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Research Article

DEVELOPMENT AND CHARACTERIZATION OF ACECLOFENAC ENTERIC COATED TABLETS

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ABSTRACT

Aceclofenac is an antipyretic and antiinflammatory drug. On regular intake of Aceclofenac it may cause Ulcer and that is the major side effect of the NSAID. To protect the Ulceration the enteric coated tablets are designed. The Enteric coated tablets of Aceclofenac are designed with the Aim to provide sustained Action and prevents the drug release into stomach. The Enteric coated tablets of Aceclofenac was designed by using carriers like Xanthan gum, Carbopol, HPMC K4M. All the carrier affects the release profile of the Drug. The Enteric coating of the Formulation was carried out by using Colorcoat and Acetone. In the following research the tablet SECT2 is found as Best with the better release (99.78) than remaining all.

Keywords: HPMC K4M, Carbopol, Colorcoat, Peptic Ulcer.

INTRODUCTION

In the present investigation the gastric ulcer can be avoided by using enteric coating tablet of aceclofenac appropriate quantity of suitable polymer was blended with diluents after adding glidant and lubricant agent enteric coated tablet was prepared by wet granulation method.Aceclofenac enteric coating tablets provides protection of active pharmaceutical ingredients, from the acidic environment of the stomach. Aceclofenac enteric coating tablets minimizing first pass metabolism of drugs[1,2,3].

ANALYSIS OF ACECLOFENAC

Determination of Absorption maxima

A UV absorption maxima was determined by scanning a 10ug/ml solution of Aceclofenac in 5% (v/v) methanolic Sorenson buffer pH 6.8 between 200- 400nm.

Calibration Curve Data of Aceclofenac

The calibration curve of Aceclofenac was prepared in Sorenson's Buffer pH 6.8 at 256 nm and the absorbance values of different concentrations of Aceclofenac solutions in

Table No. 1 Calibration Curve Data of Aceclofenac

Concentration	Absorbance (nm)
0.0	0.000
2.0	0.122
4.0	0.243
6.0	0.356
8.0	0.469
10.0	0.586
12.0	0.700
14.0	0.816
16.0	0.931
18.0	1.058

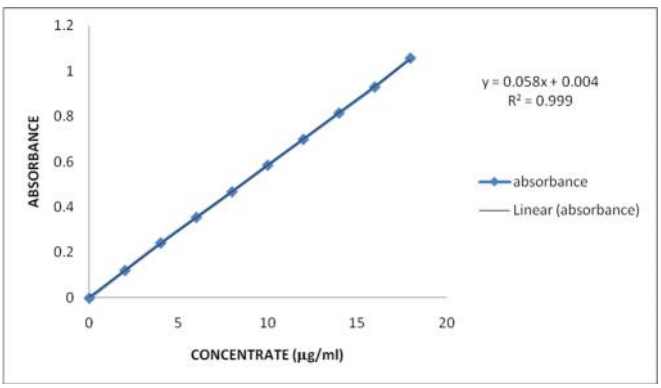

Figure 1 Standard Curve of Aceclofenac

Sorenson's Buffer pH 6.8 are shown above.

FTIR: The identity of a compound was confirmed by comparison with that of an authentic sample and verification of the presence of functional groups in an unknown molecule was done by IR spectra. The IR spectra obtained was elucidated for important chromophore groups. The IR spectra showed peaks at1715.88cm-1, 1619.84cm-1 ,1456.27cm-1 and 1241.26cm-1 corresponding to the functional groups C=O, COOH, NH and OH bending. The various peaks are depicted in below Figure:

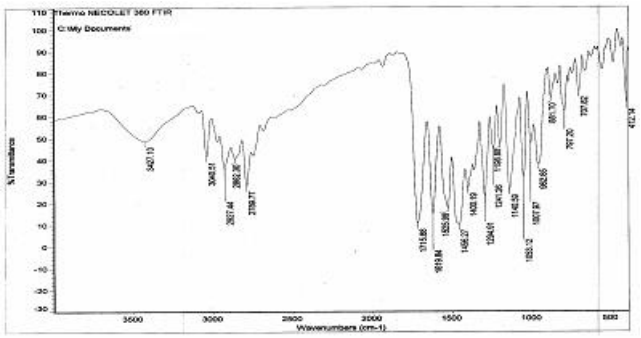

Figure 2 IR Spectra of Aceclofenac

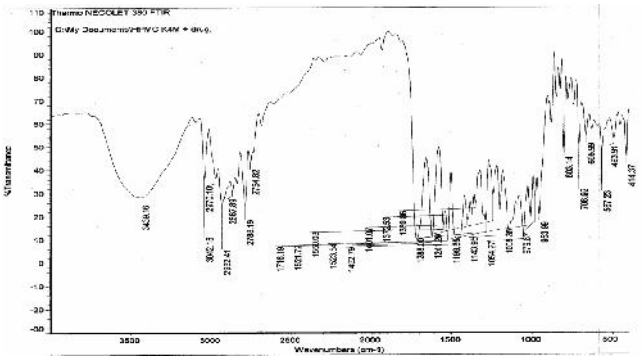

Figure 3 IR Spectra of mixture of Drug and HPMC K4M

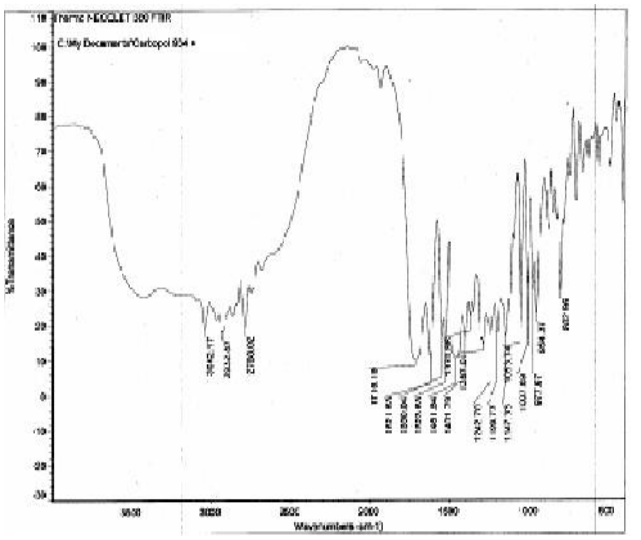

Figure 4 IR Spectra of mixture of Drug and Carbopol 934P

Table No. 2 Principles peaks at Wave number

Mixture	Principles peaks at Wave number (cm^{-1})
Drug	1715.88, 1619.84,1456.27, 1241.26
Drug+ HPMC K4M	1716.19,1621.72, 1462.79, 1241.29
Drug+Carbopol 934	1716.19, 1621.63, 1461.54,1242.70

Materials and method

Aceclofenac was procured as a gift sample from Torrent Pharmaceuticals, Gujarat and coating polymer colorcoat was obtained from Corel Pharma Chem., Gujarat and remaining all the ingredients were provided from the institution.

Preparation of Aceclofenac Tablet

Aceclofenac granules for tableting were prepared by wet granulation method. Specified quantity of Aceclofenac, Polymer (Hydroxypropyl methylcellulose (HPMC) or Carbapol or Xanthan gum) and Avicel pH 102 were weighed according to the formula (Table) and transferred in a mortar and pestle and mixed thoroughly. The powder mass was mixed with 5% starch paste to obtain a sluggy mass and this was passed through sieve no. 12 to obtain the granules. The granules prepared were dried at 50◦C for 4 h. The dried granules were screened through sieve no. 22 & 44 and stored for further studies. The specified quantity of magnesium stearate and talc were finally added and mixed for the compression of tablets. Ideal mixtures of granules were directly punched into tablets weighing about 250 mg containing 100 mg of Aceclofenac , using rotary tablet compression machine. The different batches of Aceclofenac tablets were collected and stored in air tight containers.

Composition of coating solution

Colorcoat EC4S

Acetone.

Preparation of spraying dispersion for coating

The enteric coating solution was prepared by using Colorcoat EC4S and acetone. The solvent was prepared by simple dispersing Colorcoat EC4S in acetone.

Table No. 3 Formulation of tablet

INGREDIENT	SECT1	SECT2	SECT3	SECT4	SECT5	SECT6
Aceclofenac	100	100	100	100	100	100
HPMC K4M	30	60	-	-	-	-
Xanthan Gum	-	-	30	60	-	-
Carbopol934	-	-	-	-	30	60
Avicel PH102	30	40	30	40	30	40
Talc	2	2	2	2	2	2
Mg.Stearte	4	4	4	4	4	4
Lactose	84	44	84	44	84	44
Total weight	250	250	250	250	250	250

Table No. 4 Characterization of blend of Aceclofenac tablet

Parameters / Formulation	Bulk Density (mg/ml)	Tapped Density (mg/ml)	Hausners Ratio	Carr's Index (%)	Angle of Repose (º)
$SECT_1$	0.473	0.520	1.09	9.03	25.28
$SECT_2$	0.485	0.554	1.14	12.45	27.29
$SECT_3$	0.462	0.558	1.20	17.20	28.54
$SECT_4$	0.475	0.540	1.13	12.03	27.67
$SECT_5$	0.454	0.550	1.21	17.45	29.37
$SECTT_6$	0.482	0.558	1.15	13.62	28.48

Table No.5 Characterization of Enteric coated tablets of Aceclofenac

Parameters / Formulation	Diameter (mm)	Thickness (mm)	Weight (mg)	Hardness (Kg/cm^2)	Friability (%)	Disintegration Time (Min)
$SECT_1$	*7*	*5*	249.61±0.39	5.0±0.1	0.48±0.12	147±18
$SECT_2$	*7*	*5*	251.14±0.12	5.2±0.3	0.52±0.07	132±28
$SECT_3$	*7*	*5*	250.48±0.19	5.1±0.1	0.47±0.09	128±32
$SECT_4$	*7*	*5*	248.89±0.41	5.2±0.4	0.48±0.13	158±15
$SECT_5$	*7*	*5*	249.38±0.87	5.1±0.1	0.51±0.08	154±14
$SECT_6$	*7*	*5*	251.54±0.28	5.0±0.2	0.50±0.09	162±16

Table No. 6 In vitro release data of Aceclofenac enteric coated tablet -Zero Order Release

Time hr	SECT1	SECT2	SECT3	SECT4	SECT5	SECT6
1	0	0	0	0	0	0
2	2.59	3.125	1.45	2.1	1.99	2.996
4	16.489	17.26	14.78	15.98	15.1	16.986
6	41.10	42.496	29.88	40.5	40.06	41.907
8	60.09	72.694	68.68	69.45	59.0	70.66
10	87.99	89.67	85.06	86.10	85.65	88.69
12	98.10	99.78	96.65	97.69	97.0	98.67

Table No. 7 Fit of Various Kinetic Models for Enteric coated Tablet of Aceclofenac

FORMULATION CODE	ZERO ORDER R^2	FIRST ORDER R^2	HIGUCHI MODEL R^2	KORSEMEYER MODEL R^2
SECT1	0.985	0.818	0.964	0.943
SECT2	0.986	0.839	0.989	0.949
SECT3	0.966	0.859	0.965	0.918
SECT4	0.981	0.852	0.978	0.946
SECT5	0.985	0.836	0.978	0.940
SECT6	0.981	0.832	0.988	0.949

Pre compressive parameters

Parameter	Result observed
Bulk density	0.454 to 0.485 gm/cm^3
tapped density	0.520 to 0.558 gm/cm^3
Carr's index	9.03 to 17.45
hausner's ratio	1.09 to 1.21
angle of repose	25.28 to 29.35^0

Post compressive parameter

Parameter	Result observed
average weight	248.89 to 251.61 mg
Hardness	5.0 to 5.2 Kg/cm^2
content uniformity	97.28 to 101.99%
percent friability	0.47-0.52%
Disintegration time(Minutes)	128-162

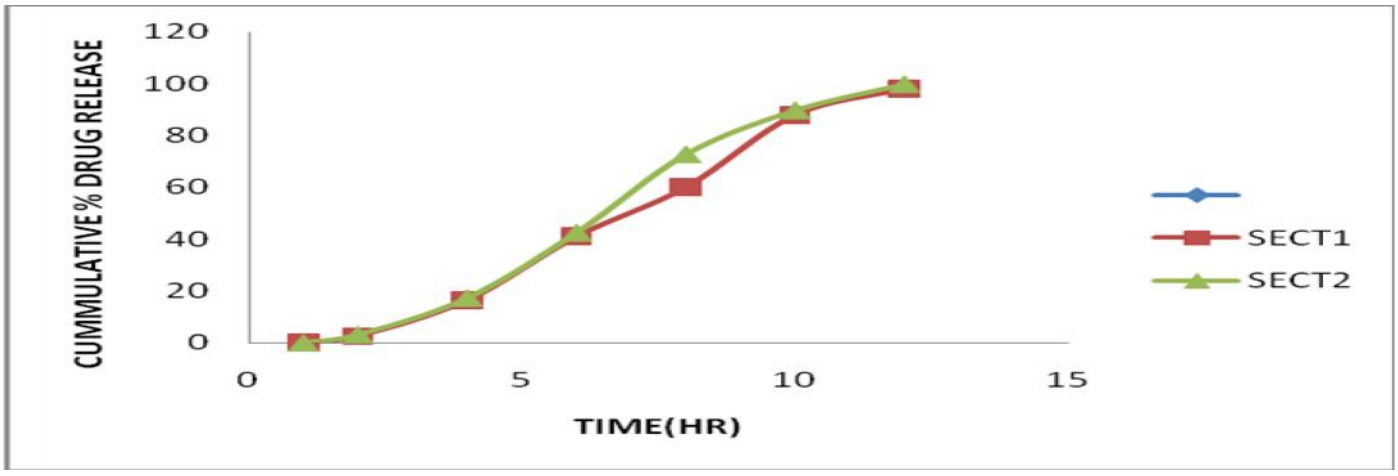

Figure 5 In vitro release curve of Aceclofenac enteric coated tablet -Zero Order Release (SECT1-SECT2)

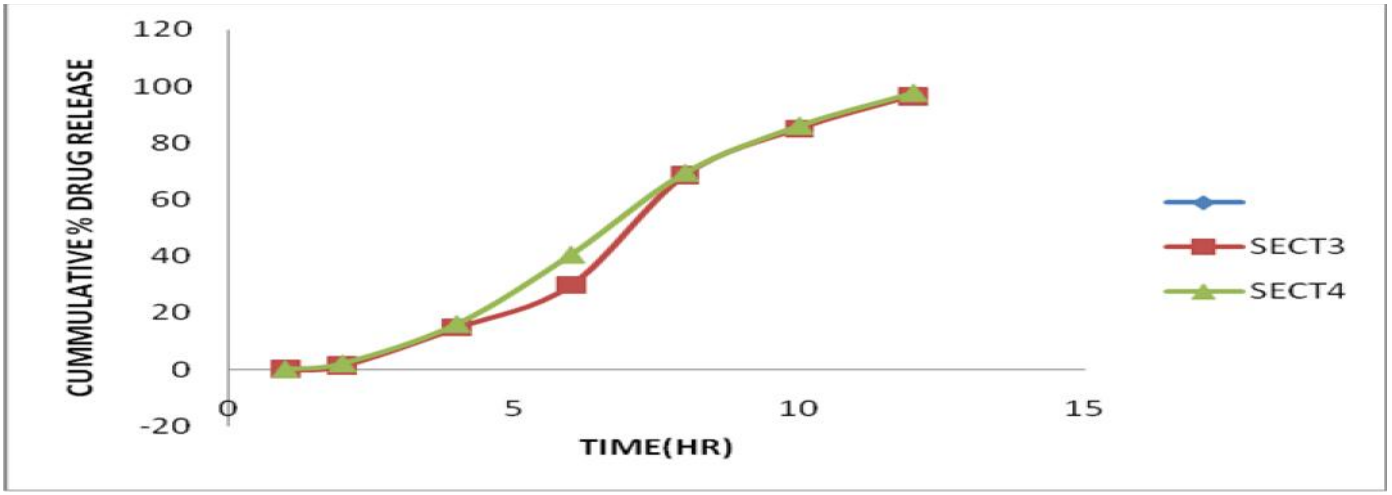

Figure 6 In vitro release curve of Aceclofenac enteric coated tablet -Zero Order Release (SECT3-SECT4)

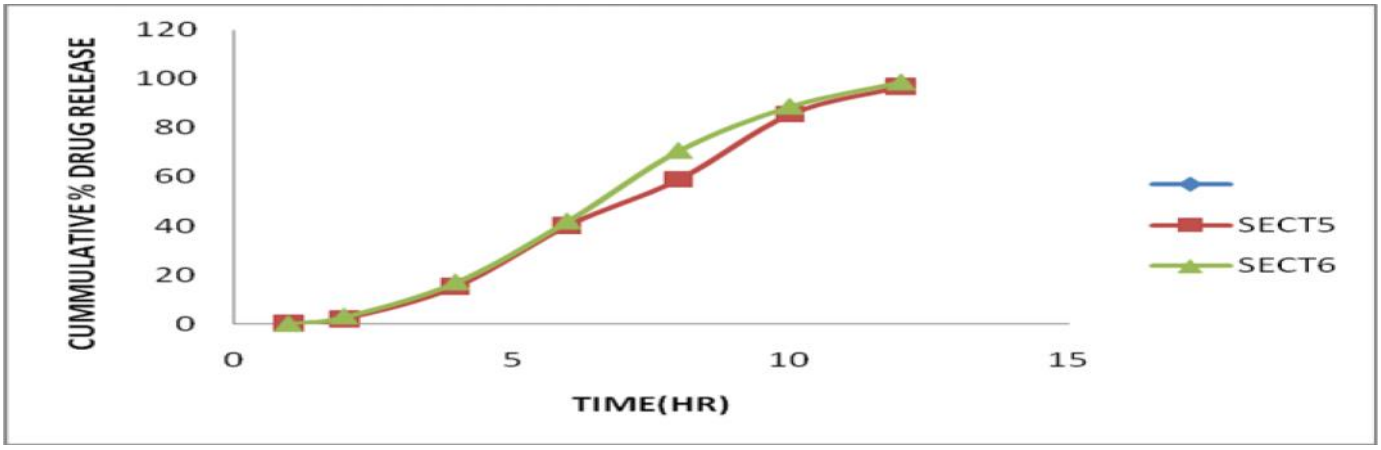

Figure 7 In vitro release curve of Aceclofenac enteric coated tablet -Zero Order Release (SECT5-SECT6)

Enteric coating of Aceclofenac compressed tablets by Spray dried method

For the coat, the tablets were coated by Pan coating apparatus, and in-process samples were taken to check if the target polymer weight gain was achieved. Coating was continued until complete polymer weight gain was achieved. After the coating, the tablets kept a side for 10 min after which they were cured at 40 ◦C

PREFORMULATION STUDIES

Bulk density

Bulk density is given by the mass "M" of the powder occupying a known volume 'V' according to the relationship.

Pb =(M/V)g/cc

It depends on particle size, shape, tendency of particle to adhere.

Tapped density

Weighed powder sample was transferred to a graduated cylinder and was placed on tapped density apparatus, was operated for a fixed number of taps (100).It is the ratio of weight of sample to tapped volume.

Tapped density=mass/tapped volume

Angle of repose

Angle of repose has been used as indirect methods of quantifying powder flow ability, because of their relationship with inter particle cohesion. A static heap will slide when the angle of inclination is large enough to overcome frictional forces and stop when gravitational forces balance the forces. The sides of heap will make an angle with horizontal which is called angle of repose.

Angle of repose=tan-1h/r

Where h is height of pile and r is radius of pile.

Carr's Index

Based on the apparent bulk density and the tapped density , the percentage compressibility of the bulk drug was determined by using the following formula.

%Compressibility= tapped density-bulk density/tapped density X100

Hausner's Ratio

The ratio of tapped density to bulk density of the powders is called the Hausner's ratio.

EVALUATIONS OF ENTERIC COATED TABLETS

Appearance: The general appearance and elegance of tablet was identified visually, which include tablet size, shape, color, presence or absence of an odor, surface texture etc[4].

Hardness: The tablet crushing strength was tested by commonly used Pfizer tablet hardness tester. A tablet is placed between the anvils and the crushing strength, which causes the tablet to break, was recorded[5].

Thickness: Tablet was selected at random from individual formulations and thickness was measured by using venire caliper scale, which permits accurate measurement. tablet thickness should be controlled within a ± 0.2% variation of standard value[6].

Friability: Tablet strength was tested by Roche friabilator. Preweighed (Model: ED-2, Electrolab) tablets were given 100 revolutions in 4 min and were dedusted. The percentage weight loss was calculated by reweighing the tablets[7].

% Loss =Initial wt.of tablet−Final wt.of tablet/Initial wt.of tablet

Uniformity of weight: Randomly selected twenty tablets from all the three formulations were weighed individually and together on electronic balance (Metteler Toledo electronic balance: Model P G 03-S) .The average weight was noted[8].

Disintegration time: Disintegration time was determined using the disintegration apparatus USP (Electrolab, Bangalore, India) in 0 .1 N HCl for 2 h and then in phosphate buffer pH 6.8 for 1 hour maintaining the temperature at 37±2°C[9] .

Dissolution test: The tablets were evaluated for in vitro drug release was carried out using USP dissolution apparatus. the following conditions were applied. USP Dissolution apparatus: Type II (Paddle) Media : 0.1N HCl for two hours followed by 6.8 pH phosphate Buffer Volume of dissolution media : 1000 mL Speed of paddle rotation : 100/50 RPM Temperature : 370 ± 0.50C Six tablets were subjected to two hours exposure in 0.1N HCL buffer followed by immediate transfer to a dissolution bath containing 6.8 pH phosphate buffer and % drug released was measured. Buffer phase: - Samples were withdrawn from the dissolution vessels at 1, 2, 4, 6, 8, 10, 12 hours interval. The % drug release was measured U.V method[10].

CONCLUSION

The Enteric coated Tablet of Aceclofenac were preapared and evaluated successfully, and It was concluded that the tablet Prepared with HPMC K4M provide better release in the intestine and also found a best tablet. The Enteric coated tablets that were prepared passes all the parameters and the Results are satisfactory.

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