

PREPARATION AND EVALUATION OF COLON SPECIFIC IBUPROFEN TABLETS

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ABSTRACT

The aim of the present study was done to evaluate drug release at the colon specific region by developing the formula which can deliver the drug at the colonic region of the GIT. For this particular study the pelletization process was adopted and the pellets which were formed were compressed into the tablets and the tablets which were formed were coated with Eudragit L100. The in vitro dissolution studies were carried out and test like hardness, friability and weight variation were carried out. In brief the formulation that was developed was the pH dependent one the widely used method for the developing the colon specific drug delivery.

KEYWORDS: Colon specific, Pelletization, coating, Eudragit L100

INTRODUCTION

The colon is a site where both local and systemic delivery of drugs can take place. Local delivery could, for example, allow topical treatment of inflammatory bowel disease. Treatment could be made more effective if it were possible for drugs to be targeted directly on the colon. Systemic side effects could also be reduced. Colon specific systems might also allow oral administration of peptide and protein drugs, which are normally inactivated in the upper parts of the gastrointestinal tract. Furthermore, there is urgent need for delivery to the colon of drugs that are reported to be absorbable in the colon, such as steroids, which would increase efficiency and enable reduction of the required effective dose. The treatment of disorders of the large intestine, such as irritable bowel syndrome (IBS), colitis, Crohn's disease and colon disease, where it is necessary to attain a high concentration of the active agent, may be efficiently achieved by colon-specific delivery. The necessity and advantages of a colon-specific drug delivery system (CDDS) have also been extensively reviewed elsewhere in the literature. In the study pellets were formed using mini glatt coater. The pellets formed were mixed with the spray dried lactose and croscarmellose sodium was used as the disintegrant. The compressed were coated with the Eudragit L100. The final tablet formed was evaluated for the hardness test, friability test. In vitro dissolution study was carried out using USP basket apparatus using various dissolution media according to GIT transit time. The final result was tabulated in the Microsoft excel.

MATERIAL AND METHODS

Ibuprofen was obtained as a gift sample from Shreya Pharmaceutical, Aurangabad. Eudragit L100 was Obtain as gift sample from Concept Pharma Aurangabad. Spray dried lactose was formed at the lab Using mini Spray drier.

Method of preparation

Formation of pellets: Pellets were formed using the sugar beads which pass From sieve no 20 and retain on sieve no 40. The pellets were formed in the mini glatt coater. The ibuprofen was dissolved in ethanol and was sprayed on the fluidizing beads. The pellets forms were evaluated for the content uniformity test.

Preparation of tablets: The pellets were mixed with spray dried lactose and croscarmellose sodium. The resulting mixture was compressed using 11mm punch in tablet rotatry press.

Coating of the tablet: The tablet formed was coated in mini pan coater using eudragit L100 as the coating solution in 12% concentration. The coating on the tablet was applied upto 5%, 8% and 10% in the various formula.

Dissolution Studies

The dissolution study was carried out using 900 ml of *phosphate buffer pH 7.8* as the medium and rotating the paddle at 100 rpm for 12 hours. Withdraw a suitable volume of the sample and filter promptly through a membrane filter disc with an average pore diameter not greater than 1.0 mm. Reject the first few ml of the filtrate and dilute a suitable volume of the filtrate with the same solvent. Measure the *absorbance* of the resulting solution at the maximum at about 221. The data of the dissolution obtained for all the three formulation and cumulative drug release was calculated for all the preparation. The result and the drug release profile are given below in the following table and the figure.

RESULT AND DISCUSSION

The main aim of this study was prepare a robust formula of the colon specific ibuprofen tablet. For this particular study Eudragit was selected as the coating polymer as from literature survey it was came to know that it would degrade at the colonic pH. The pelletization technique was adopted so as to get sustain release of the drug from the dosage form.

CONCLUSION

From the present study it was concluded that as the concentration of the coating polymer was increase the release of the drug was retarded.

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Table 1: Formulation 1

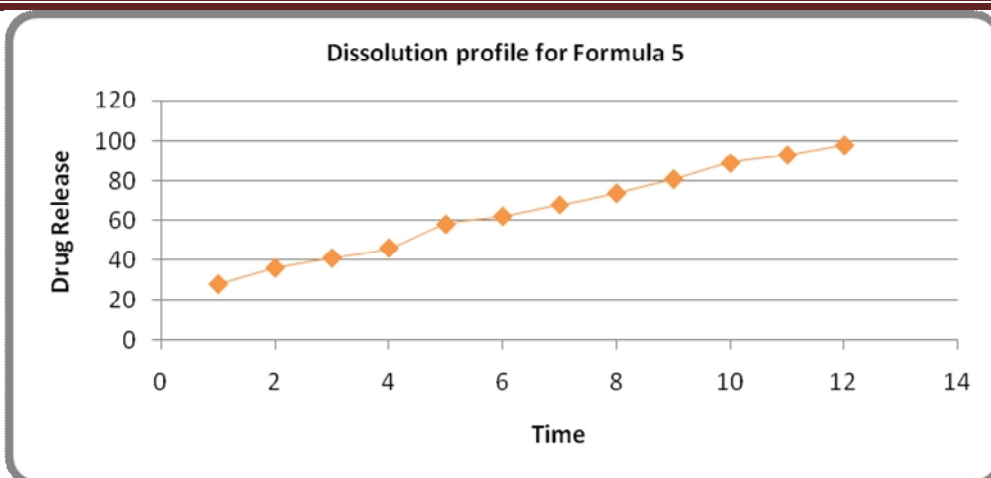
| Sr. No | Ingredients | Qty per tab(mg) | Qty per 20 tab(mg) |
|--------|---------------------|-----------------|--------------------|
| 1 | Ibuprofen Pellets | 400 | 8000 |
| 2 | CMC | 100 | 2000 |
| 3 | Spray Dried Lactose | 100 | 2000 |
| 4 | Coating Solution 5% | 30 | 600 |

Table 2: Formulation 2

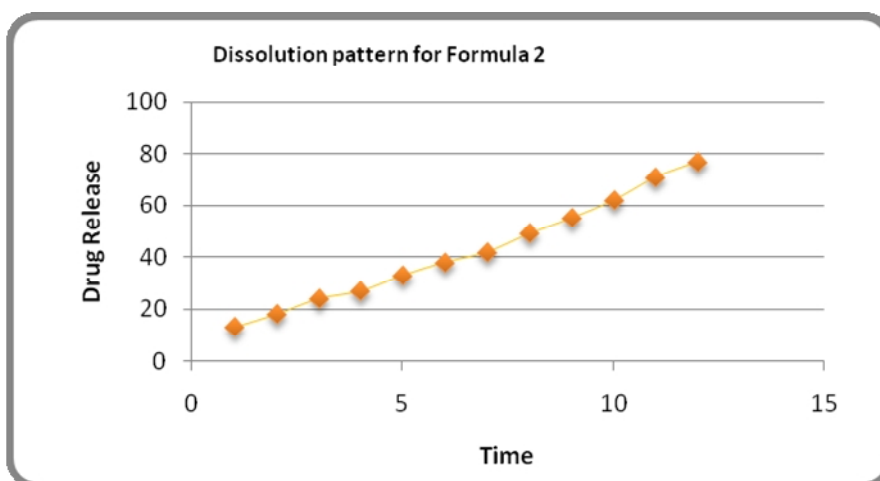
| Sr. No | Ingredients | Qty per tab(mg) | Qty per 20 tab(mg) |
|--------|---------------------|-----------------|--------------------|
| 1 | Ibuprofen Pellets | 400 | 8000 |
| 2 | CMC | 100 | 2000 |
| 3 | Spray Dried Lactose | 100 | 2000 |
| 4 | Coating Solution 8% | 48 | 960 |

Table 3: Dissolution Profile (Drug Release in%)

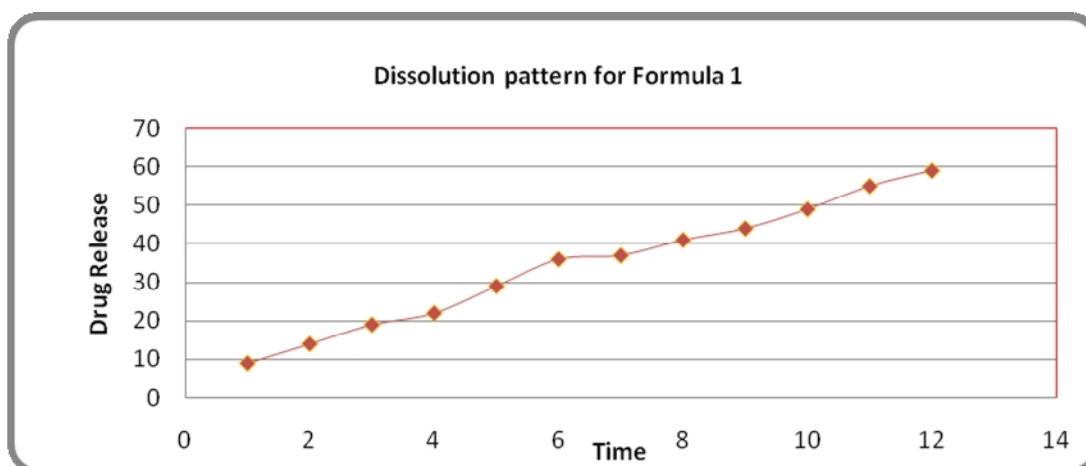
| Time (hr) | Formula 1 | Formula 2 | Formula 3 |
|-----------|-----------|-----------|-----------|
| 1 | 28 | 13 | 9 |
| 2 | 36 | 18 | 14 |
| 3 | 41 | 24 | 19 |
| 4 | 46 | 27 | 22 |
| 5 | 58 | 33 | 29 |
| 6 | 62 | 38 | 36 |
| 7 | 68 | 42 | 37 |
| 8 | 74 | 49 | 41 |
| 9 | 81 | 55 | 44 |
| 10 | 89 | 62 | 49 |
| 11 | 93 | 71 | 55 |
| 12 | 98 | 77 | 59 |



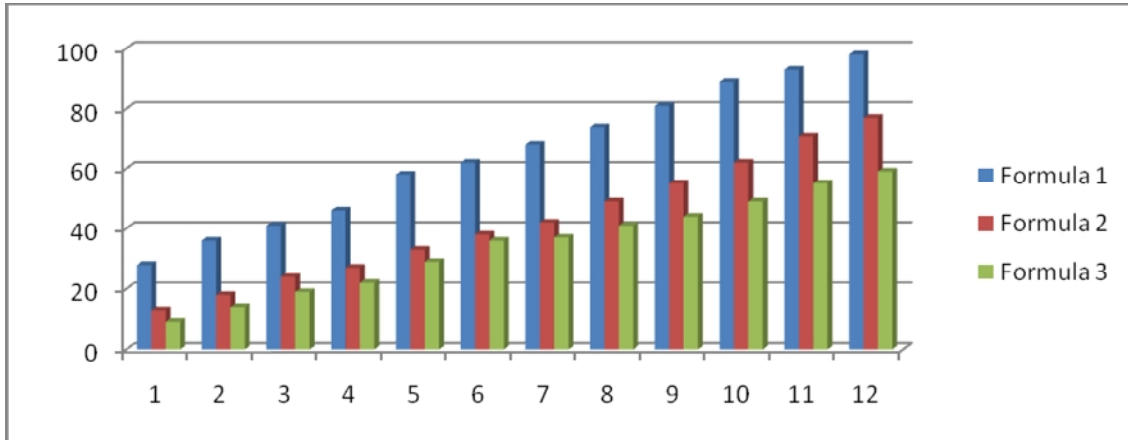
Formulation 1(fig 1): Dissolution Pattern for



Dissolution Pattern for Formulation 2(fig 2):



Dissolution Pattern for Formulation 1(fig 3)



Drug Release Comparison of all the Formula

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