of particle size distribution and flow properties of granules prepared by different granulation techniques

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The distribution in particle size is a factor for the processing behaviour of a powder during pharmaceutical manufacturing. There is, however, still a need for reports providing evidence for a correlation between the particle size distribution and the manufacturability of powders. Large granule porosity in wet processed granules has been related to a large fragmentation during compaction, resulting in mechanical stronger tablets. A decreased primary particle size increases the tablet strength. However, this assumption is provided that the particles stay intact during compaction. The interaction between the particles can be complex and depend on physical properties such as particle size, shape, deformation behavior etc. Powder flow properties deteriorate nearly exponentially with decreasing particle size. For a powder exhibiting marginal flow properties during powder handling, granule size enlargement is an effective means to improve flow properties and manufacturability. To obtain constant powder flow of a given formulation, granule/particle size should be carefully controlled. Hence aim of present work was to study particle size distribution and flow properties of granules prepared by different granulation techniques which affect final tablet performance. In this study granules were prepared by different granulation techniques and characterized for its physical properties. Results showed that, primary particle size had a strong effect on granule growth rate, granule size distribution, granule porosity and also on hardness of tablet.

Biography

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Overview of quality management in clinical trials

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Quality control and quality assurance are integral part of quality management. Quality control is focused on fulfilling quality requirements, whereas quality assurance focuses on providing confidence that quality requirements are satisfied. Quality of the clinical trials depends on data integrity and subject protection. Globalization, outsourcing and increasing the complexity of the clinical trials have made the target of achieving global quality challenging. To meet the regulatory expectations, the sponsors need to improve quality by developing systems with specific standards for each clinical trial process. These recent initiatives will go a long way in improving quality of the clinical trials. It is mandatory for the sponsors of clinical trials and contract research organizations alike to establish, manage and monitor the Quality Control and Quality Assurance systems along with their integral standard operating procedures and other quality documents as well to provide high-quality products and services to full fill the customer need and expectations. The 13th principle in the International Conference on Harmonization Good Clinical Practice (ICH GCP) guideline clearly states us that the systems and procedures that assure the quality of every aspect of the (clinical) trial should be implemented. We suggest that to improve the successful, timely delivery of important clinical trials for patient benefit; however it is time to produce standard trial management guidelines and develop robust methods of evaluation in clinical trials quality management.

Biography

Vema Ravi is a presently a student of JSS College of Pharmacy, JSS University Mysore. He has completed his B.Pharm from JSS College of Pharmacy, Mysore. He is presently pursuing his M.Pharm in Industrial Pharmacy in the same college. His areas of research are NDDS, Novel Drug development and R&D.

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