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Formulation and Evaluation of Colon Targeted Drug Delivery

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Abstract: *Every day, advancements are being made in the area of colon-specific drug delivery systems. Extensive research is currently being conducted in this field, as this method is not only effective for targeting medications needed for treating colon-related diseases such as Crohn's disease and ulcerative colitis, but it also serves as a promising site for both local and systemic delivery of peptides, proteins, and various therapeutic drugs, including anti-asthmatic, antihypertensive (such as Isosorbide, Cyclosporine, and Desmopressin), and anti-diabetic agents. The colon, being the final segment of the gastrointestinal tract (GIT), has gained significant attention for its role in drug delivery for both local and systemic applications.*

To successfully achieve colon-targeted drug delivery, it is essential to protect the drug from degradation, release, and absorption in the upper sections of the gastrointestinal tract, ensuring a controlled or abrupt release in the proximal colon. This system focuses on delivering drugs to the lower part of the GIT, primarily the large intestine, which is crucial for those medications that are typically inactivated in the upper regions of the GIT. For optimal site-specific and time-dependent drug delivery to the colon, the combination of two or more strategies is often favored over single approaches, particularly due to the limited success of traditional methods, leading to a preference for newly developed techniques.

The oral route is widely regarded as the most convenient method for administering medications to patients. Upon oral intake, conventional dosage forms typically dissolve in the gastric or intestinal fluids and are subsequently absorbed in these areas of the gastrointestinal tract (GIT). The extent of absorption is influenced by the physicochemical characteristics of the drug. This presents a significant limitation in scenarios where targeted delivery of medications to the colon is necessary or when a drug must be shielded from the harsh conditions of the upper GIT. Administering drugs orally to the colon is particularly beneficial for treating colonic diseases such as ulcerative colitis, Crohn's disease, carcinomas, and infections, as it allows for high local concentrations while reducing side effects associated with drug release in the upper GIT or unnecessary systemic absorption. The colon is abundant in lymphoid tissue, and the uptake of antigens into the mast cells of the colonic mucosa facilitates rapid local antibody production, enhancing the efficacy of vaccine delivery.

There is growing interest in the colon as a site for improving the bioavailability of poorly absorbed drug molecules. The colon is considered to have a less hostile environment compared to the stomach and small intestine, characterized by reduced diversity and intensity of activity. Furthermore, the colon offers a longer retention time and shows a strong response to agents that promote the absorption of poorly absorbed drugs. In addition to retarding or targeting dosage forms, effective colonic drug delivery could serve as a crucial foundation for the colonic absorption of orally administered, undigested, unchanged, and fully active peptide drugs. Given that the large intestine is relatively devoid of peptidases, such specialized delivery systems have a promising opportunity to achieve adequate drug absorption following oral administration..

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Keywords: colon-specific tablet, Guar gum, Xanthan gum, Crohn's disease, carcinomas, bioavailability, vaccine delivery, oral application

I. INTRODUCTION

Administration is another route used for colon targeting, but it shows less compliance(uncomfortable) and becomes difficult to reach the colon. Conventional dosage forms that areused in the prevention of colon diseases (ulcerative colitis, crohn's diseases, amoebiasis) arefailing as an improper amount of drug reaches site of action.The aim of a targeted drug delivery system is to provide a desired drug concentration in thebody by delivering a therapeutic amount of drug to a target site. It is suitable and requiredfor the drugs having instability, low solubility, short half-life, a large volume of distribution,poor absorption, low specificity, and therapeutic index. Targeting may provide maximumtherapeutic activity (by preventing degradation or inactivation of drug).Ongoing research in the area of oral delivery of drugs, a discipline which has basked in thespotlight of pharmaceutical sciences for the past 70 years, has led to improved and profoundinsights into the physiology, biology and physical chemistry (pharmacokinetics, partitioningphenomenon) of organs, compartments, cells, membranes, cellular organelles and functional proteins (e.g. transporters) associated with absorption processes of drugs in thegastrointestinal tract (GIT).

Majority of the research has focused on delivery of drug to thesmall intestine. The large intestine, however, because of its remoteness and relativelydifferent physiology acquired the status of an outcast. From last two decades, interest in areadevelopment of oral colon targeted drug delivery systems (CTDDS) has increased, fortreatment of local colonic disorders.Colonic delivery offers several potential therapeutic advantages as a site for drug delivery,(a) The colon is rich in lymphoid tissue, uptake of antigens into the mast cells of the colonicmucosa produces rapid local production of antibodies and this helps in efficient vaccinedelivery. (b) The colon is attracting interest as a site where poorly absorbed drug moleculemay have an improved bioavailability. (c) The colon has a longer retention time and appearshighly responsive to agents that enhance the absorption of poorly absorbed drugs. (d)Reduced proteolytic activity in the colon may be helpful in achieving reasonable absorptionof certain drugs that are enzymatically labile in small intestine. (b) Reduced fluid motility andmotility in the colon when compared with small intestine is advantageous formulationconsists of multiple components such as permeation enhancers that must reach epithelial, layer to achieve close spatial proximity with each other. (e) The colonic region has somewhatless hostile environment with less diversity and less intensity of activity as compared tostomach and small intestine.[1-3]

Advantages of colon targeted drug delivery system

1. Localized Treatment of Colonic Diseases:

Targeted delivery: Colon-targeted systems deliver drugs directly to the colon, allowing for more effective treatment of local conditions like inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and colon cancer.

Reduced systemic exposure: By targeting the colon, these systems minimize the amount of drug absorbed into the bloodstream, leading to fewer systemic side effects.

Optimized drug concentration: Colon-targeted systems can maintain higher drug concentrations at the target site, leading to improved therapeutic efficacy with lower doses.

2. Enhanced Oral Delivery of Drugs Vulnerable to Upper GI Degradation:

Protection from degradation: The colon-targeted systems can protect drugs from degradation by stomach acid and enzymes in the upper gastrointestinal tract.

Improved bioavailability: By protecting drugs from degradation, the colon-targeted systems can improve the bioavailability of drugs that are poorly absorbed in the upper GI tract, such as peptides and proteins.

Reduced first-pass effect: Colon-targeted systems can bypass the first-pass effect, where drugs are metabolized by the liver before reaching systemic circulation.

3. Improved Patient Compliance and Convenience:

Reduced dosing frequency: Colon-targeted systems can allow for less frequent drug administration, improving patient compliance.

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Increased patient comfort: By reducing the need for injections or other invasive methods, colon-targeted systems can improve patient comfort and convenience.

4. Other Advantages:

Treatment of systemic conditions:

Targeting the colon can also allow for the treatment of systemic conditions by influencing the gut microbiome or enteric immune system.

New therapeutic targets: The colon is a complex environment with various targets, including the microbiome, enteric immune system, and lymphatic system, opening up new possibilities for drug development.

Improved drug stability: Colon-targeted systems can improve the stability of drugs in the harsh environment of the gastrointestinal tract.[4]

Limitations of colon targeting drug delivery system

1. Distal Location and GI Physiology:

Long Transit Time: The colon is located at the end of the gastrointestinal tract (GIT), requiring the drug delivery system to traverse the stomach and small intestine, which can be time-consuming and subject to variability.

Complex GIT Environment: The GIT has a complex environment with varying pH levels, fluid volumes, transit times, and the presence of food, enzymes, and bacteria, which can impact drug stability and absorption.

pH Fluctuations: The pH of the colon is near neutral, which can affect drug solubility and stability, especially for drugs that are pH-sensitive.

Viscosity: The colonic contents are viscous due to water absorption, which can hinder drug absorption.

Enzymatic Degradation: Colonic bacteria can degrade drugs, rendering them ineffective.

Mucus Barrier: The mucus layer in the colon can act as a barrier to drug absorption.

2. Drug Solubility and Stability: Low Colonic Fluid Volume:

The low volume of fluid in the colon can limit drug solubility and absorption.

Drug-Content Interactions: Drugs can interact non-specifically with colonic content, like dietary residues, intestinal secretions, mucus, or fecal matter, which can negatively impact drug stability.

3. Challenges in Designing Colon-Targeted Systems:

Precise Targeting: Achieving precise drug release in the colon while avoiding premature release in the stomach or small intestine is a challenge.

Maintaining Drug Stability: Ensuring the drug remains stable during transit through the GIT and in the colonic environment is crucial.

Overcoming the Mucus Barrier: Developing strategies to overcome the mucus barrier and facilitate drug absorption in the colon is essential.

Variability in GI Transit Time: Individual differences in GI transit time can affect the timing and location of drug release, making it difficult to achieve consistent and predictable drug delivery.

Food Effects: Food intake can influence GI transit time and pH, further complicating the design of colon-targeted systems.

Bacterial Flora: The presence of a large population of bacteria in the colon can degrade drugs or interfere with their absorption.

Drug Degradation: The colonic environment can lead to drug degradation, reducing its bioavailability and efficacy. [5]

Disadvantages of Colonic Drug Delivery [6,7]

1. There are variations among individuals with respect to the pH level in the small intestine and colon which may allow drug release at

undesired CSDDS site. The pattern of drug release may differ from person to person which may cause ineffective therapy.

2. The pH level in the small intestine and caecum are similar which reduces site specificity of formulation.

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3. The major disadvantage of colonic delivery of drug is poor site specificity.
4. Diet and diseases can affect colonic microflora which can negatively affect drug targeting to colon. Nature of food present in GIT
can affect drug pharmacokinetics. In disease conditions pH level of GIT differs from pH level of healthy volunteers which alters the
targeted release of formulations which release the drug according to pH of desired site.
5. Enzymatic degradation may be excessively slow which can cause interruption in polymer degradation and thus alters the release
profile of drugs.
6. Substantial variation in gastric retention time may cause drug release at the undesired site in case of time dependent colonic drug
delivery system.
7. Lack of manufacturing Reproducibility and efficacy
8. Need of advanced technology.
9. Low dose loading and Higher need of excipients

II. LITERATURE REVIEW

1. Gauri Bhawna et al.,(2011)[8] The objective of this study was to create a targeted system for colon cancer treatment. Metronidazole using guar gum and xanthan gum. Matrix: Formulations containing various proportions of guar gum and. Xanthan gum was made by the wet granulation method, using a 10% concentration. Starch based paste. Later on, multilayer tablets were prepared by using 50. Mg and 100 mg of guar gum were used as a release control layer on either side. Side of (m5) guar gum matrix tablets of metronidazole. All the. The formulation appears to be promising for colonic drug delivery and. Only 12.3% of the drug is released in the first 5 hours, while other matrix tablets release a different percentage. Released 12-33% of metronidazole in physiological environment of. The stomach and small intestine are the organs that digest food. When research was extended in the rectum. Fluids, tablet forms of the medication were released with nearly 100% efficacy. Although,: Metronidazole multilayer formulations did not discharge medication. The stomach and small intestine were the primary sites of drug delivery, but the drug was ultimately delivered to the colon. The drug was absorbed slowly, allowing it to be released locally.

2. Mehta, Rohit et al.,(2013)[9] The purpose of the present investigation was to prepare matrix tablets of naproxen using a hydrophobic polymer, i.E., eudragit rlpo, rspo, and combination of both, by wet granulation method. The tablets were then coated with varying amounts of eudragit s-100, a pH-sensitive polymer, using the dip immerse method. In vitro drug release studies of tablets were carried out in different dissolution media, i.E., 0.1 n hcl (ph 1.2), phosphate buffers ph 6.8 and 7.4, with or without rat cecal content. The research team conducted extensive studies on the optimized formulation. All the formulations' physicochemical parameters were found to meet the standards set by the pharmacopoeial guidelines. The impact of the dissolution medium on the surface of the matrix tablet was investigated using scanning electron microscopy. The stability tests of all the formulations were conducted in accordance with the guidelines provided by the International Council for Harmonisation (ICH).

3. Chetan Singh Chauhan et al.,(2010)[10] The objective of this study was to develop prednisolone ph-dependent release tablets. Assess the benefits of using a colon as a targeted drug delivery system. Prednisolone not soluble in. In the gastric environment, water and unstable substances were transformed into tablets that were dependent on pH levels for their stability. The combination of two methacrylic acid copolymers, eudragit l100 and eudragit s100, was used in the production process. The: The impact of core tablet compositions, polymer combination ratios, and coating levels on the internal structure of the tablet was studied. The release rate of prednisolone from coated tablets was examined in a laboratory setting. The findings indicated that. Within a span of 2 hours, less than 10% of the drug was released, while the remaining 90% remained intact. The phosphate buffer was released into the ph 7.2 solution within 6 hours. Colon drug delivery is advantageous in the treatment of. The treatment of colonic diseases and the oral administration of drugs

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that are unstable or susceptible to enzymatic degradation are challenging. Decline in upper gastrointestinal tract. In this study, coated tablets that are resistant to gastric and small intestine were tested. Intestinal ph conditions can be easily dissolved in colonic ph. The outcomes of the current study. Research has shown that the ph-dependent tablet system is a promising vehicle for. Preventing the rapid breakdown of substances in the stomach and enhancing their absorption in the mouth. Prednisolone for the treatment of ulcerative colitis.

4. A.Swapna et al.,(2011)[11] Mesalamine (5-asa) is a medication that helps reduce inflammation in the body and is commonly prescribed for the treatment of Crohn's disease and ulcerative colitis. Mesalamine is quickly absorbed from the small intestine and it is. It is essential to create a delivery system that is tailored to the colon. In the ongoing care of individuals with ulcerative colitis, it may be necessary to administer repeat doses of medication. Since mesalamine (5-ASA) is. The majority of drugs are absorbed from the upper intestine, but selectively delivering drugs into the colon is considered a more effective and safer method of drug delivery with fewer side effects. The main goal of this study is to create and assess mesalamine microspheres for their ability to target the colon. These nanoparticles were synthesized by solvent evaporation. Method using different ratios of mesalamine, hydroxy propyl methyl cellulose (hpmc) and ethylcellulose (ec), stirring speed (1000rpm) and emulsifier concentration(0.5%w/.5%w) was used to prepare the emulsion.The researchers examined the surface characteristics, particle size distribution, drug entrapment rate, yield, and in vitro drug release of cellulose-coated mesalamine microspheres. Studies: Drug release studies were conducted in an acidic solution (0.1nhcl) for 2 hours and in a phosphate buffer solution with a pH of 7.4 up to 12 hours. In an acidic environment, the release rate was significantly slower, but in alkaline medium, it was much faster. The medication was promptly made available at a pH level of 7.4 in the phosphate buffer solution. Microspheres were created by combining a drug and a polymer in a 1:2.5 ratio, stirring at a speed of 1000 rpm, and adding a concentration of 0.5% wt/vol of tween. 80 (emulsifier) were chosen as an optimized formulation. Based on the findings of the current study, it can be concluded that mesalamine microspheres have the potential to serve as effective controlled release carriers for the drug. Medication-delivery system that targets the colon.

5. Seth Amidon et al.,(2015)[12] Colon-specific drug delivery systems (cdds) are highly sought after for the treatment of various localized conditions. Diseases like ulcerative colitis, Crohn's disease, irritable bowel syndrome, chronic pancreatitis, and pancreatic cancer can cause inflammation in the digestive tract. Colorectal cancer. Furthermore, the colon can serve as a location for the absorption of multiple medications into the bloodstream. Treat non-colonic conditions. Proteins and peptides that are known to degrade in the body are often targeted by drugs for therapeutic purposes. If the gastric ph is not broken down in the stomach, it can be absorbed by the colon's lining. In: To ensure successful therapeutic outcomes, it is crucial that the designed delivery system is implemented effectively. The drugs are delivered to the colon specifically. Several experimentation techniques have been investigated in the. Creation of drug delivery systems that target specific areas in the colon. These approaches utilize formulation. Elements that engage with one or more components of gastrointestinal (gi) physiology, such as the. The variation in pH along the gastrointestinal tract, the presence of colonic microflora, and enzymes, are necessary to achieve a healthy colon. Targeting: This article focuses on the factors that affect drug delivery to the colon and its absorption, as well as the challenges posed by cdds. The review provides a comprehensive discussion of. There are several conventional and newer formulation approaches/technologies currently being used. Utilized for the development of cdds.

6. Amish Ashvinkumar Dangi et al.,(2013)[13] The objective of this study was to create and assess a sustained release tablet specifically designed for the colon. Levetiracetam (lev), a biodegradable polymeric carrier (pectin), coating material, and matrix forming agent. Polymers are large molecules composed of repeating subunits called monomers. They have many applications in various fields, such as medicine, engineering, and packaging. The tablet was made using the wet granulation technique, with varying percentages of the ingredients. Pectin serves as a matrix carrier, while starch mucilage acts as a binding agent. Additionally, hpmc k-100 is used as a swellable polymer and coated with a protective layer. Polymers based on Eudragit. The compatibility of pectin, drug, and physical mixture was assessed through a fourier analysis. ftir and dsc. All the sets of matrix. Tablets (F1-F4) were tested in a laboratory setting to

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determine their ability to dissolve in simulated gastric fluids, making them suitable for use in the colon. Targeted drug delivery system.

7. Thiruganesh Ramasamy et al.,(2011)[14] The purpose of this study is to create a drug delivery system specifically designed for the colon, using xanthan gum as a carrier, to deliver aceclofenac. In this study, multilayer coated system that is resistant to gastric and small intestinal conditions but can be easily degraded by colonic bacterial enzymes was designed to achieve effective colon delivery of aceclofenac. The xanthan gum, the drug, and the physical mixture were analyzed using Fourier transform infrared spectroscopy (ftir) and differential scanning calorimetry (dsc). All the formulations were assessed for hardness, uniformity of drug content, and other physical properties. The release of aceclofenac in simulated gastrointestinal fluid and colonic fluid with enzymes was studied. Based on these findings, the eudragit coated system demonstrated resistance to the release of aceclofenac in the stomach and small intestine. The sudden surge in the release of aceclofenac was discovered to be a result of the breakdown of the xanthan gum membrane by bacterial enzymes. The developed system has the potential to be utilized as a vehicle for delivering aceclofenac to the colon, controlling the release of the drug in both the stomach and small intestine.

8. Godge G. R et al.,(2014)[15] The oral route is generally considered to be the most convenient method for delivering drugs to patients. When taken orally, the conventional dosage drug typically dissolves in the stomach fluid or intestinal fluid and is absorbed from these areas of the gastrointestinal tract. The uptake of a drug is influenced by its physical and chemical characteristics. In situations where targeted delivery of drugs to the colon is necessary or when a drug needs protection from the harsh conditions of the upper gastrointestinal tract, it is a significant drawback. Oral delivery of drugs to the colon is valuable in the treatment of diseases of colon (ulcerative colitis, crohn's disease,carcinomas and infections) whereby high local concentration can be achieved while minimizing side effects that occur because of release of drugs in the upper git or unnecessary systemic absorption. The colon is rich in lymphoid tissue, uptake of antigens into the mast cells of the colonic mucosa produces rapid local production of antibodies and this helps in efficient vaccine delivery. The colon is gaining attention as a potential location where poorly absorbed drug molecules can have a better chance of being absorbed by the body. Colon is considered to have a slightly less hostile environment compared to the stomach and small intestine, with less diversity and intensity of activity. Furthermore, the colon has a longer retention time and shows a high level of responsiveness to agents that improve the absorption of drugs that are not easily absorbed.

9. Sumedha Saxena et al.,(2018)[16] This review primarily focuses on the targeted delivery of drugs to the colon, which is highly desirable for localized treatment. Inflammatory bowel disease, including ulcerative colitis, crohn's disease, amoebiasis, colonic cancer, and other conditions, can be treated with immunosuppressive drugs. Systemic delivery of protein and peptide drugs. The colon is a location where topical treatment can be delivered locally. Inflammatory bowel disease and the systemic delivery of drugs can occur simultaneously. Treatment of colon can be made. If the drug can be specifically delivered to the colon, it is effective because the drug release and absorption should not be affected. The abdomen and small intestine should be thoroughly examined, and it is crucial to ensure that bioactive agents are not broken down and that drug release is facilitated. Into the colon. Targeting drugs to the colonic region is not only linked to the treatment of colonic disorders but also has implications for other medical conditions. Locally but also delivering drugs such as protein and peptide for their systemic effects, which are broken down and eliminated from the body. The bioavailability of the substance is significantly reduced due to the instability in the gastrointestinal tract.

10. M. K. Chourasia et al.,(2008)[17] Researchers have been studying a system that combines the ability to detect pH levels and the ability to break down in the colon, which could be used to deliver metronidazole specifically to the colon. The cross-linked chitosan microspheres were created by utilizing an emulsion system, where liquid paraffin served as the external phase and a solution of chitosan in acetic acid acted as the disperse phase. The multiparticulate system was created by coating cross-linked chitosan microspheres using eudragit® l-100 and s-100 as pH-sensitive polymers. The morphology and surface characteristics of the formulations were analyzed using scanning electron microscopy. The size

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of the chitosan microspheres was measured using optical microscopy, while the size of the coated microspheres was measured using a particle size analyzer. In vitro drug-release studies were conducted in conditions that mimicked the movement of drugs from the stomach to the colon, both with and without the presence of rat caecal contents. The microspheres were tiny in size and successfully encapsulated within eudragit® microspheres, creating a system with multiple reservoirs. By applying eudragit® ph-dependant release profiles to the microspheres, the desired release characteristics were achieved. No release was observed at acidic pH, but when the formulation reached the pH where eudragit® starts dissolving, there was a continuous release of the drug. Additionally, the study revealed that the release of the drug was greater when it was exposed to rat caecal contents, suggesting that the chitosan matrix is vulnerable to the enzymes present in rat caecal matter.

11. M. K. Chourasia et al.,(2002)[18] Although oral delivery has become a. Common method of delivering treatment. - Drugs, the gastrointestinal tract presents several challenges. Challenges in Medication Administration Colonic drug delivery has gained traction. The significance of drug delivery has grown beyond just the act of administering medications. For the therapy of nearby afflictions related to the. Colon is not only a part of the digestive system but also plays a crucial role in the transportation of proteins. And medicinal peptides. To attain a successful outcome. Delivery, a medication, must be shielded from being absorbed by the body. (git) and then be abruptly released into the proximal Colon, which is believed to be the most suitable location for delivering drugs specifically to the colon. Colon targeting is inherently part of. Value for the topical treatment of diseases of the colon, such as. Diseases of the colon, Crohn's disease, ulcerative colitis, colorectal cancer and. Amebiasis is an infection caused by parasites of the Amoeba genus. Symptoms include diarrhea, abdominal pain, flatulence, and weight loss. Treatment involves antibiotics and rest. Peptides, proteins, oligonucleotides, and vaccines have the potential to be used as drugs for treating colon-related conditions.

12. Kumar, P. et al.,(2008)[19] In the last two decades colon targeted drug delivery has gained increased importance not just for the deliver drugs for the treatment of various colonic diseases but also for its potential for delivery of proteins and therapeutic peptides. In the past various traditional approaches used for colon targeted delivery like prodrugs, ph, time dependent, and microflora activated systems, have achieved limited success. For successful colon targeted drug delivery, the drug needs to be protected from absorption and/or the environment of the upper gastrointestinal tract and then be abruptly released into the colon. Hence continuous efforts have been made on designing colon targeted drug delivery systems with improved site specificity and versatile drug release kinetics to fulfill different therapeutic needs. In last couple of years few new systems have been developed for colon targeted drug delivery such as pressure dependent systems, codes™ technology, micrsponges, pectin and galactomannan coating, microbially triggered osmotic systems, lectins and neoglyconjugated etc. Which are reported to have better in-vivo site specificity and design rationale than the earlier approaches. This review article gives an overview of various approaches for colonic targeted drug delivery with emphasis on newer systems, their merits and demerits, in vitro/ in-vivo evaluation and market status of such delivery systems..

13. Suruse Pravin et al.,(2022)[20] The objective of the present study was to develop colon targeted drug delivery system of Metronidazole using guar gum as the carrier. **Methods:** Matrix tablets containing various proportions of guar gum were prepared by direct compression technique. Rapidly disintegrating Metronidazole core tablets were prepared and compression coated with guar gum and 20% of microcrystalline cellulose. The tablets were evaluated for hardness, thickness, drug uniformity and subjected to in vitro drug release studies under conditions mimicking mouth to colon transit.

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14. Krishnaiah, Y. S. R et al.,(2002)[21] The objective of the current investigation is to develop colon-targeted drug delivery systems for tinidazole using guar gum as a carrier for the treatment of amoebiasis. Fast-disintegrating tinidazole core tablets were compression-coated with 55%, 65%, and 75% of guar gum. All formulations were evaluated for hardness, drug content uniformity, and subjected to in vitro drug release studies. The amount of tinidazole released from the tablets at different time intervals was estimated using the HPLC method. The compression-coated formulations released less than 0.5% of tinidazole in the physiological environment of the stomach and small intestine. When the dissolution study was continued in simulated colonic fluids, the compression-coated tablet with a 55% guar gum coat released 99% of tinidazole after degradation by colonic bacteria at the end of the 24-hour dissolution study. The compression-coated tablets with 65% and 75% of guar gum coat released approximately 67% and 20% of tinidazole, respectively, in simulated colonic fluids, indicating the susceptibility of the guar gum formulations to rat caecal contents. The results of the study indicate that compression-coated tinidazole tablets with either 55% or 65% of guar gum coat are most likely to provide targeted delivery of tinidazole for local action in the colon due to their minimal release of the drug in the first 5 hours in the physiological environment of the stomach and small intestine. The tinidazole compression-coated tablets showed no change in physical appearance, drug content, or dissolution pattern after storage at 40°C/75% RH for 6 months.

15. Prabhakar Reddy Veerareddy et al.,(2012)[22] The intent of the present investigation is to develop colon targeted compression coated flurbiprofen pulsatile release tablets that retard the drug release in the upper gastro intestinal system but progressively release in the colon.Flurbiprofen core tablets were prepared by direct compression method and were compression coated with hydroxypropyl methylcellulose and Eudragit S100. The formulation is optimized based on the in vitro drug release study and further evaluated by X-ray imaging and pharmacokinetic studies in healthy humans for colonic delivery.

III. AIM AND OBJECTIVE

Aim

Formulation and Evaluation of Colon Targeted Drug Delivery System

Objectives

The objectives of formulating and evaluating a colon-targeted drug delivery system (CTDDS) are to achieve localized and sustained drug release in the colon, protecting the drug from degradation in the stomach and small intestine, and potentially enabling systemic delivery of proteins and peptides

Targeted Delivery to the Colon:

Local Treatment:

CTDDS aims to deliver drugs directly to the colon for the treatment of localized diseases like inflammatory bowel disease (IBD) and colon cancer.

Protection from Degradation:

CTDDS protects drugs from degradation by stomach acid and enzymes in the small intestine, ensuring they reach the colon intact.

Reduced Systemic Side Effects:

By targeting the colon, CTDDS can minimize systemic exposure to the drug, reducing potential side effects.

2. Sustained and Controlled Release:

Optimized Drug Concentration:

CTDDS aims to maintain a therapeutic drug concentration in the colon for an extended period, enhancing the effectiveness of the treatment.

Improved Bioavailability:

Colon-targeted delivery can improve the bioavailability of certain drugs, particularly those poorly absorbed in other parts of the GI tract.

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3. Systemic Delivery of Proteins and Peptides:

Oral Administration:

CTDDS can be used to deliver therapeutic proteins and peptides orally, which are typically administered by injection.

Enhanced Stability:

The colon's environment (compared to the stomach and small intestine) can be more suitable for the stability and absorption of these labile molecules.

4. Formulation and Evaluation Considerations:

In Vitro Studies:

Evaluation of CTDDS often involves in vitro dissolution studies to assess drug release profiles in simulated colonic fluids.

In Vivo Studies:

Animal studies are used to assess the efficacy and safety of the CTDDS in a real-world setting.

Polymers and Coatings:

Various polymers and coating materials are used to control drug release, such as pH-sensitive polymers (e.g., Eudragit) or biodegradable polymers.

Stability Studies:

CTDDS formulations are evaluated for their physical and chemical stability over time.

PLAN OF WORK

The present work was carried out to formulate the colon targeted tablets of Prednisolone and to evaluate the various parameters. It wasplanned to carryout this work as outlined below.

To carry out the Preformulation studie stomaximize the chance informulating an acceptable, safe, efficacious and stable product.

1.EvaluationofAPI

- Description
- Solubility
- Melting point
- Particle size distribution
- Losson drying

2.Drug excipient compatibility studies

- Physical observation
- FT-IRstudies.
- Formulation of uncoated tablets by direct compression method.
- Evaluation of the granules such as
- Angle of repose
- Bulk density
- Tapped density
- Compressibility index
- Hausner'sratio
- Evaluation of physical parameters for compressed tablets.
- Weight variation
- Thickness
- Hardness
- Friability

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- Disintegration
- Determinationofdrugcontent
- Evaluationofthecoated tablet.
- Evaluation ofthemost satisfactoryformulation.
- In-vitro DrugReleaseStudies.
- To carry out the stabilitystudiesforthe bestformulation

IV. MATERIAL AND EQUIPMENTS

Table 1. Material In The Investigation

Sr.no.	Name of ingredients	Category	Manufacturing
1	prednisolone	Activeingredient	Yarrowcamlab, Mumbai.
2	Microcrystallinecellulose	Binder,Diluent	FMCInternational
3	Sodium starch glycolate	Superdisintegrant	Shreeji Pharma International
4	Corn starch	Asorbent, filler,binder Disintegrant	Pruthvi Foods
5	Talc	Thickingagentlubricant	VijayMineral
6	MagnesiumStearate	Lubricant	SunshineOrg.

Equipment

Sr.No.	Instruments	Manufacturer
1.	Weighing balance	shimadhu
2	Bulkdensityapparatus	Thermonik
3	Compressionmachine	Accura
4	Coatingpan	Electrolab
5	Hardnesstester	Thermonik
6	Thicknesstester	japan
7	Friabilitytester	Electrolab
8	Disintegrationapparatus	Labindia
9	Dissolutionapparatus	Electro ab
10	PHAnalyzer	Labindia
11	UVspectrophotometer	Shimadhu
12	Electromagneticshaker	Electropharma

Experimental Work

Materials

prednisolone IP, microcrystalline cellulose,sodium starch glycollate, corn starch, isopropyl alcohol, talc, magnesium stearate, Eudragit L100, Eudragit S 100, DEP, TIO2. All the material was provided by Lincoln Pharmaceutical Ltd. Equipments used included: Rotary tablet machine, Roche friabilator, Bulk Density measuring apparatus (Electro lab B.D/T.D. measuring apparatus), Monsanto Hardness Tester.

Table 2:Tablet formulation

Sr.No.	Ingredients	SF1	SF2	SF3	SF4	SF5	SF6
1	Prednisolone	20	20	20	20	20	20
2	Microcrystallinecellulose	63	64	65	64	64	63
3	SodiumStarchGlycollate	8	7	6	6	4	6

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4	Corn starch	2	2	2	2	2	2
5	Talc	2	2	2	2	2	2
6	MagnesiumStearate	2	3	2	3	3	2

METHOD

Preparation of core tablets

The core tablet of prednisolone 100 mg were prepared by direct compression method of manufacture usingMCC (AVICEL) as the main constituent. Prednisolone,MCC, SSG,sodim starch glycolate were passed through sieve no #40 and thoroughly mixed in a polythene bag (approx. 10 min). Loss on Drying (LOD) was measured by halogen moisture balance (Mettler Toledo). Above mixer was lubricated granules were lubricated with talc,corn starch and Magnesium stearate which were already passed through sieve no # 60 and compressed in to tablets on a 35 station single rotary machine using 8/32 inch Standard concave, Plain/Plain punch. The compression pressure level was kept constant for all the batches by adjusting the pressure control knobs to the same setting.

Table 3: Composition of coating solution.

Sr. No	Ingridents	SF1 (5%)	SF2 (5%)	SF3 (7%)	SF4 (7%)	SF5 (7%)	SF6 (10%)
1	EudragitL100	30	15	30	25	20	20
2	EudragitS100	30	20	25	25	30	30
3	DEP	2.4	2.4	3	3	4	4
4	TIO2	2.4	2.4	2.4	2.4	2.4	2.4
5	Acetone	150	150	150	150	150	150
6	IPA	350	350	350	350	350	350

Coating of the tablets

It was done by using the standard coating pan, where fixed numbers of tablets were coated each time by atomizing the polymeric coating solution through the means of spray gun. The scale-up variables including pan loading, pan speed, number of spray guns, spray rate, and inlet airflow etc. were considered. About 500 tablets of prednisolone tablet were taken and allow to coatings in pan coater at 30 rpm and 50^{o}Ctemperature. Coating was carried out with praying method and dried with same.

Evaluation of pharmaceutical powder properties Micromeretic propertic (Bulk Density and Tapped Density**)**
Flow properties (Angle of repose, Compressibility index, Hausner ratio**)**

Bulk Density

Bulk density was determined according to usp method 1. Accurately weighed quantity of powder, which was previously passed through sieve 18 and carefully poured into graduated cylinder. Then the cylinder the powder bed was made uniform without disturbing. Then the volume measure was called as the bulk volume and the bulk density is calculated byfollowing formula.

Bulkdensity=Weightofpowder/Bulk volume.

TappedDensity

Tappeddensitywasdeterminedbyuspmethod2.Thepowder sample under test was screened through sieves no 18 and tablet blend was filledmin 100ml cylinder after measuring the bulk volume the same measuring cylinder was set into tap density apparatus. The tapped density apparatus was set to 250tap drops per minutes and operated for 500 tap. Volume was noted as and and again tapped for 750 times and volume was noted as. The tapped density is calculated by

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the following formula.
Tapped density=Weight of poweder/Tapped volume

Carrs index
Compressibilityindexaremrasureofthepropensityofapowdertobecompressed.As such they are mresure ofrelative importance of interparticulateinteraction.Itis one of the most important parameter to characterize the nature ofpowders and granules. At can be calculated from the following formula, Carrsindex=Tappeddensity–Bulkdensity/ Tappeddensity*100.

Hausner Ratio
Housnerratioisanimportantcharactertodeterminetheflowpropertyofpowderand granules. This can be be calculation bythe following formula,
Hausner Ratio=Tapped density/Bulk density
property of powders. The tangent of angle repose is equal to the coefficient of friction between the particles. Angle of repose was determined using funnel to pour the powder on the powder on the surface from a fixedheight of 2 cm, the radius base of a pile was measured at5 different point and average was teken for calculataing angle ofrepose using following formula

Tan=h/r

The prepared tablets were evaluated for the following parameters Hardness, measured by tablet hardness tester; schleuniger in kp (Kilo Pascal), Weight variation (Average weight of ten tablets by electronic weighing balance), Thickness which was measured by Vernier Caliper in millimeter (mm), Friability was checked by USP apparatus (Roche friabilator) for 100rpm.

Table4:Evaluation of uncoated tablet.

Formulation	Hardness	Friability (%)	Thickness (mm)	Weight variation(Mg)	Average Weight(Mg)
SF1	7.4	0.3	2.72	0.2	100
SF2	8.9	0.4	2.8	0.3	100
SF3	9.2	0.3	2.9	0.4	100
SF4	11.5	0.2	2.72	0.5	100
SF5	8.6	0.7	2.86	0.4	100
SF6	9.4	0.4	2.84	0.3	100

The in-vitro dissolution studies were carried out using USP dissolution apparatus type II in different medium.
Acidstage: Twohoursin900 ML0.1NHCLat75rpm.
Buffer stage: Three hour in 900 ML pH 4.5 phosphate buffers at75 rpm, 1 hourin 900 ML pH 7.2 simulated colonic fluid at 75 rpm. Dissolution test was carried out for a total period of 6hours.AnalysisforprednisolonewasdonebyUVdetectedat247nm

Table 5:Cumulative percentage drug release of prednisolone P^Hdependent Tablets.

Time(hr)	1	2	3	4	5	6
pH	1.2		4.5		7.2	
SF1	5.49	9.82	10.9	14.9	18.9	102.3
SF2	3.84	4.74	8.08	12.2	16.2	98.10
SF3	2.75	9.30	11.56	15.79	18.96	101.2
SF4	1.5	2.5	5.1	5.30	11.56	91.86
SF5	2.0	3.0	5.3	7.3	12.2	94.8

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SF6	1.08	2.5	5.7	9.0	10.2	94.8
SF7	1.08	2.5	5.7	9.0	10.2	94.8

Organoleptic characteristics

Sr.No.	Characteristics	Result
1	Colour	off-white
2	Odour	Odorless
3	Meltingpoint	234°C
4	BoilingPoint	570.5±50.0°Cat 760 mmHg

Table No. 6:Organolepticcharacteristics.

The physical appearance of sample of Prednisolone was carried out as per USP. It shows that off-white in color, odorless and the melting point was carried out by capillary method and it was found to be 235^{0}C.

PREFORMULATION STUDY

Determination of wavelength maxima (λ_{max})of Prednisolone

The solution of 10µg/ml in phosphate buffer pH 6.8 (few drops of ethanol) was prepared and scanned in the range of 200-400 nm and wavelength maxima was determined at 315 nm by using shimandzu U.V. spectrophotometer

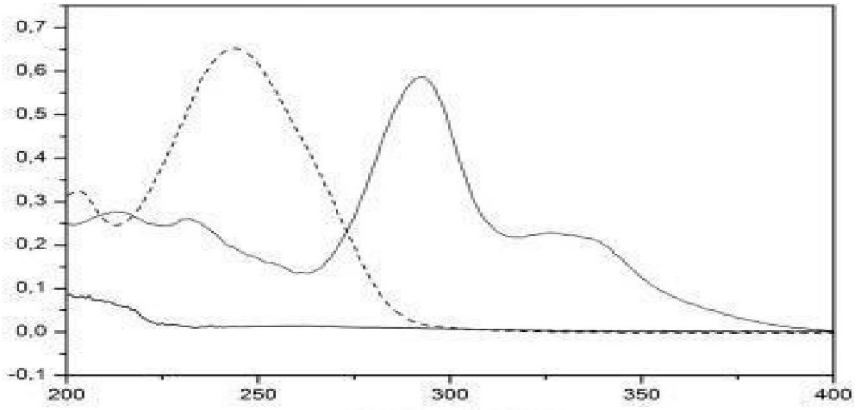

Figure1:MaximumabsorbancespectraofPrednisolone.

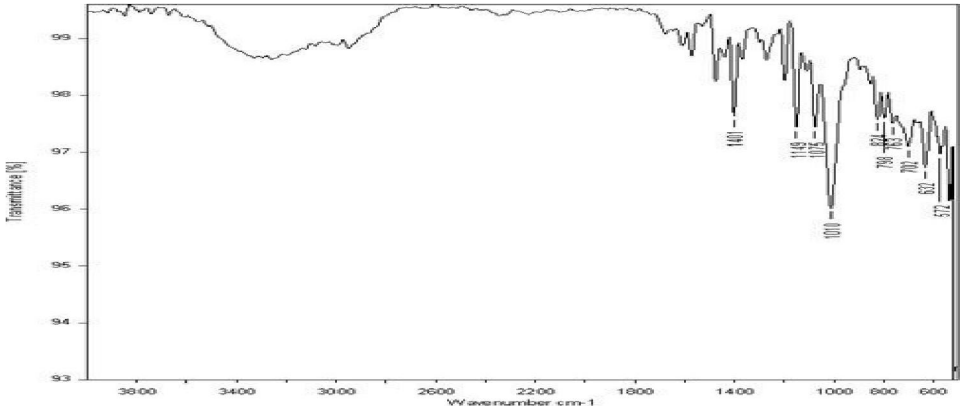

Figure2:FTIRspectrumofthephysicalmixtureofPrednisolone+Sodium starchgly collate + Microcrystalline cellulose

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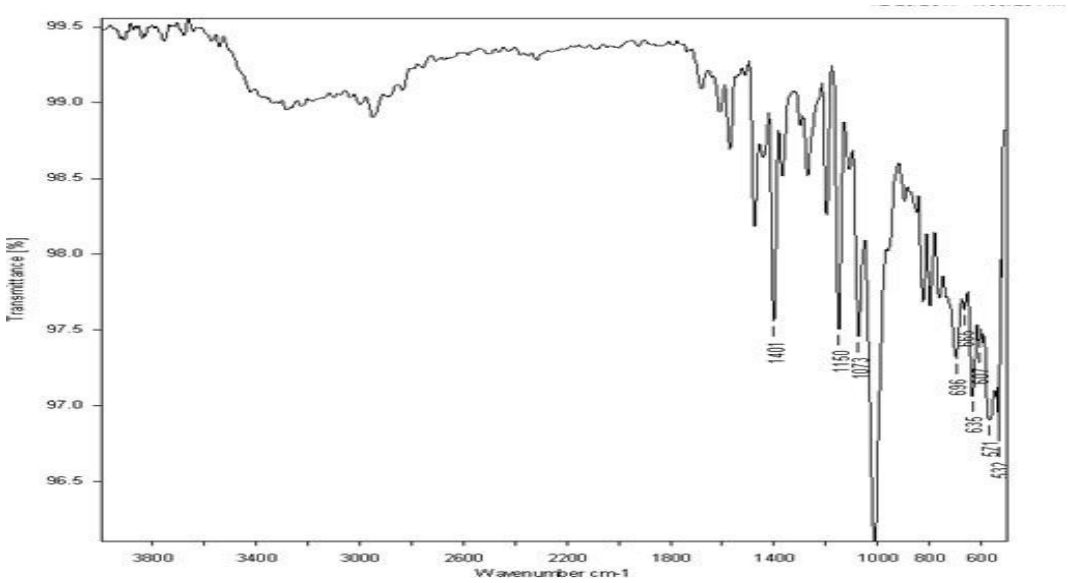

Figure 3: FTIR spectrum of the physical mixture of Prednisolone + Microcrystalline cellulose.

PRE-COMPRESSIONPARAMETERS

TableNo.7:Physicalcharacteristicsevaluationofpowdermixture(n=3).

Formulation code	Bulkdensity (gm/cm^3)	Tapped density (gm/cm^3)	An angle ofrepose (°)	Compressibilit yindex (%)	Hausner's ratio
F1	0.312±0.032	0.390±0.068	32.55±1.25	20.51±1.230	1.25±0.103
F2	0.297±0.018	0.368±0.050	31.72±1.28	19.23±1.115	1.23±0.102
F3	0.340±0.034	0.416±0.061	29.04±1.19	18.18±1.196	1.22±0.112
F4	0.326±0.026	0.394±0.075	33.54±1.17	17.39±1.479	1.21±0.015
F5	0.312±0.020	0.375±0.049	30.10±1.11	16.60±1.146	1.20±0.105
F6	0.310±0.011	0.387±0.052	30.85±1.29	20.01±1.188	1.25±0.113
F7	0.312±0.045	0.371±0.047	33.35±1.35	16.01±1.050	1.19±0.107
F8	0.283±0.069	0.330±0.036	27.40±1.18	14.28±0.986	1.16±0.110
F9	0.389±0.046	0.518±0.043	34.32±1.31	25.12±1.137	1.33±0.116
F10	0.364±0.013	0.478±0.015	31.75±0.14	23.80±0.956	1.31±0.104
F11	0.356±0.007	0.440±0.054	29.44±0.23	19.04±1.543	1.23±0.117
F12	0.318±0.019	0.418±0.013	34.46±0.36	24.33±1.678	1.31±0.111

POST-COMPRESSIONPARAMETERS

TableNo.8:Evaluation Of formulated tablet(n=3).

Formulationcode	Average weight (gm)	Thickness (mm)	Hardness (kg/cm^2)	% Friability	Wetting time(sec)	Water absorption ratio(%)	Content uniformity (%)	Disintegration time (sec)
F1	201±1.15	2.68±0.12	4.2±0.17	0.932±0.16	13±1.11	65.00±0.20	92.58±0.24	63±1.14
F2	204±2.05	2.47±0.24	4.2±0.15	0.866±0.2	12±1.15	71.42±0.40	93.94±0.11	63±1.16

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				8				
F3	199±1.17	2.33±0.36	4.4±0.18	0.943±0.11	12±1.10	77.27±0.30	91.64±0.18	54±1.21
F4	204±1.13	2.62±0.14	4.2±0.10	0.834±0.24	12±1.15	80.00±0.63	94.45±0.15	38±1.15
F5	201±2.58	2.77±0.18	4.3±0.12	0.816±0.30	13±1.14	76.19±0.48	93.94±0.19	41±1.25
F6	204±2.31	2.83±0.39	4.6±0.19	0.910±0.29	12±1.17	83.33±0.32	90.80±0.16	39±1.16
F7	201±1.97	2.36±0.50	4.0±0.21	0.934±0.15	12±1.20	85.00±0.44	97.65±0.25	32±1.18
F8	200±2.10	2.73±0.19	4.5±0.25	0.934±0.26	10±1.13	90.90±0.11	98.19±0.16	24.±1.10
F9	199±3.15	2.11±0.29	4.3±0.09	0.866±0.33	24±1.11	57.5±0.17	96.28±0.23	68±1.23
F10	207±1.48	2.54±0.64	4.4±0.28	0.919±0.17	22±0.16	60.00±0.21	91.97±0.38	65±1.29
F11	207±1.29	2.63±0.10	4.4±0.13	0.778±0.14	22±1.19	61.90±0.27	90.24±0.30	59±1.24
F12	201±2.11	2.14±0.25	4.1±0.14	0.834±0.18	20±1.12	78.94±0.16	94.45±0.26	40±1.31

In-vitro dissolution studies

TableNo.9:PercentagecumulativedrugreleasedataforformulationsF1-F4,(n=3).

Time(min)	F1%CDR	F2%CDR	F3%CDR	F4%CDR
0	0	0	0	0
1	30.85±0.31	33.14±0.24	41.54±0.18	30.53±0.47
2	35.25±0.15	36.08±0.16	44.06±0.13	41.54±0.57
5	42.20±0.23	51.54±0.67	57.57±0.61	58.55±0.38
10	44.93±0.46	56.68±0.55	66.57±0.52	69.56±0.17
15	46.79±0.59	71.03±0.39	75.58±0.40	72.06±0.29
20	58.33±0.11	73.99±0.48	86.59±0.23	86.90±0.45
25	78.38±0.19	83.68±0.13	91.11±0.09	92.26±0.10
30	86.52±0.25	87.90±0.10	92.35±0.28	94.60±0.21

Kinetics of in-vitro drug release

The in-vitro drug release data of all the Prednisolone tablet formulations were subjected tothegoodness of fit test by linear regression analysis according to zero order and first order kinetic equations, Higuchi's and Korsmeyer–Peppas models to ascertain the mechanism of drug release.

TableNo.10:Kinetic study of formulations

Formulation code	Release Kinetics				
	Zero-order R^2	Firstorder$_R2$	Higuchi$_R2$	Peppas	
				R^2	N
F1	0.851	0.873	0.892	0.815	0.263
F2	0.824	0.974	0.955	0.992	0.297

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F3	0.765	0.973	0.922	0.992	0.254
F4	0.798	0.972	0.951	0.984	0.319
F5	0.811	0.931	0.934	0.952	0.296
F6	0.824	0.963	0.957	0.985	0.302
F7	0.749	0.921	0.912	0.965	0.268
F8	0.856	0.993	0.977	0.979	0.390
F9	0.842	0.919	0.968	0.987	0.334
F10	0.821	0.932	0.932	0.957	0.264
F11	0.855	0.969	0.966	0.976	0.306
F12	0.784	0.954	0.945	0.991	0.308

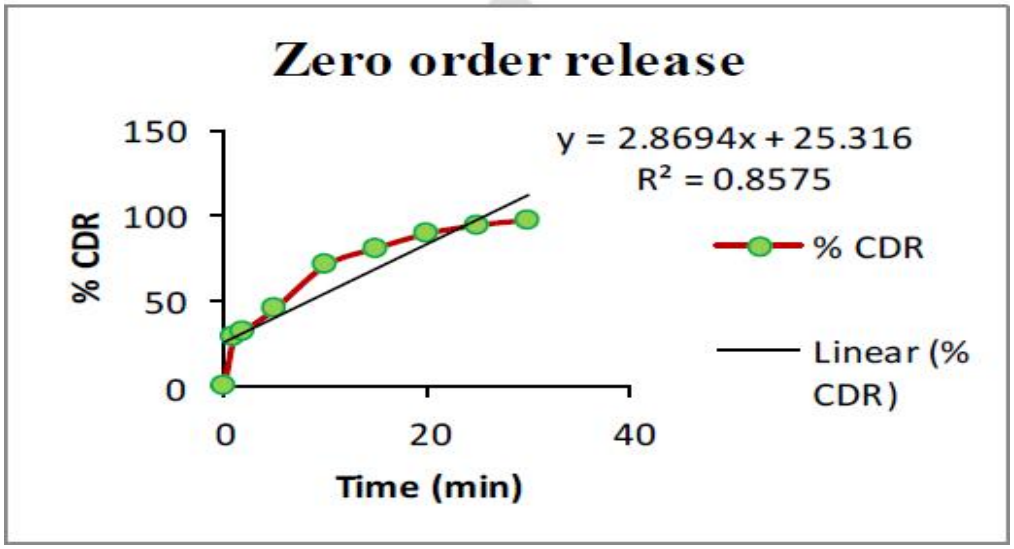

Figure4:Zero-order release kinetic sprofile of optimiz.

Stability studies

Stability studies were carried out on optimized formulation F8for a period of one month.The comparison of the parameters before and after stabilitystudies was represented in a table No. 26.

TableNo.11:Comparisonofparametersbeforeandafterstabilitystudies

Parameters	**Beforestabilitystudies**	**Afterstabilitystudies**
Appearance	Off-whitecolor	Off-whitecolor
Wettingtime(sec)	10±1.13	10±0.23
Waterabsorptionratio (%)	90.90±0.11	89.50±0.14
Disintegrationtime(sec)	24±1.10	24±1.05
%CDR	98.19±0.16	97.12±0.29

The results obtained from the stability studies showed that the optimized formulation F8showed onlyaslight decreasein thewettingtime,waterabsorption ratio, thedisintegration time of Prednisolone tablet at 40°C after 1 month of storage. Thein vitro drug release also slightly decreased after the stability period.There was no change in the appearance of the formulation. From the stability studies, it was confirmed that the optimized formulation of Prednisolone remained stable at 40ºC and 75% relative humidity.

The expected in vitro release pattern selected for the colon targeting was not morethan 10%of drug release up to the end of 5hrs.Eudragit L-100 and Eudragit S-100 were used indifferent concentration; 5%, 7% and 10% coating level. The batch SF1 and SF2 with 5% coating showed a release of more than 10% in less than five hours i.e. 19.1 % & 16.2 %

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respectively, which is not acceptable. Hence these formulations were excluded from further studies. However the SF7 and SF8 formulation showed a release of less than10% in the first five hour of dissolution study.

The drug release was directly related to the concentration of polymer in solution andthe%coatinglevel.Percentofdrugreleasevs.timeplotshowsthatthedissolutionratewasinversely proportional to the coating level applied. A significant difference was observed in thepercentageof drug released fordifferent coatinglevel. All thecoated tablets withvariable coating level showed a nearly complete drug release in the 6 hr.

In the formulation SF3,SF4 and SF5 where 7% polymer coating was applied in the ratio 3:2,1:1,2:3. The % drug release after 5hr was 18.96 %, 11.56 %, 12.1 % respectively. The solubility of the films from various combinations of Eudragit L100– Eudragit S100, and the release rate of drug from the coated tablets in various pH media could be controlled by varying the ratios of the two polymers

For formulation SF6, SF7 and SF8 where, 10% coating in the ratio 3:2, 1:1, 2:3; was applied. The drug release at 5^{th} hr and 6^{th} hour 10.4% 95.4% respectively in the formulation SF5 observed. In the SF7 & SF8 polymer was able to control the drug releaseafter 5^{th} hr the drug release was well within the desired limits of less than 10% i.e. 6.7% and 5.6%. The drug released from these formulations at the end of dissolution run was 98.2% & 99.1%. It was observed that the drug release was controlled by increase the coating level. Based on the above studies, the optimum formulation, formulation SF8 coated with Eudragit L100– Eudragi S100 at a combination ratio of 2:3 and at the coating level of 10%, was chosen for studying the effect of pH of the buffer media on the release profiles, as shown in Figure. As anticipated, the release profiles were obviously faster in pH 7.2 than in pH 4.5 buf fer media.

V. CONCLUSION AND RESULT

The present study was carried out to investigate the ability oftargeting the drug release in colon. From results obtained in the present study, it was concluded that the resulted optimum formulation was the one coated. The in vitro studies showed that this formulationsuccessfully deliver the maximum amount of drug in intact form to the colon. The combined action of the super disintegrant; cross carmellose sodium and sodium starch glycollate have been contributed to such a fast disintegration property. It prevents the drug release in the stomach and intestine so we can solve the problem of side effect of anti inflammatorydrug in this area & also prevents ulcerative colitis

The Prednisolone tablets were successfully formulated by direct compression method using the selected excipient quantities. The formulated tablets were evaluated for both pre- compression and post-compression parameters as per requirements of standards. And the results were complied with the pharmacopoeia specification. The formulated Prednisolone tablets were coated with enteric by pancoating method.

Drug delivery to the diseased colon are advantageous in reducingsystemic side effects,lower dose of drug, supply of the drug only when it is required and maintainance of the drug in its intact form as close as possible to the target site. Better colonic delivery could be achieved by protecting the drug from absorption and /the environment of the upper GIT and then abruptly released in to proximal colon, which isthe site for colonic targeted delivery of drugs. All the approaches provide means for treatment of local diseases associated with the colon or for systemic absorption of poorly absorbed drugs. The colon is rich in microflora which can be used to target the drug release in the colon.

Colon targeted based tablets of prednisolone coated were successfully prepared by the wet granulation technique and optimized using full factorial design. DSC studies indicated compatibilityof drug with other excipients. As the amount of HEG in the tablet formulations increases, the drug release decreases and as the percentage coat weight gain increases, the drug release also decreases. From the results of full factorial design formulation F9containing 30% HEG and 9% CWG evolved as optimized formulation and it released only 10.09% of drug in upper part of GIT. The accelerated stability studies established physical integrityof the formulation and chemical stabilityof the drug. The present studycorroborates colonic delivery of prednisolone tablets dually coated with Eudragit L100 and Eudragit S100 (1:4)to be a potential systems storestrict the release of drug to colon with the merits of Reduced systemic exposure and enhanced potency.

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