ORIGINAL ARTICLE

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# EVALUATION OF ORAL COLONTARGETED TABLET OF 5 –AMINOSALISYLIC ACID &CAMYLOFINE DIHYDROCHLORIDE

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***Abstract*** *Inflammatory bowel diseases (IBD) are immune-mediated, unknown etiology diseases that affect the gastrointestinal ( GI) tract. There are at least it where various types of IBD, ulcerative colitis and crohn's disease are present. IBD are most commonly chronic recurring diseases involving terminal illuminated colon inflammation, although these canial diseases affect many sites throughout the food tract. Obviously I predispose individuals to IBD growth through geneti c factors. In addition, the climate contributes to the development of IBD*

***Keywords*** *Bilayered Matrix Tablet, Amino Salisylic Acid, Drug Release, IBD Development*

## INTRODUCTION

**INFLAMMATORY BOWEL DISEASE (IBD)**Inflammatory bowel disease ( IBD) includes both ulc erative colitis (UC) and Crohn's disease(CD)conditions; it is unclear whether these are two disti nct entities or manifestations at either end o a spectrum. Crohn's disease is also called regional e nteritis, terminal ileitis, or ileocolitis granulomatous. IBD are polygenic diseases that present the mselves to the clinician as a number of interacting events arising from multiple factors of geneti c, immunological and environmental origin,resulting in chronic relapse inflammation that prese nts itself in two primary forms: ulcerative colitis (UC) and Crohn's disease (CD).For the clinically involved practitioner, the lack of effective biomarkers for proper diagnosis and thus acceptable treatment protocol is still a major problem. Inflammatory bowel disease is a condition in which inflammatory cells chronically infiltrate the stomach and/or intestine. It is characterized by some cells which invade the intestine wall. The cells are those associated with inflammation leading to an insult or damage in the body. Impairment of the function of the intestinal epithelial barrier is generally recognized as a key pathogenic step in initiating and developing chronic human inflammatory bowel diseases (IBD).

## ULCERATIVE COLITIS

UC is a condition in which the inflammatory response remains confined to the colon and orphological changes. 95 per cent of patients are active in the rectum, with varying degrees of proximal extension. Inflammation is mainly confined to the mucosa and consists of persistent involvement of varying extent along the length of the colon with ulceration, edema, and hemorrhage.

## CROHN 'S DISEASE

Unlike UC, CD can involve any portion of the gastrointestinal tract from the oropharynx to the perianal area. Diseased segments are often separated by the intervention of normal intestines, leading to the term "skip areas." Inflammation can be transmural, often extending up to t serosa, leading to the formation of sinus tracts or fistula. Histological findings include small superficial ulcerations over the patch of a Peyer (aphthoid ulcer) and focal chronic inflammation that extends to the submucosa, sometimes accompanied by noncaseating granuloma. The mostcommon site is the ileocecal region, followed by the ileum terminal alone, diffuse small intestine or isolated colonic disease in decreasing order of frequency.

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**EXPERIMENTAL METHOD**

***PROCEDURE:***

**OBSERVAL METHOD**

- Weighted quantity of 5-amino salicylic acid, CamylofineDihydrochloride, HPMC, sodium bicarbonate, citric acid and MCC were taken according to formulae F1,iF2,iF3 and F4 (Table:1.1) and, if ill, by mesh # 44.
- -These materials were mixed in separate pestle mortar and granulated with a PVP k30 solution and isopropylial alcohol.
- The granulated material was dried at 40-45 degrees Celsius in a hot air oven. They sifted the dried granules through mesh # 30.
- Weighed quantities of talc and magnesium um stearate were added and mixed to these granules.-For formulae F1 , F2 , F3 and F4.
- Colour coated by Spray.

| S.NO | Ingredients | FT1 | FT2 | FT3 | FT4 |
|---|---|---|---|---|---|
| 1 | 5-AminoSalicylicacid | 250img | 250img | 250img | 250img |
| 2 | CamylofineiDihydrochloride | 250img | 250mg | 250mg | 250mg |
| 3 | HPMC | 70img | 80img | 90img | 100img |
| 4 | Sod.iBicarbonate | 100img | 100img | 100img | 100img |
| 5 | Citriciacid | 40img | 30img | 20img | 10img |
| 6 | MCC | 15img | 15img | 15img | 15img |
| 7 | PVPiK30 | 20img | 20img | 20img | 20img |
| 8 | Magnesiumistearate | 5img | 5img | 5img | 5img |
| 9 | Talc | 5img | 5img | 5img | 5img |
| 10 | IPA | q.s | q.s | q.s | q.s |

(Table1.1)

**OBJECTIVE**

The aim of the project study is to use 22factorial design to make a Floating 5 Aminosalsylic Acid and CamylofineDihydrochloride tablet. The 22 factor design-based optimization was used to investigate the effect of two independent process variables (factors), i.e., the quantity of citric acid and HPMC K15 on dependent variables such as floating time and percentage of drug release. Factorial design to achieve dissolution of NLT 85 percent in 7 hours. The Citric Acid and HPMC K15 are considered as two factors for optimization of 5-Aminosalsylic Acid and CamylofineDihydrochloride floating tablets as per 2 ^ 2 Factorial design. Four floating tablet formulations of 5Aminosalic Acid and CamylofineDihydrochloride of the 2 Factors i.e., HPMC K15 and citric acid as per 2^2 Factorial designs were prepared. On increasing the concentration of HPMC K15 and decreasing the concentration of Citric Acid, An Increase in % Drug Release was observedAnd an increase in Floating Time was observed. The result suggests that the concentration of both the factors have significant effect on the drug release and Floating Time.

**RESULT & DISCUSSION**

The Main objective of the study was to prepare and evaluate 5-Amino Salisylic acid &CamylofineDihydrochloride Tablet. An attempt was made to prepare. Drug 5-Amino Salisylic acid &CamylofineDihydrochloride was selected after looking in various research studies of Floating Tablet. First Organoleptic properties of drug was studied .Then Melting point of the drug was identified by Capillary method and it was found to be 324$^{o}$C. Solubility of 5-Amino Salisylic acid &Camylofinedihydrochloride as determined in various aqueous and non-aqueous solvents. The drug was found to be soluble in DMSO, Ethanol and Methanol and Insoluble in chloroform.

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Calibration curve of the drug were prepared in DMSO with the help of UV spectrophotometer. The method used for the estimation of drug followed Beer Lambert's law in the concentration range 2 to 20 µg/ml with good accuracy, which is evident from regression coefficient obtained for each calibration curve.

## CONCLUSION

From results it concludes that the floating lag time increased as hardness increased and F4 had better controlled release than the other formulations. So, formulation F4 provides a better option for Controlled release action and improved bioavailability of 5-Amino Salisylic acid &Camylofinedihydrochloride Hydrochloride.

On the basis of present study it was concluded that floating tablets of 5-Amino Salisylic acid &CamylofineDihydrochloride hydrochloride can increase the gastric residence time as well as bioavailability and thus better patient compliance can be achieved.

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