

An approach to enhance dissolution rate and bioavailability by spray drying with silica

Dhanashri S. Yadav
Shivaji University, India

Solid dispersions have attracted considerable interest as an efficient means of improving the dissolution rate and hence the bioavailability of a range of poorly water-soluble drugs. Solid dispersions of poorly water-soluble drugs with water-soluble carriers have been reduced the incidence of these problems and enhanced dissolution. Spray drying is an efficient technology for solid dispersion manufacturing since it allows extreme rapid solvent evaporation leading to fast transformation of an API-carrier solution to solid API-carrier particles. Solvent evaporation kinetics certainly contribute to formation of amorphous solid dispersions, but also other factors like the interplay between the API, carrier and solvent, solution state of the API, formulation parameters (e.g. feed concentration or solvent type) and process parameters (e.g. drying gas flow rate or solution spray rate) will influence the final physical structure of the obtained solid dispersion particles. The present study was carried out by using silica adsorbents such as aerosil 200, sylsya 350 as carrier for solid dispersion preparation by spray drying technique. The conversion of crystalline form of poorly water soluble API into amorphous form in silica based carrier results into enhanced dissolution rate and bioavailability.

Biography

Dhanashri Yadav, doing M. Pharm. (Pharmaceutics) at Shivaji University, Kolhapur. She has presented various posters in national conferences and has published two research articles in international journals. She is a Life Member of Indian Pharmaceutical Association.

y.dhanashri90@gmail.com

Quality by design (QBD) for abbreviated new drug applications (ANDAs)

Chaganti Dhanunjaya Reddy¹, Raghunandan H.V and N. Vishal Gupta
JSS University, India

Quality by design is an essential part of the modern approach to pharmaceutical quality. This paper discusses quality by design for ANDAs and presents a summary of the critical to quality parameters (CTQ) like particle size, bulk density, compressibility, excipients compatibility etc. The elements of quality by design are examined and a consistent nomenclature for quality by design, critical quality attribute, critical process parameter, critical material attribute, and control strategy is proposed. Agreement on these key concepts will allow discussion of the application of these concepts to abbreviated new drug applications to progress. The Food and Drug Administration (FDA) and pharmaceutical industry are talking about quality by design, and there are many important terms that are used as part of this discussion. However, industry comments indicate that there is still much confusion in the generic industry as to the meaning of quality by design and its associated nomenclature. This paper provides a consistent set of definitions to provide a clearer understanding of quality by design for abbreviated new drug applications (ANDAs).

Biography

Chaganti Dhanunjaya Reddy is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2012. Presently he is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. He has presented posters at national level and has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, analytical method development of novel drugs.

chagantikoolguy@gmail.com