



## Formulation, Evaluation and Optimization of Enteric Coated Tablets of Erythromycin Stearate by Multivariate Anova Method

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### ABSTRACT

The present investigation concerns with the event, optimization and evaluation of an enteric coated tablets of Erythromycin stearate. Tablets were prepared by wet granulation method. Enteric coating of Erythromycin stearate tablets were done using two hydrophilic polymers like ethyl cellulose and pectin by multivariate ANOVA method by alternating the two variables X and Y in rows and columns. Polyethylene glycol was used as a plasticizer while isopropanol & water was incorporated as a solvent. The effects of polymers and isopropanol as a binder on drug release profile, gastro-resistant properties and matrix integrity of tablet were investigated.

Developed formulations were evaluated for their physical characteristics, drug content, disintegration time, friability, hardness, thickness, swelling index, weight variation, In vitro drug release profile etc. On the basis of various physical characteristics parameters, it was found that all the formulations shows good result. On comparative kinetic modeling study like (Zero order, First order, Higuchi model and Korsmeyer-Peppas) it had been found that each one of the formulations follow Higuchi model and coefficient of correlation ( $R^2$ ) values were nearer to unity. Among those formulations, F4 showed  $R^2$  value of Higuchi model more near as compared to the opposite formulation.

Oral controlled release drug delivery have recently been of accelerating interest in pharmaceutical field to realize improved therapeutic advantages, like simple dosing administration, patient compliance and adaptability in formulation.<sup>1,2</sup> Drugs with short half-lives and drugs that easily absorbed from gastrointestinal tract (GIT) are eliminated quickly from the systemic circulation.

For these sorts of drugs the event of oral sustained-controlled release formulations is an effort to release the drug slowly into the alimentary canal (GIT) and maintain an efficient drug concentration in the systemic circulation for a long time.<sup>3,2</sup> The basic goal of any drug delivery systems is to provide a therapeutic amount of drug to the proper site of body

to achieve therapeutic level promptly and then maintain the desired drug concentration in systemic circulations.<sup>4</sup> The most important objectives of these new drug delivery systems are: First, it would be single dose, which releases the active ingredient over an extended period of your time. Second, it should deliver the active entity on to the location of action, thus, minimizing or eliminating side effects. To overcome the limitations of conventional drug delivery system, enteric coated tablets have been developed. An enteric coating may be a barrier that controls the situation of oral medication within the gastrointestinal system where it's absorbed. The word "enteric" indicates small intestine; therefore enteric coatings prevent release of medication before it reaches the tiny intestine. The enteric coated polymers remain unionise at low pH, and thus remain insoluble. But because the pH increases within the GIT, the acidic functional groups are capable of ionisation, and therefore the polymer swells or becomes soluble within the intestinal fluid.

Erythromycin stearate was selected as a model drug which was obtained from Kwaliti pharmaceuticals Pvt. Ltd. as a gift sample. The reagents used were pectin, ethyl cellulose, lactose, isopropyl alcohol, polyethylene glycol, magnesium stearate, talcum powder, sodium hydroxide and potassium dihydrogen orthophosphate.

Tablets were prepared by wet granulation method. Wet granulation is that the most generally used process of granulation within the pharmaceutical industry. It involves addition of a liquid solution (with or without binder) to powders, to make a wet mass or it forms granules by adding the powder along side an adhesive, instead of by compaction. The wet mass is dried then sized to obtain granules. The liquid added binds the moist powder particles by a mixture of capillary and viscous forces within the wet state.<sup>7</sup> More permanent bonds are formed during subsequent drying which leads to the formation of agglomerates.

Enteric coated tablets of Erythromycin stearate were prepared using two hydrophilic polymers like ethyl cellulose and pectin by multivariate ANOVA method by alternating the two variables X and Y in rows and columns. Eight formulations were prepared. All those formulations showed good acceptable Pharmacotechnical characteristics but F4 showed very

excellent result as compared to the opposite formulations and ready to survive the steadiness testing. Formulations like F4 showed higher stability as well as more steady state drug release profile. On comparative kinetic modeling study (such as Zero order, Higuchi model, First order and Korsmeyer-Peppas model) it had been found that each one the formulations follow Higuchi model and coefficient of correlation ( $R^2$ ) values were near to unity. Among those formulations, F4 showed  $R^2$  value of Higuchi model more near as compared to the other formulations. The research entitled and result obtained reveals that the combine effect of enteric coated agent in different ratio was suitable for long protection of active pharmaceutical ingredients, from the acidic environment of the stomach and to provide a delayed-release component for repeat action thus minimizing the first pass metabolism of drugs.

Keywords: Erythromycin stearate, Ethyl cellulose, Pectin, Polyethylene glycol, Isopropyl alcohol.

