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Research Article

DESIGN AND OPTIMIZATION OF DEXAMETHASONE MATRIX TABLETS FOR THE TREATMENT OF INFLAMMATION IN COLON CANCER

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ABSTRACT

The purpose of the present study was to prepare & characterize the colon targeted matrix tablet of dexamethasone for treatment and management of inflammation in colon cancer. The matrix tablet was prepared by wet granulation method. The matrix tablet was then coated with different concentration of shellac solution by dip coating method to prevent drug release in stomach. The prepared matrix tablets were evaluated for hardness, weight variation, friability and (in-vitro) dissolution. The in-vitro drug release of different formulation was found to be minimum 84.84±2.16 and maximum 99.41 ±0.96. The formulation F5 shows best result in in-vitro drug release.

Keywords: Wet granulation, Inflammation, Matrix tablet.

INTRODUCTION

Cancer is one of the major public health problems worldwide prevalence of cancer is known to vary from region to region. The idea behind Microspheres forColon specific drug delivery system is intended because it may reduce the Systemic side effect because of low dose of the drug. The absorption of the poorly absorbed drug is increase because of increase retention time in the colon. (Vyas S.P*et al*, 2002,CherukuriSowmya*et al*., 2012).

Dexamethasone is used in reducing the inflammation in colon cancer.The aim of the study was to develop colon targeted Matrix tablets of dexamethsone using Chitosan and xanthan gum as carriers in the treatment of colon cancer.

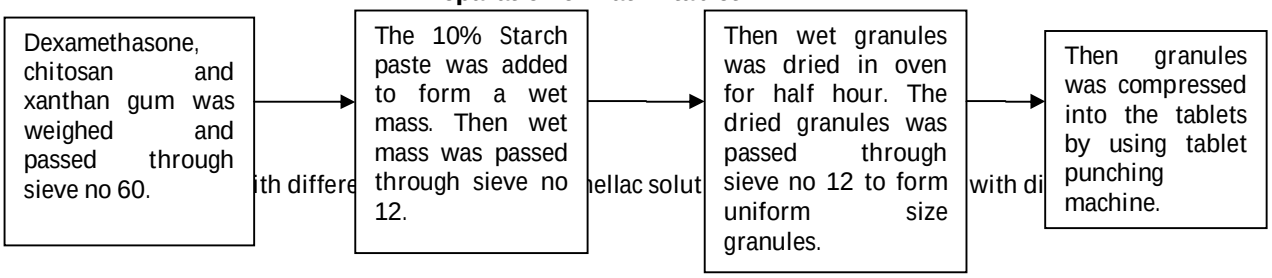
Significance of this Research Investigation

Increase the absorption and bioavailability of the drug via delayed release formulation.Utilize the non-toxic and biodegradable nature of Chitosan and Xanthan gum that makes it safer for patients as compared to other synthetic polymers it is also economical. Reduce the dose and administration frequency.Reduce the incidences of adverse drug reaction.

MATERIALS AND METHODS

Dexamethasone, Chitosan and Xanthan Gum was purchased from the balaji pharmaceutical Pvt.Ltd. The Shellac was obtained from the central drug store.

Preparation of matrix tablet



Evaluation of tablets

Table 2: Methods for evaluation of tablets

S. No	Parameters	
1.	Weight variation	20 individual tablets were selected and average weight was calculated. Not more than two ofthe individual weights deviate from the average weight bymore than the percentage shown in the table and none deviatesby more than twice that percentage. The weight variation tolerances were listed below.

Average weight of tablet (mg)	Maximum percentage deviation allowed
80 mg or less	10
More than 80 mg but less than 250 mg	7.5
250 mg or more	5

2.	Hardness	The hardness of tablets was determined by Monsanto hardness tester. On testing, tablet was placed between two plungers. The lower plunger was placed in contact with the tablet, and a zero reading was taken. Then upper plunger was forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed, The force of fracture was recorded, and the zero force reading was deducted from it
3.	Friability	Friability of tablets was determined by laboratory friability tester, known as Roche friabilator.
4.	*In-vitro* dissolution	*In vitro* dissolutiontest was conducted in USP 2 apparatus at 75 rpm and atemperature of 37±0.5^{0}C. Sampling was done at predetermined time intervals and the same were estimated for drug content after suitable dilution by using double beam UV-VIS spectrophotometer. Initial drug release studies were conducted in 900 ml of 0.1N HCl for 2 hours. Then, 900 ml of 6.8 potassium phosphate buffer solution for next 22 hours

RESULT AND DISCUSSION

PREFORMULATION STUDIES

- **Solubility**

Table 3: Solubility of the drug

S. No	Properties	Observation
1.	Ethanol	Soluble
2.	Acetone	Freely soluble
3.	Chloroform	Slightly soluble
4.	Distilled Water	Insoluble

ACKNOWLEDGEMENT

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CONCLUSION

On the basis of above study it may be concluded that the formulation ensures the major portion of drug (more than 80%) to be released at colon even in absence of colonic microflora. The matrix tablet formulation developed holds tremendous potential to deliver a variety of drugs in colon diseases (viz anticancer drugs) specifically at colon and ensures maximum drug concentration at colon even in case of

disturbed GIT microflora on one hand while reduce the dose and frequency of the drug and consequently lowers drug-associated side effects on other.

Table 1: Formulation Composition of tablet

S. No	Formulation Code	Drug(mg)	Chitosan (mg)	Xanthan gum (mg)
1.	F1	5	100	0
2.	F2	5	80	20
3.	F3	5	60	40
4.	F4	5	50	50
5.	F5	5	40	60
6.	F6	5	20	80
7.	F7	5	0	100

- **FTIR Spectroscopy**

FTIR spectroscopy was performed for Dexamethasone, Chitosan and Xanthan Gum

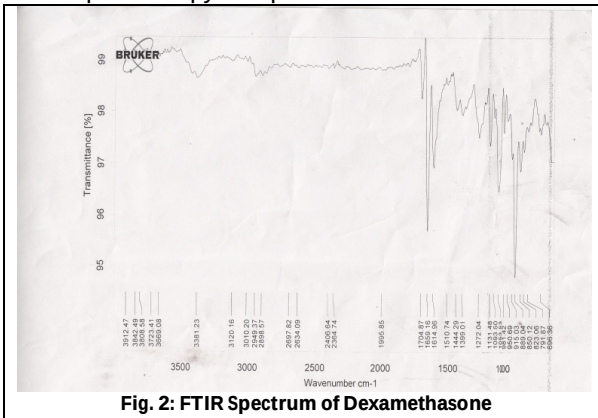


Fig. 2: FTIR Spectrum of Dexamethasone

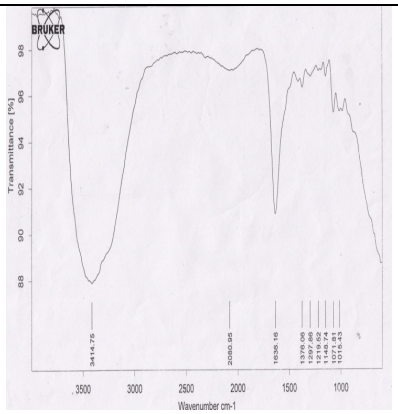


Fig. 3: FTIR Spectrum of Chitosan

S. No	Groups	Wavenumber Observed (cm^{-1})
1.	-C=O	1700.80
2.	C=C	1610.41
3.	C-F	1061.07
4.	CH_3	1446.72

S. No	Groups	Wavenumber Observed (cm^{-1})
1.	-OH Free	3414
2.	CH_2OH	1015
3.	CH-OH	1071
4.	C-O-C	1219

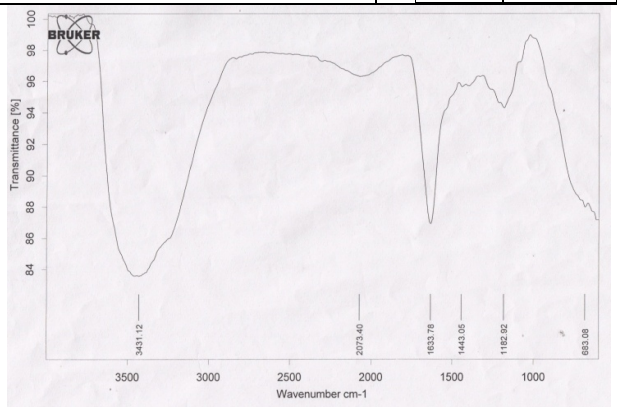
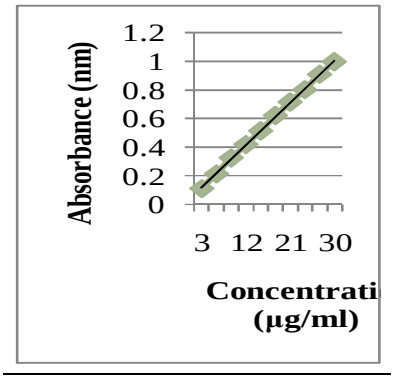


Fig. 4: FTIR Spectrum of Xanthan Gum

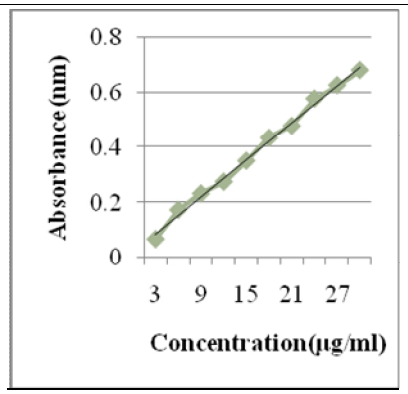
S. No	Groups	Wavenumber Observed (cm^{-1})
1.	CH_2OH	1112
2.	C-O-C	1280
3.	C=O	1632
4.	-OH	3419

➢ **Standard Curve of Dexamethasone**



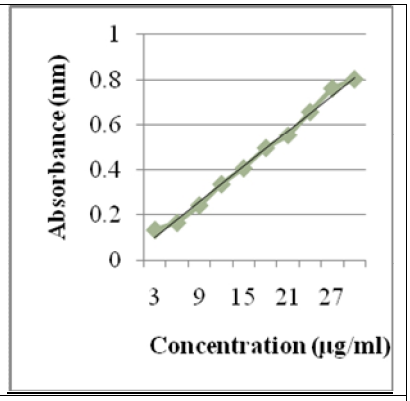
Straight line equation
y = 0.098x + 0.019
R^2 = 0.999

Fig. 6: Calibration Curve of Dexamethasone in 0.1N HCl pH



Straight line equation
y = 0.067x + 0.018
R^2 = 0.995

Fig. 7: Calibration Curve of Dexamethasone in Phosphate buffer pH 7.4



Straight line equation
y = 0.078x + 0.023
R^2 = 0.993

Fig. 8:Calibration Curve of Dexamethasone in Phosphate buffer pH 6.8

Evaluation of Tablets

Table 2: Evaluation of tablets

S. No	PROPERTY	F1	F2	F3	F4	F5	F6	F7
1.	Weight variation	250.15	250.60	251.20	250.10	250.50	250.85	251.35
2.	Friability	0.82	0.89	0.57	0.70	0.75	0.93	0.71
3.	Hardness	3.15	3.20	3.25	3.30	3.40	3.15	3.20

***In-vitro* dissolution studies of uncoated tablets**

S. No	Time (hours)	F1	F2	F3	F4	F5	F6	F7
1.	2	10.14	10.24	10.28	10.31	10.33	10.14	10.04
2.	5	32.11	32.31	38.24	35.21	98.10	36.17	35.20
3.	7	59.47	61.40	64.31	66.24	71.09	68.18	65.28
4.	9	77.99	80.87	82.82	84.76	92.51	85.14	82.83
5.	12	84.83	86.77	87.72	90.66	97.4	90.66	87.75
6.	15	86.80	87.77	89.71	91.66	99.42	91.66	90.67
7.	18	86.81	87.87	90.30	92.63	99.53	91.76	90.79
8.	21	86.90	87.97	90.69	93.11	99.62	91.86	90.88
9.	24	86.90	87.97	90.69	93.12	99.62	91.86	90.88

***In-vitro* dissolution of 2% Shellac coated tablets**

S. No	Time (hours)	F1	F2	F3	F4	F5	F6	F7
1.	2	7.15	7.34	7.63	7.72	7.82	7.80	7.74
2.	5	11.05	11.15	11.79	12.02	12.2	12.15	12.11
3.	7	24.59	25.55	30.39	33.28	41.9	38.11	35.22
4.	9	33.35	34.32	38.21	42.09	53.70	49.84	45.97
5.	12	50.78	52.72	57.57	62.42	69.23	64.39	60.61
6.	15	65.36	68.27	73.13	77.02	84.70	76.06	71.21
7.	18	73.17	76.08	79.01	82.89	92.59	82.88	76.10
8.	21	79.97	82.88	85.80	88.72	96.49	87.75	82.88
9.	24	84.84	86.78	90.66	92.61	99.41	91.64	89.68

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