

ADVANCED CHARACTERIZATION TECHNIQUES IN REVERSE ENGINEERING OF INNOVATOR PRODUCTS CONTAINING SMALL DRUG MOLECULES

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ABSTRACT

This review article enlists the Advanced Methods and Techniques for reverse engineering of the innovator drug products involving material characterization studies and novel instrumental analytical evaluation to decode the information related to the physicochemical information and related critical material attributes of the product components including principal active substance, the drug and thus to predict the critical material attributes and tentative manufacturing process that have been adopted by the innovator and tentative to decide the tentative qualitative and quantitative composition. The outcome of these studies are very vital as input information in designing and development of generic drug products for improved cost effectiveness and economical drug products availability in the market for enhanced accessibility by all section of people in developing countries.

