Pharm Anal Acta 2018, Volume 9
DOI: 10.4172/2153-2435-C1-034

Designing the novel polymeric-based trans-dermal drug delivery systems

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The aim of the studies is to develop the novel polymeric matrices to adjust the release profile and tailor the administration frequency using various processing techniques for trans-dermal drug delivery purposes. Trans-dermal delivery systems have been extended in the last decade due to advantages such as bypassing first pass liver metabolism and circumventing GI enzymatic degradation particularly of protein-based drugs, vaccines and enzymes. They can be formulated as tablets, pellet or films produced by casting or molding of solids and semisolids polymeric matrices. The idea of novel polymeric matrices design using disruptive formulation process is to modify the solid-state form of API and tailoring the release profile via freeze drying and hot melt extrusion. The advantage of these techniques is generation of amorphous API in combination with the most stable crystal form to maintain the stability as well as a pulsatile drug release profile. This generates the steady drug concentration over a long period of time. The modified polymeric based formulations can be developed as implants, films or depo suspensions which are suitable alternatives to deliver drugs less frequently. The DSC analysis determines the Tg values for polymers, drugs and excipients that was implemented in lyophilization cycle design. The speed of freezing should be optimized as well as temperature range and drying period. Annealing is potentially a constructive process to stabilize the solid dosage form as well as the mechanical strength of pellets. The drug polymorphism status determines the release profile that will be identified with XRPD and DSC studies. The TGA thermogram indicates the moisture content for each lyophilization cycle samples and hence determines the most suitable cycle. The drug permeation in formulation will be correlated to excipients selection that needs to be determined by *in vivo* or *ex vivo* studies.

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