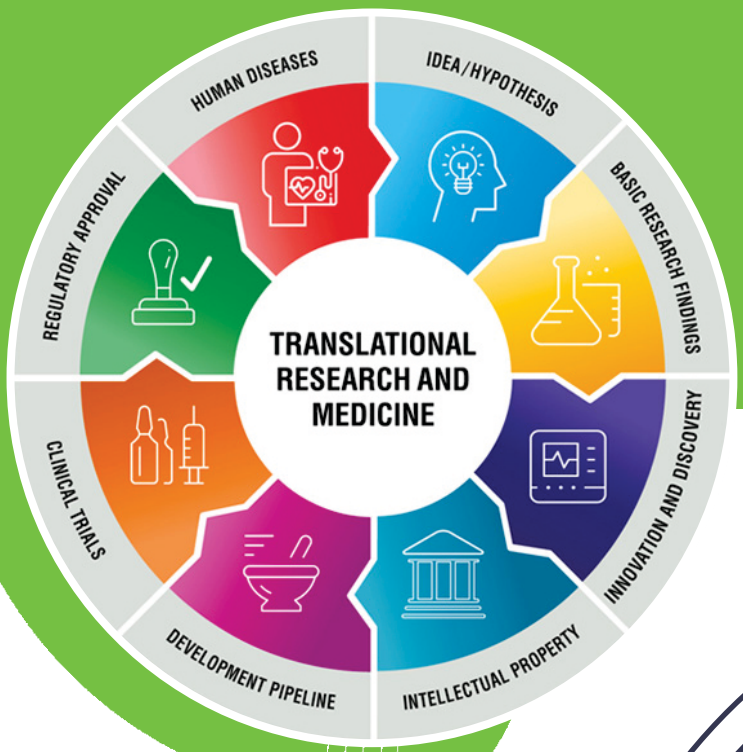

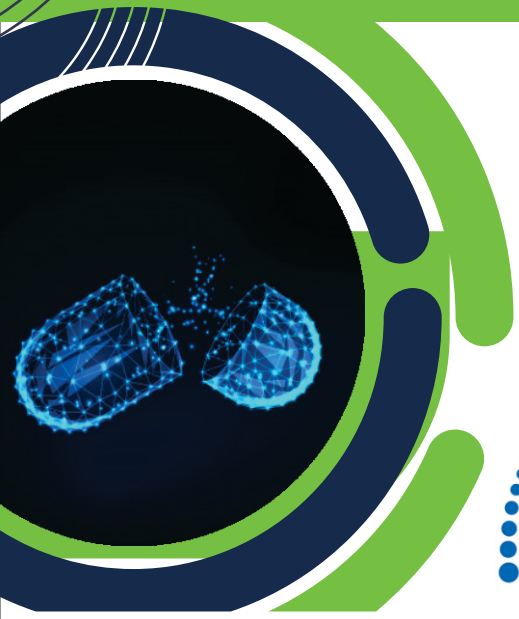

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FORMULATION AND DEVELOPMENT AND EVALUATION OF IMMEDIATE RELEASE TABLETS OF ANTINEOPLASTIC DRUG

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Abstract:

Oral drug deliveries has been known for decades as the most widely utilizedroute of administered among all the various routes that have been employed for the systemic delivery of drug via various pharmaceutical products of different dosage forms. A generic version of IR tablets was developed that is safe, efficacious and to get the comparable dissolution profile and also bioequivalent to the Reference product. The formulation of immediate release tablets was done by wet granulation by using PVP K30 and Purified water as a binder solution which shows improve stability and drug release profile that was in line with innovator product. Drug release is usually the rate limiting process for absorption of a Biopharmaceutical Classification System (BCS) Class IV compound like Antineoplastic Drug due to its low solubility and low permeability. Therefore, the dissolution of Antineoplastic Drug was thoroughly evaluated. The dissolution of the reference product tablets was thoroughly evaluated in Release media & as well as in different media (0.001N HCl, 0.1N HCl, pH 4.5 phosphate buffer, pH 4.5 acetate buffer, pH 6.8 phosphate buffer). By understanding the concept of pH dependent solubility nature we were required to use sodium lauryl sulphate (SLS as solubilizer) in the dissolution media to increase the solubility of Antineoplastic Drug during multimedia dissolution. During discriminating dissolution media, we have performed dissolution with various concentrations of SLS. Based on solubility data and IR formulation pH 4.5. Hence Antineoplastic drug can be successfully formulating immediate releasetablets.

Keywords

Generic, Discriminating.