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FORMULATION AND EVALUATION OF MATRIX TABLETS TO TREAT INFLAMMATORY DISEASE

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ABSTRACT

Dexamethasone is a glucocorticoid medication. This study was to develop guar gum-based colon targeted tablets of dexamethasone in the prevention of inflammatory bowel disease (IBD).The powder mix was subjected to micrometric evaluation (like bulk density and Carr's index) and drug content uniformity. Powder mix showed high values of Carr's index indicating low compressibility and drug content uniformity tests how uniformity of drug content that proved mixing uniformity. Matrix tablets containing 40% (DX-40), 50% (DX- 50), 60% (DX-60), 70% (DX-70) and 80% (DX-80) of guargum were prepared by direct compression technique. Dexamethasone matrix tablets containing various proportions of guar gum ranging from 40 to 80% of guar gum were subjected to measurement of mass degree of swelling and gel strength. This indicates that swelling of the guargum-based formulations is increasing as percentage of guargum is increasing. When subjected to post compression evaluation like hardness and friability formulations DX-70 and DX-80 containing 70% and 80% of guargum respectively showed very low hardness and friability 1.67 and 0.43kg/cm^2 respectively. Hence, further studies like *in-vitro* release studies, scanning electron microscopy (SEM) and short-term stability study were not conducted on these formulations. Formulation DX-40 containing 40% of guar gum released about 87% of its drug content within 18 h in the physiological environment of colon. This may result in the release of drug in the last part of the small intestine itself. The tablet formulation DX-50 containing 50% of guargum also release about 88%of drug content in the physiological environment of colon at the end of 24hrs of the study. However, at the end of 24 hour dissolution study, the matrix tablets of dexamethasone DX-60 containing 60% of guar gum released about 58% of the drug in the physiological environment of colon.

KEYWORDS

Dexamethasone, Matrix tablets, Guar gum and Magnesium stearate etc.

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INTRODUCTION

Inflammatory bowel disease (IBD) affects approximately two million Americans, usually before the age of 40. In the United States, complications of these diseases are believed to claim 1000 lives a year. Inflammatory bowel disease (IBD) describes two major chronic, non-

specific inflammatory disorders of the gastro-intestinal (GI) tract, ulcerative colitis (UC) and Chorns disease (CD), the causes of which remain unknown. UC is usually limited to the colon and rectum[1]. The colon and rectum are parts of the body ís digestive system which remove nutrients from food and stores waste until it passes out of the body. Corticosteroids were the first agents demonstrated in controlled trials to have efficacy in UC. Corticosteroids have been successfully used to treat moderate to severe forms of IBD since the 1950s.

The approaches available in achieving colon-specific drug delivery includeA

Coating with pH dependent polymers

Design of timed- release dosage form and

The use of carriers that are degraded exclusively by colonic bacteria.

However, studies on the use of carriers that are degraded exclusively by colonic bacteria are found promising in providing colon-specific drug delivery. The most promising of the colonic drug delivery systems that are dependent on the enzymatic action of colonic bacteria are those based on polysaccharides. The polysaccharides are biodegradable, abundantly available and also cheap. The polysaccharides that are under active investigation for colon-specific drug delivery include pectin and its salts, chondroitin sulphate, amylose, dextran and chitosan. Earlier it was reported that guar gum is a potential carrier for colon-specific drug delivery.

Guar gum is a polysaccharide derived from these eds of cyamopsistetragonolobus, family Leguminosae. It consists of linear chains of (1-4)-D-mannopyranosyl units with D-galacto pyranosyl units attached by (1-6) linkages.

It is cheap, safe and abundantly available and is being used in pharmaceutical formulations as disintegrant, suspending agent, thickening agent and binder. In the light of above information guar gum-based colon targeted drug delivery systems may be useful for the prevention and treatment of inflammatory bowel disease (IBD).

AIM

To develop guar gum-based colon- targeted drug delivery systems of dexamethasone for the prevention of inflammatory Bowel Disease (IBD).

OBJECTIVES

To formulate matrix tablets of dexamethasone with varying quantity of guar gum and immediate release tablets.

To carry out on various guar-gum based formulations and reference formulation (immediate release tablets) so as to optimize the guar gum content in guar gum-based matrix tablets that would probably release the drug in physiological environment of colon by comparing with reference formulation (immediate release tablets).

The formulation could be analysed by scanning electron microscopy (SEM), etc., and stability studies would be done.

DRUG PROFILE

DEXAMETHASONE (BAN, rINN)

Synonyms: Dexamethasone; Dexamethasone; Dexamethasonum.

Chemically dexamethasone is 9-fluoro-16-methyl prednisolone; Hexade cadrol.9-Fluoro-11, 17, 21-trih ydroxy-16-methylpregna-1, 4-diene-3, 20-di-one.It is a white or almost white odourless crystalline powder, practically insoluble in water; sparingly soluble in alcohol in dehydrated alcohol, in acetone in dioxan and In methyl alcohol; slightly soluble in chloroform and in dichloromethane; very slightly soluble in ether. Protect from light.

Molecular Formula: $C_{22}H_{29}FO_5$CAS-50-02-2[50].

Pharmacology: Dexamethasone have both anti-inflammatory (glucocorticoid) and salt retaining (mineralocorticoid) properties. Glucocorticoids cause profound and varied metabolic effects. In addition, it modify the body ís immune responses to diverse stimuli. It is used as replacement therapy in adrenocortical deficiency states and may be used for their anti-inflammatory effects.

GUAR GUM[45]

The USPNF XVIII describes guar gum as a gum obtained from the ground endosperm of Cyamops is tetra gonolobus (Linne) Taus. (Family Leguminosae). It consists chiefly of a high molecular weight colloidal polysaccharide, composed of galactan and mannan units combined throughgly coside link ages, which may be described chemically as galactomannan.

Synonyms: Gum flour, Jaguar gum, E412

Chemical name: Galactomannan polysaccharide

Empirical formula: $(C_6H_{12}O_6)_n$

Guar gum consists of linear chains of (1□4)-□-D-mannopyranosyl units with □-D- galacto pyranosyl units attached by (1□6) linkages. Ther of D-galactoseto D- mannose is 1:2.

Pharmaceutical Uses

Guar gum is used as a binder (upto10%)and disintegrating agent in solid dosage forms. It is also used as a suspending, thickening and stabilizing agent (up to 2.5%) in liquid oral and topical products.

Therapeutic uses

Guar gum is used as a part of the diet of the patients with diabetic mellitus. It is also used as a bulk laxative and appetite suppressant.

In cosmetics, guar gum is used as a thickening agent and in food products as a stabilizer in ice creams, emulsifier in salad dressings and thickening agent in beverages.

Safety

Excessive consumption of guar gum may cause gastrointestinal disturbances such as flatulence, nausea or diarrhoea. Therapeutically daily oral doses up to 25g of guar gum have been administered to patients with diabetes mellitus.

Pre-formulation Study

Determination of Melting Point

Take a fine capillary of length 5-6cm. seal its one end by inserting the end of the capillary tube horizontally into the extreme edge of a small steady Bunsen flame for a few seconds, rotating the capillary meanwhile. Take a small quantity of the compound whose melting point is to be determined on a porous plate and powder it with a spatula. Introduce the powdered compound in the capillary tube by introducing the open end of the capillary tube into the powdered compound and gently rotating it. Gently tap the capillary tube against the porous plate so that the compound sinks into the closed end. Repeat the procedure of introducing and tapping three to four times. Moisten the bulb of thermometer with Conc. Sulphuric acid or liquid paraffin and attach the capillary to the lower end of the thermometer. Place the thermometer with the capillary tube in the melting point apparatus containing at least two third of its volume liquid paraffin in such a way that the closed end of the capillary remains below the surface of Liquid paraffin. Now heat the beaker gently and note down the temperature from time to time and finally note down the temperature at which the compound starts melting and completely melts. Repeat the experiment with a new capillary tube and fresh quantity of the substance.

Compatibility studies of dexamethasone and formulation components

The compatibility of drug and polymer under experimental conditions is important pre requisite before formulation. It is therefore necessary to confirm that the drug does not react with the polymer and excipients under experimental conditions and affect the shelf life of product or any other unwanted effects on the formulation. This can be confirmed by carrying out by infrared spectroscopy studies.

Pre-compression Evaluation of Powders Mix

Micrometric Evaluation of Powder Mix

Bulk Density

Both loose bulk density (LBD) and tapped bulk density (TBD) were determined. The accurately weighed amount of sample (5gm) taken in a 25ml measuring cylinder Borosil measured/recorded the volume of packing and tapped 100 times on a plane hard wooden surface and tapped volume of packing recorded and LBD and TBD calculated by following formula

$$\text{LBD (Loose bulk density)} = \frac{\text{Mass of Powder}}{\text{Volume of Packing}}$$

$$\text{TBD (Tapped bulk density)} = \frac{\text{Mass of Powder}}{\text{Tapped volume of packing}}$$

Percentage compressibility

Percent compressibility of powders mix was determined by Carrís Compressibility Index calculated by following formula

$$\text{Carrís Index (\%)} = \left(\frac{\text{TBD ñ LBD}}{\text{TBD}}\right) \text{x100}$$

Powders mix drug content uniformity test

The final powder blend (1 to 3 times unit dose) was sampled using at from 10 different locations (5 from top, 3 from middle and 2 from bottom). Powder sample collected mixed properly in a glass mortar and pestle. Accurately weighed 388.88 mg of powder (equivalent to 10mg dexamethasone) transferred to 50ml volumetric flask and dissolved in 25ml absolute ethanol, sonicated, filtered through What's man filter paper No.41 and made up the volume with distilled water (stock solution). 1ml from stock solution taken, transferred to 10ml volumetric flask and volume made up to 10ml. The absorbance at 242nm and powder drug content was calculated with the help of standard calibration curve and recorded.

Post-Compression Evaluation of Tablets

Thickness and Diameter Test

Thickness and diameter test permits accurate measurement and provides information on the variation between tablets. 5 tablets were taken and the thickness and diameter was measured using dial caliper. The table its thickness and diameter should be controlled within a 5% variation of a standard value.

Weight Variation Test

The procedure described in the I.P. 1996 was employed to determine the weight variation of the tablets. Ten tablets from each formulation were weighed on an electronic balance and the mean weight was taken. The mean weight was calculated. Each tablet was then weighed separately and the standard deviation in weight was calculated for each formulation (Table No.5.6).

Hardness Test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using the strokes ñ Monsanto hardness tester. It is expressed in kg/cm^2. In all cases the mean of 10 replicate were determined and the mean and standard deviation values was calculated.

Friability Test

The friability of the tablets from each formulation was tested by using Campbell Electronics made friabilator. It is expressed in percentage (%). Ten tablets were weighed initially ($W_{initial}$) and placed in the friability test apparatus and allowed to fall six inches on each turn of the friabilator at25 rpm. After four minutes of treatment or 100revolutions, the tablets were loss due to abrasion or fracture was the measure of table friability. The tablets were weighed again (W_{final}). The % friability was then calculated by,

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \text{x100}$$

% Friability of tablets less than 1% are considered acceptable.

Measurement of mass degree of swelling

Each tablet from all formulations reweighed and allowed to equilibrate with100ml of water for 5 h. The tablets were removed, blotted using tissue paper and weighed. The mass degree of swelling then was calculated using the formula

$$Q = \frac{\text{Mass of the swollen gel}}{\text{Mass of the dry polymer}}$$

Measurement of Gel Strength

The gel strength of hydrated matrix tablets was determined by using method reported by P. Van Aerde. A beaker was balanced on one plate of two armed balance, at the underside of which a cone shaped pin was fixed .Water was continuously added to the beaker because of which the pin exerted an increasing force on to

the tablet. The gel strength was defined as total amount of water (ml) necessary to perforate the tablet and was determined after complete hydration of matrix (8hours) shown in Plate.

Determination of drug content

The reference formulation (immediate release tablets formulated in laboratory) and guar gum-based colon targeted dexamethasone Matrix tablets were tested for their drug content. Ten tablets were ground individually to fine powder, powder equivalent to10mg dexamethasone was accurately weighed and transferred to 50Ml volumetric flask containing about 25ml absolute ethanol and allowed to stand for 6 hours with intermittent sonication to ensure complete solubility of the drug. Then the volume was made up with distilled water, mixture was centrifuged at 2500rpm for 15min, 1ml of the supernatant liquid was suitably diluted to 50ml and volume was made-up to volume with distilled water, filtered through G-5 borosil filter and analyzed for dexamethasone content by U.V. spectrophotometric method.

UV-Spectrophotometric estimation of dexamethasone in dissolution samples

About 1mL of absolute ethanol was added, to the dissolution sample containing in 10mL volumetric flask, sonicated well for complete dissolution of the drug and made-up to the volume with methanol. The mixture was centrifuged, filtered through G-5 borosil (bacteria proof filter) and was analyzed for dexamethasone by UV-spectrophotometric method.

Scanning Electron Microscopy (SEM)

SEM has been used to determine particle size distribution, surface to pography, and texture and to examine the morphology of fracture dor sectioned surfaces. The SEM is most commonly used for generating three dimensional surface relief images derived from secondary electrons. The examination of the surface of polymeric drug delivery systems can provide important information about the porosity and microstructure of the device. Most importantly, the distribution of encapsulant in the polymer matrix and the interaction of drug with surrounding polymer can be analyzed as well as crystallinity differences in the polymer matrix itself.

Stability Studies

Stability of a drug has been defined as the ability of a particular formulation, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specifications.

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light and enables recommended storage conditions, re-test periods and shelf-lives to be established.

I.R. Spectra of Formulation DX-80 AND DX-IR

For pre compression evaluation, the powder mix was subjected to micrometric evaluation (bulk density and Carrís Index) and drug content uniformity to check the mixing uniformity. The loose bulk density (LBD), tapped bulk density (TBD) and Carrís Index (percentage compressibility) were found 0.3030 to 0.4764gm/ml, 0.4464 to 0.6896gm/ml and 30.96 to 34.48%. The matrix formulations showed the high Carr's Index values, that indicating low compressibility of powder mix. The powder mix was found to contain 98.94 to 100.17% of the labeled amount indicating uniformity of drug content that proved mixing efficiency. The guar gum-based matrix tablets and immediate release (reference formulation) were prepared by applying 7 ton (7000kg) and 0.5 ton (500kg) pressure respectively to get the disintegration time less than 60 seconds, and the hardness of the tablets was found to be in range of 0.43 to 5.74kg/cm^2 and 4.30±0.296kg/cm^2 respectively. Dexamethasone guargum-based matrix tablets containing various proportion of guar gum ranging from 40 to 80% of guar gum and immediate release (reference formulation) containing 5% sodium starch glycollate (super disintegrant at 5% level) were prepared and were subjected to thickness test, diameter test, weight variation test, hardness test, friability test and drug content uniformity test, and

tablets were found to be in range of 3.19±0.020 to 3.62±0.049 (mm), 10.04±0.008 to 10.11±0.008 (mm), 346.91±1.218 to 353.00±0.892 (mg), 0.43±0.210 to 5.74±0.309 (kg/cm^2), 0.223 to 2.961% and drug content uniformity 99.22 to 100.34% of the labeled amount respectively. All the tablet formulations passed the above tests except formulation DX- 80, which failed the friability test. Prepared tablets were subjected to measurement of mass degree of swelling and gel strength was found to be in the range of 2.68 to 3.70 and 5.21 to 15.50 (ml) respectively. The swelling of the guar gum-based formulations found linear with increasing percentage of guar gum.

The matrix tables containing 70 and 80% of guar gum (DX-70 and DX-80) showed high friability (0.702% and 2.961% respectively) and low hardness 1.67±0.173 kg/cm^2 and 0.43±0.210kg/cm^2 respectively). This might be due to higher guar gum content in the matrix tablets. Hence, the DX-70 and DX-80 formulations were not subjected to *in-vitro* drug release studies.

Dexamethasone Matrix Tablets containing 40% (DX-40), 50% (DX-50), 60% (DX-60), 70% (DX-70) and 80% (DX-80) of Guar gum and 5% Sodium Starch Glycollate (DX-IR)

S.No	Ingredients	Quantity (mg) per each matrix/ I.R. tablet					
		DX-40	DX-50	DX-60	DX-70	DX-80	DX-IR
1	Dexamethasone	9	9	9	9	9	9
2	Guar gum	140	175	210	245	280	--
3	Sodium starch glycolate (dry)	--	--	--	--	--	17.5
4	Microcrystalline Cellulose (M.C.C.)	190.5	155.5	120.5	85.5	50.5	313
5	Talc	7	7	7	7	7	7
6	Magnesium Stearate	3.5	3.5	3.5	3.5	3.5	3.5
7	Total (mg)	350	350	350	350	350	350

Micrometric evaluation of powder mix

S.No	Formulation Code	Mass of Powder (gms)	Volume of Packing (ml)	Taped Volume of Packing (ml)	LBD (gm/ml)	TBD (gm/ml)	Carrís Index (%)
1	DX-40	5	14.5	9.5	0.3448	0.5263	34.49%
2	DX-50	5	13.0	8.75	0.3846	0.5714	32.7%
3	DX-60	5	13.0	8.0	0.3846	0.6250	38.4%
4	DX-70	5	11.0	7.5	0.4545	0.666	31.8%
5	DX-80	5	10.5	7.25	0.4761	0.6896	30.9%
6	DX-IR	5	16.5	11.0	0.3030	0.4545	33.3%

Swelling Studies

S.No	Matrix Formulation	Mass Degree of Swelling (Q)*	Gel Strength (ml)
1	DX-40	2.68	5.21
2	DX-50	2.94	7.35
3	DX-60	3.15	9.52
4	DX-70	3.48	11.20
5	DX-80	3.70	15.50

Characteristics*of Dexamethasone Matrix and Immediate Release Tablets

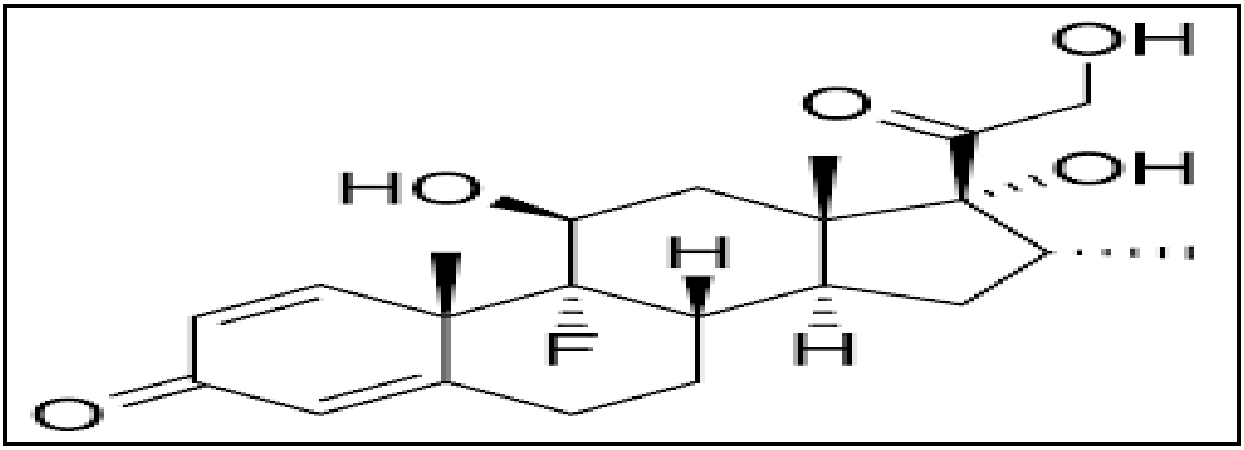
S.No	Matrix Formulation	Hardness (kg/cm^2) Mean ±SD (n=10)	% Drug Content (tab) Mean ±SD (n=10)	% Drug Content (Powder mix) Mean±SD (n=10)	Tablets Thickness (mm) Mean ±SD (n=10)	Tablets Diameter (mm) Mean ±SD (n=10)	Tablets Weight Variation (mg) Mean ±SD (n=10)	Friability (%) (n=10)
1	DX-40	5.74	100.13	99.82	3.196	10.049	350.79	0.282
		±0.309	±1.263	±0.674	±0.020	±0.008	±0.5906	
2	DX-50	3.99	99.94	100.11	3.269	10.05	351.89	0.421
		±0.234	±0.639	±0.700	±0.020	±0.010	±1.302	
3	DX-60	2.56	100.03	100.17	3.28	10.06	350.59	0.503
		±0.297	±0.893	±0.915	±0.024	±0.006	±3.181	
4	DX-70	1.67	100.34	99.93	3.36	10.08	351.97	0.702
		±0.173	±0.583	±0.0647	±0.020	±0.006	±1.658	
5	DX-80	0.43	99.225	98.94	3.40	10.11	346.91	2.961
		±0.210	±1.140	±0.864	±0.016	±0.008	±1.218	
6	DX-IR	4.80	101.04	100.05	3.62	10.06	353.00	0.223
		±0.296	±0.727	±0.569	±0.049	±0.004	±0.892	

*Value shown in the table indicates Mean ±SD

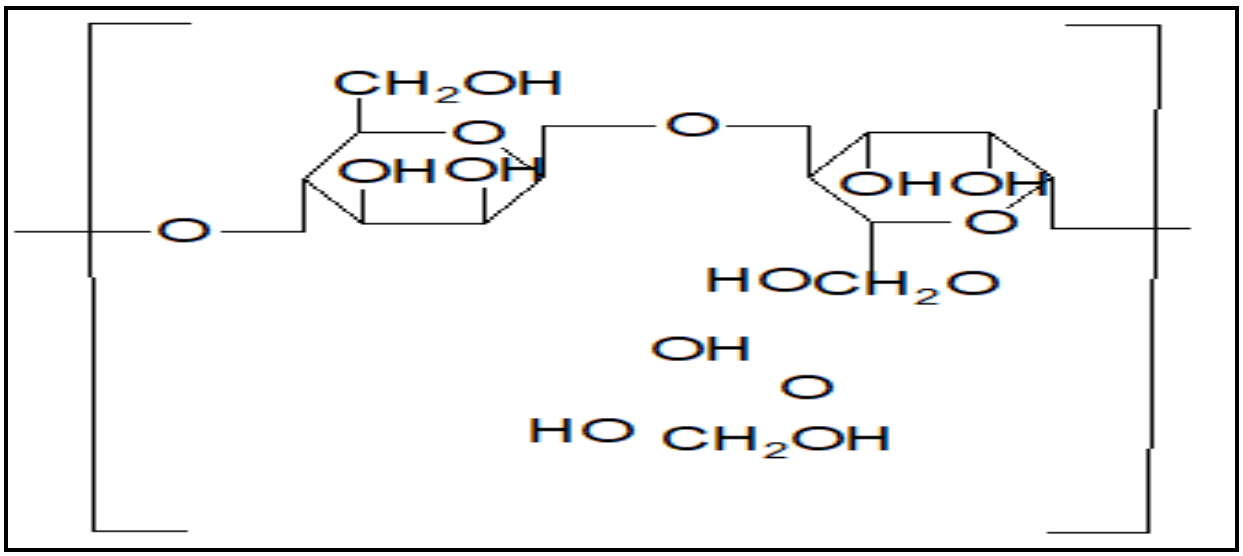
Calibration of the U.V. Spectrophotometric method for estimation of dexamethasone

S.No	Concentration of Dexamethasone g/ml)	Mean of Absorbance (n=5) ±S.D	Percent of Coefficient of Variation (%CV)
1	2	0.106±0.0020	1.88
2	4	0.191±0.0014	0.73
3	8	0.360±0.0027	0.75
4	12	0.514±0.0022	0.42
5	16	0.668±0.0028	0.42
6	20	0.834±0.0026	0.31
7	24	0.999±0.0020	0.20

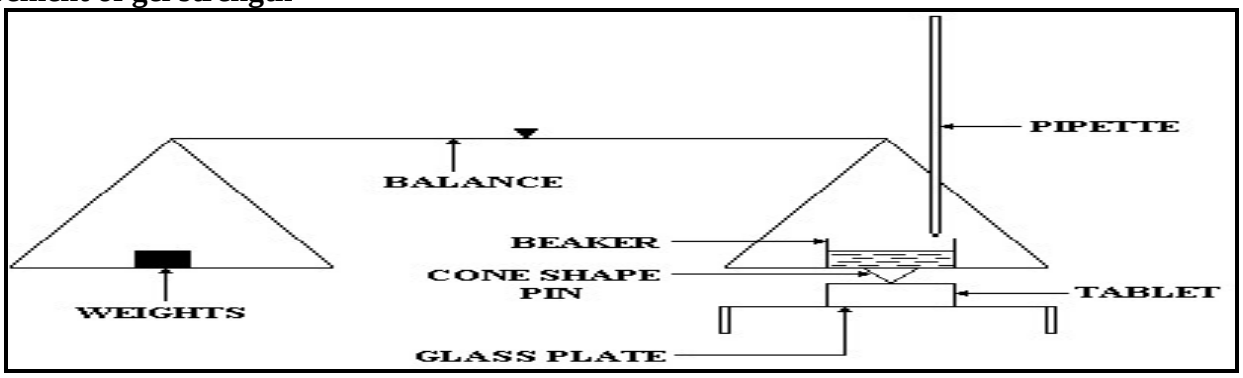
Structural formula of Dexamethasone[51]



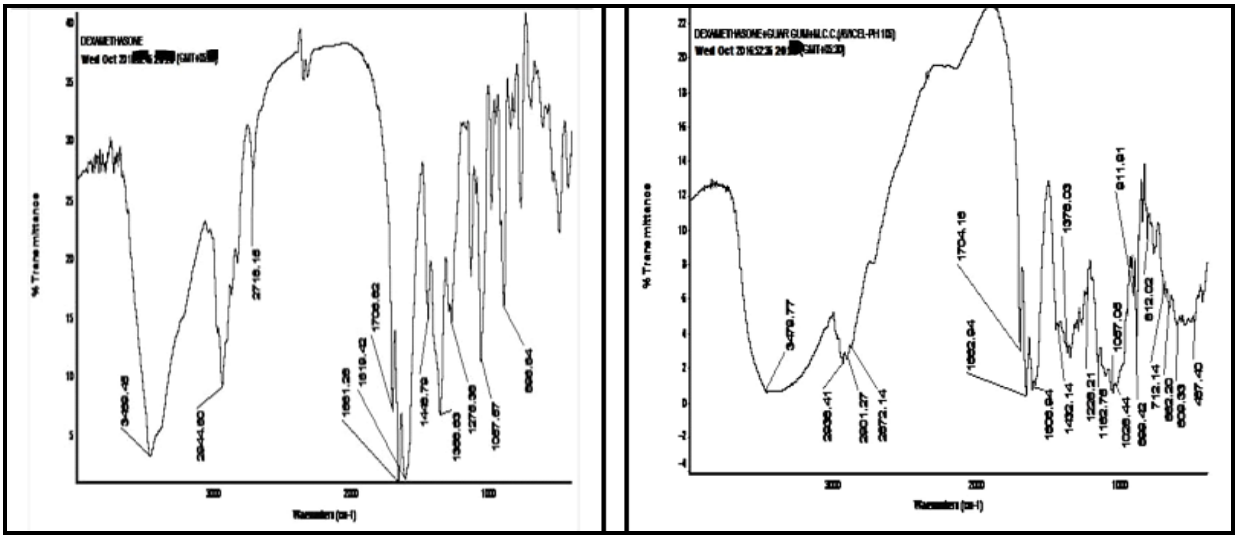
Structural Formula

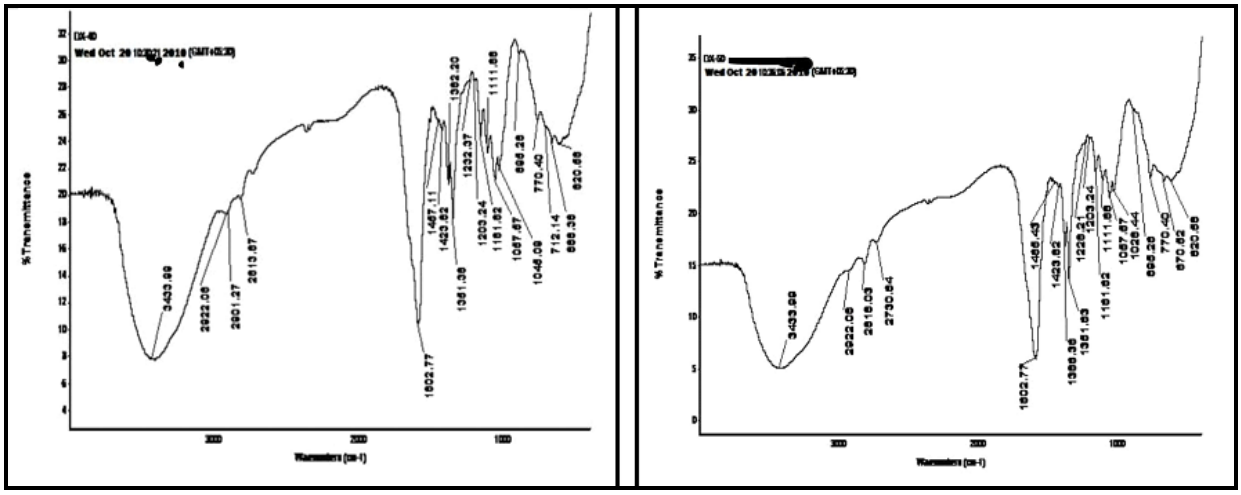


Measurement of gel strength

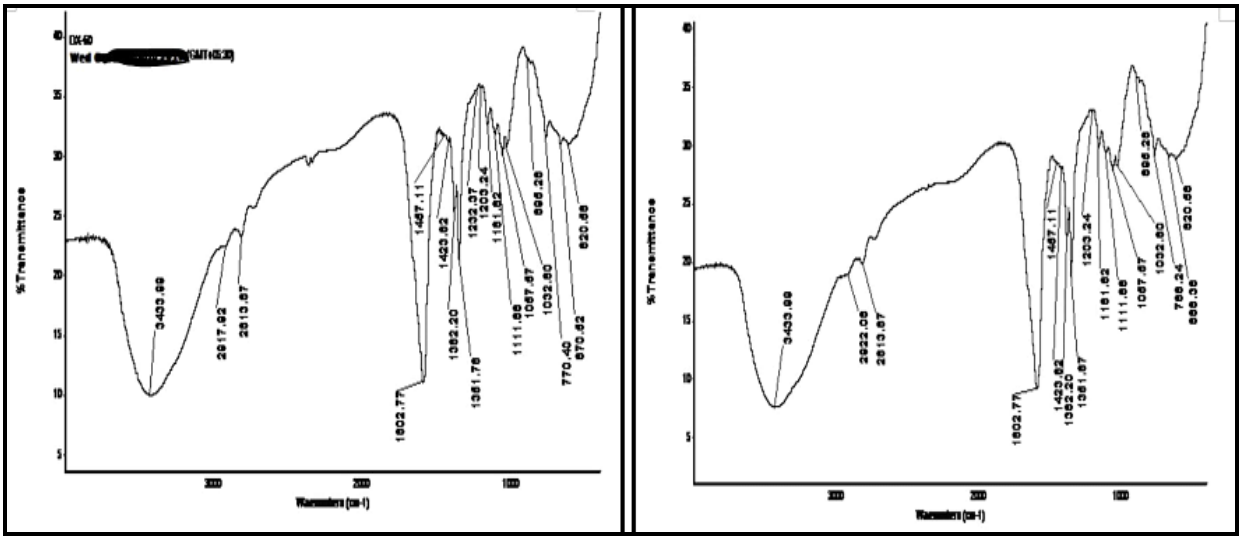


I.R. Spectra of Physical Mixture of Components in Guar gum matrix formulations

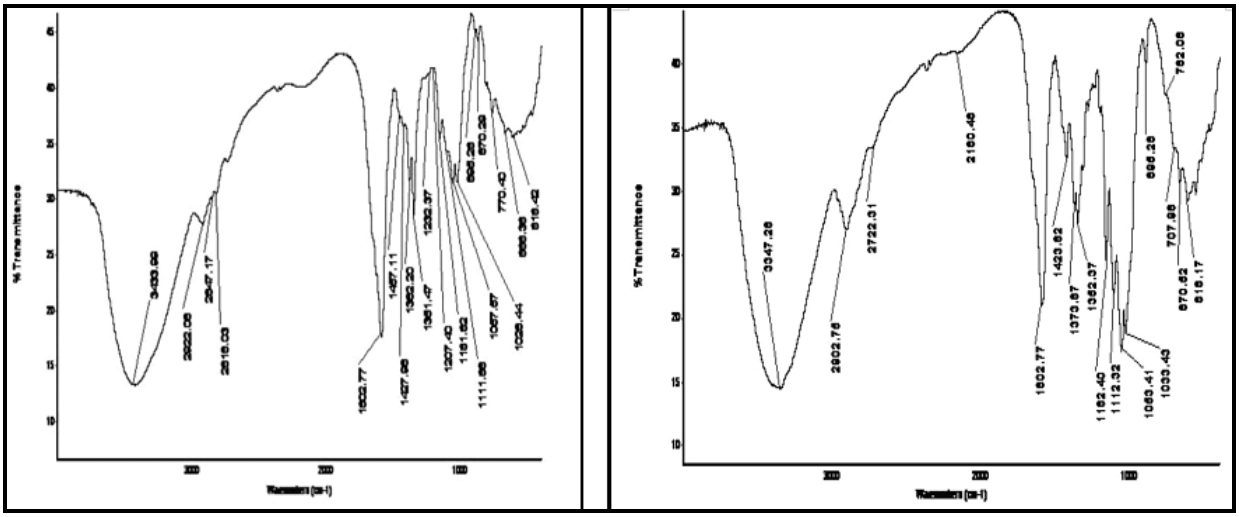




I.R. Spectra of Formulation DX-40 AND DX-50



I.R. Spectra of Formulation DX-60 AND DX-70



SUMMARY AND CONCLUSION

The broad objective of the study was to develop guar gum-based colon targeted tablets of dexamethasone in the prevention of inflammatory bowel disease (IBD).

The compatibility of drug, polymer and excipients were determined by I.R. spectroscopy. Results showed that drug is compatible with polymer and all excipients.

The powder mix was subjected to micrometric evaluation (like bulk density and Carr's index) and drug content uniformity. Powder mix showed high values of Carr's index indicating low compressibility and drug content uniformity test showed uniformity of drug content that proved mixing uniformity.

Matrix tablets containing 40% (DX-40), 50% (DX-50), 60% (DX-60), 70% (DX-70) and 80% (DX-80) of guargum were prepared by direct compression technique.

All the matrix tablets formulations complied with content uniformity.

Dexamethasone matrix tablets containing various proportions of guargum ranging from 40 to 80% of guar gum were subjected to measurement of mass degree of swelling and gel strength. The results indicate that swelling of the guargum-based formulations is increasing as percentage of guargum is increasing.

When subjected to post compression evaluation like hardness and friability formulations DX-70andDX-80 containing 70% and 80% of guar gum respectively showed very low hardness and friability 1.67 and 0.43kg/cm^2 respectively. Hence, further studies like in -vitro release studies, scanning electron microscopy (SEM) and short-term stability study were not conducted on these formulations.

The guar gum-based matrix tablets meant for colon-targeting of drug are expected to release minimal quantity of drug in the physiological environment of stomach and small intestine, but should release majority of their drug content in the physiological environment of colon.

The *in-vitro* drug release study, established in our laboratory for this purpose, was used to optimize the quantity of guar gum in the matrix-tablets of dexamethasone for targeting the drug to the physiological environment of colon was performed on formulations (DX-40, DX-50 and DX-60).

When subjected to *in-vitro* drug release studies, the matrix formulation DX-40 containing 40% of guargum degraded within 10h of the study.

Formulation DX-40 containing 40% of guar gum released about 87% of its drug content within 18 h in the physiological environment of colon. This may result in the release of drug in the last part of the small intestine itself.

The tablet formulation DX-50 containing 50% of guar gum also release about 88% of drug content in the physiological environment of colon at the end of 24 h of the study.

However, at the end of 24h of dissolution study, the matrix tablets of dexamethasone DX-60 containing 60% of guar gum released about 58% of the drug in the physiological environment of colon.

The results indicate that matrix tablets of dexamethasone containing 50 and 60% of guar gum are most likely to target the drug to the physiological environment of colon. The relative usefulness of these formulations in targeting the drug to human colon needs to be assessed in human volunteers by conducting bioavailability studies.

The results of scanning electron microscopy indicate that both formulations (DX-50 and DX-60) showed uniform matrix which proves the uniformity in mixing of all ingredients of formulations with good swelling property of guar gum.

Stability study was performed (for DX-50 and CDX-60) in the present study, found both the formulations stable at 37^{o}C/60% RH and 50^{o}C/75% RH.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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