

Selection of Polymeric Excipients for Poorly Soluble Drugs

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Editorial

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Editorial

Pharmaceutical drug delivery systems consists of variety of additional constituents other than its active pharmaceutical ingredient (API) required for pharmacological activity [1]. These constituents are defined as excipients by International pharmaceutical excipients council and are required to be properly evaluated for safety before included in delivery systems [2]. Excipients, although pharmacological inert are a key determinant of delivery systems performance. They are included in a delivery systems not for their direct therapeutic action, but are added to the delivery systems to either aid in processing during its manufacture (for e.g., vehicles, co-solvents, anti-adherents, polymers), protect, support and enhance stability, bioavailability and patient acceptability (for e.g., anti-oxidants, preservatives, disintegrants, coatings, sweetening agents, flavoring agents), assist in product identification (for e.g colorants), or enhance other attributes of the safety and effectiveness of the drug delivery system during its storage and use [3].

The advancement of combinatorial chemistry and high throughput screening techniques has resulted in the development of significant number of poorly water-soluble drugs. Further, with the growth of novel drug delivery systems like nanoparticles and amorphous systems, there has been a tremendous increase in the number of conventional and new excipients (mainly polymers) being used for solubility enhancement [4-10]. Amorphous solid dispersions is a technique of dispersing an amorphous hydrophobic drug in a molecular matrix of hydrophilic polymer whereas Nanoparticles are formulations with particles in the size range of 100 nm or less which can be used for poorly-soluble drugs. Since there is a huge differences not only in the structures of poorly soluble drugs but also in the principles of drug development approaches, a detailed and through knowledge of the physical and chemical properties of polymers is essential for formulators throughout the world for rational selection of these polymers [11].

Pragmatic approach is usually opted during selection of polymers for solubility increase which results in formulators using polymers based on their conventional and reported application. However, to select the optimum polymers for solubility enhancement, following approach can be very beneficial:

1. Careful consideration of physicochemical properties of conventional polymers including safety. Rank ordering the choice of polymers based on their advantages and limitations.

2. Careful consideration of physicochemical properties of new polymers, co-polymers, blocks polymers etc. Consider utilizing

combination of polymers if required. Rank ordering the choice of polymers based on their advantages and limitations.

3. Compatibility and miscibility studies between poorly soluble drugs and polymers. In a high throughput mode or based on the selected polymers ranked in 1 and 2.

4. Solubility and stability studies. In a high throughput mode or based on selected polymers ranked in 1 and 2.

5. Rank ordering of the polymers according to their efficiency for scale up of formulations.

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