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DESIGN AND EVALUATION OF DRUG IN NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

Matrix tablet is one of the least complicated approaches to the manufacture of sustained release dosage forms involves the direct compression or granulation of blends of drug, retardant material, and additives to form a tablet in which drug is embedded in a matrix core of retardant. The physical compatibility evaluation was performed in visual basis. The study implies that the drug, polymer and other excipients were physically compatible with each other as there was no change of physical description. The result of showed that the formulation F10 follow zero order and release mechanism of drug through polymeric membrane was observed anomalous transport (Non-fickian) diffusion, which is also confirmed by Higuchi plot.

Keywords: Higuchi Model, Biodegradation

Introduction

Oral drug delivery is the most wide utilized route of administration among all the routes that have been explored for general delivery of medication via pharmaceutical product of various dose kind. Oral route is taken into consideration most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance, and efficient manufacturing methodology.[1] Pharmaceutical product designed for oral delivery ar principally immediate release kind or typical drug delivery systems, that are designed for immediate release of drug for fast absorption.

Controlled Drug Delivery Systems:

Controlled drug delivery systems have been developed that are capable of dominant the rate of drug delivery, sustaining the amount of therapeutic activity and/or targeting the delivery of drug to a tissue.[5]

Controlled drug delivery or changed drug delivery systems are handily divided into four classes.

1) Delayed release
2) Sustained release
3) Site-specific targeting
4) Receptor targeting

Oral Controlled Drug Delivery Systems[8]:

Oral controlled release drug delivery can be a drug delivery system that has the continual oral delivery of medication at predictable and duplicable kinetics for a planned quantity throughout the course of GI transit and collectively the system that focus on the delivery of a drug to a specific region at intervals the GI tract for either a local or general action. All the pharmaceutical product developed for general delivery via the oral route of administration, disregardless of the mode of delivery (immediate, sustained or controlled release) and the look of dose kind (either solid, dispersion or liquid), ought to be developed at intervals the intrinsic characteristics of GI physiology. thus the scientific framework required for the roaring development of AN oral drug delivery systems consists of basic understanding of (i) chemical science, pharmacokinetic and pharmacodynamic characteristics of the drug; (ii) the anatomic and physical characteristics of the gi tract and (iii) chemistry characteristics and additionally the drug delivery mode of the dose kind to be designed.

Osmotic Regulated Systems: [10]

It is comprised of an diffusion pressure controlled drug delivery device and an expansive floating support throughout a bioerodible capsule. inside the abdomen the capsule quickly disintegrates to unleash the intragastric osmotically controlled drug delivery device. The expansive support inside forms a deformable hollow compound bag that contains a liquid that gasifies at vital sign to inflate the bag. The diffusion controlled drug delivery device consists of two components–drug reservoir compartment and osmotically active compartment.

Objectives:

This goal can be achieved by the development of hydrodynamically balanced system or floating drug delivery system which will increase the stomachic length, decreases the diffusional distance and allow lots of of the antibiotic to penetrate through the stomachic secretion layer and act domestically at the infectious site Cefadrin, an antibiotic, can be a third-generation antibiotic like Rocephin and Mefoxin. Cefadrin is incredibly stable inside the presence of enzyme enzymes.

The present study outlines a general approach for style and development of hydro dynamically balanced tablets of cefadrin to enhance the bioavailability and therapeutic effectiveness of the drug.

- style and development of the Hydrodynamically balanced tablets of CEFADRIN.
- Study the result of various polymers on the drug unharness.
- analysis of the prepared formulation for chemistry properties and drug unharness profile.
- Analyse the drug unharness data for kinetic equations.

Methodology

The following materials that were either AR/LR grade or the best possible pharma grade available were used as supplied by the manufacturer.

Table No. 1: MATERIALS USED

S.N	MATERIALS	GRADE	
1	CEFADRIN	Pharma	S.D. Fine Chem. Ltd
2	HPMC K4M	Pharma	S.D. Fine Chem. Ltd
3	HPMC K15M	Pharma	S.D. Fine Chem. Ltd
4	Chitosan	A.R.	S.D. Fine Chem. Ltd
5	Sodium bicarbonate	L.R.	S.D. Fine Chem. Ltd
6	Lactose (Monohydrate)	A.R.	S.D. Fine Chem. Ltd
7	Magnesium Stearate	A.R.	S.D. Fine Chem. Ltd
8	Hydrochloric Acid	L.R.	S.D. Fine Chem. Ltd

Table 2: Details of Instruments Used:

1	ELECTRONIC BALANCE	Afcoset ER120A
2	HARDNESS TESTER	Monsanto
3	FRIABILITY TEST APPRATURES	Roche friabilator
4	Hydraulic Press	Kimaya engineers
5	Dial Caliper	Mitetoyo, japan
6	Dissolution Tester	Electro lab
7	Tap Density Tester	Electro lab
8	UV Spectrophotometer	Shimadzu,UVpc2401
9	FTIR Spectrophotometer	Thermoni colete

Preparation of standard calibration Curve

Method

The standardization curve is obtained by dissolving cefadrin in 0.1N Hydrochloric acid and more dilutions were created victimisation zero.1N Hydrochloric acid and absorbance measured spectrometrically at 203nm. Beer's Law was obeyed in the concentration vary of 20-120\g/ml.

Standard stock solution:-

Method:

The stock resolution was freshly ready by consideration fixed quantity of cefadrin in 100ml meter flask. The drug was dissolved in and diluted to volume with zero.1N acid.

Preparation of standardization Curve:-

The aliquots of normal resolution were taken in a series of 50ml of volumetric flasks. The mixtures were properly agitated. The ensuing samples were able to type the standardization curve. The absorbance values were measured at 203nm against reference blank, plotted against concentration to get the quality standardization curve.

II) Compatibility Studies:

They provide framework for the drug together with the excipients in the fabrication of the dosage type and establish that active drug has not undergone degradation. This will be confirmed by carrying out infrared lightweight absorption scanning spectrometry.

I.R. Studies:

It is the one of the foremost powerful analytical technique for chemical identification of drug

Method:- The pure drug and its formulation were subjected to IR studies. In the current study, the salt disc (pellet) technique was used.

III) Formulation of Hydrodyamically Balanced Tablets:

Floating matrix tablets containing cefadrin were ready by direct compression technique victimisation variable concentrations of various grades of polymers with baking soda. All the ingredients except metal stearate were blending in glass mortar uniformly. when enough intermixture of drug as well as different components, magnesium stearate was added and additionaly mixed for further 2-3minutes. The tablets were compressed with 13mm punch by use of hydraulic press as shown in Fig.12. The weight of the tablets was kept constant for formulations F1 to F5. The composition of all formulations was mentioned in

Table No.3 Composition of all formulations

Ingredients	F1	F2	F3	F4	F5
CEFADRIN	500	500	500	500	500
HPMC K4M	200	_	100	_	_
HPMC K15M	_	200	100	_	_
Chitosan	_	_	_	200	100
Sodium Bicarbonate	80	80	80	80	80
Lactose	10	10	10	10	10
Magnesium Stearate	10	10	10	10	10

IV) Evaluation of Hydrodynamically Balanced Tablets:

Evaluation was performed to assess the physicochemical properties and release characteristics of the developed formulations.

i) Pre-compression parameters:

a) Angle of Repose (θ): The resistance forces in a loose powder or granules will be measured by angle of repose. This is the most angle attainable between the surface of a pile of powder or The granules were allowed to flow through the funnel fixed to a stand at definite height (H). The angle of repose was then calculated by measure the height and radius of the heap of granules shaped.

$\tan \theta = h/r$

$\theta = \tan (h/r)$ wherever, θ = angle of repose, h = height, r = radius

b) **c**ompressibility Index:

The flowability of powder will be evaluated by examination the bulk density (Do) and taped density (Df) of powder and the rate at that it packed down.

Compressibility index is calculated by –

$$\text{Compressibility index (\%)} = \frac{Df - Do}{Df} \times 100$$

Where, Do = Bulk density

Df = tapped density

ii) Post-compression parameters:

a) Shape of Tablets:

Directly compressed tablets were examined beneath the magnifying lens for the form of the tablet.

b) Tablet Dimensions:[22]

Thickness and diameter were measured using a graduated dial caliper. 3 tablets of every formulations were picked every which way and thickness was measured singly.

c) Hardness:[21]

Hardness indicates the ability of a tablet to stand up to mechanical shocks whereas handling. The hardness of the tablets were determined victimization Monsanto hardness tester. It is then expressed in kg/cm2. 3 tablets were every which way picked and hardness of identical tablets from every tablet determined.

d) Breakableness test:[25]

The breakableness of tablets were determined victimization Roche Friabilator. it's expressed in share (%). 10tablets were at first weight (W initial) transferd in to Friabilator.The Friabilator was

rotated at twenty five revolutions per minute for four min or run up to 100 revolutions. The tablets were weight once more (W final).

The concerns friabilaty was than calculated by

F= w - W decoration X one hundred

w final weight

W initial weight

e) Tablet Density:[13]

Tablet density is a vital parameter for floating tablets. The tablet can only float once its density is less than that of stomachal fluid (1.004). The density determined using following relationship.

v = volume of tablet (cc)

r = radius of tablet (cm)

V = πr 2h d = m/v

h = crown thickness of tablet (g/cc)

m = mass of tablet

f) Weight Variation Test:[18]

Ten tablets were chosen every which way from every batch and weighed singly to check for weight variation. A very little variation is allowed in the burden of a tablet by U.S. pharmacopoeia. The following share deviation in weight variation is allowed.

Table 4 :Weight Variation Test

Average weight of a tablet	Percentage deviation
130mg or less	10
>130mg and <324mg	7.5
324mg or more	5

In all formulations, the tablet weight is a lot of than 324mg, hence 5% maximum distinction allowed.

g) Buoyancy / Floating Test:[14]

The time between introduction of dosage type and its buoyancy on the simulated stomachal fluid and the time throughout that the dosage type remain buoyant were measured. The time taken for dosage type to emerge on surface of medium referred to as Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) and total period of time by that indefinite quantity type stay buoyant is referred to as Total Floating Time (TFT).

h) Swelling Study:[19]

The swelling behaviour of a indefinite quantity type is measured by learning its weight gain or water uptake. The dimensional changes will be measured in terms of the increase in tablet diameter and/or thickness over time. Water uptake is measured in terms of p.c weight gain, as given by the equation.

$W_t = (W – W_0)x100$

Wt = Weight of indefinite quantity type at time t. W_0 = Initial weight of indefinite quantity type

i) Test for Content Uniformity:[11]

Tablet containing 500mg of drug is dissolved in 100ml of zero.1N HCL taken in volumetrical flask. The drug is allowed to dissolve in the solvent. The solution was filtered, 1ml of filtrate was taken in 50ml of volumetrical flask and diluted up to mark with zero.1N HCL and analysed spectrophotometrically at 203nm. The concentration of cefadrin in mg/ml was obtained by exploitation standard calibration curve of the drug. Claimed drug content was 500mg per tablet. Drug content studies were carried out in triplicate for every formulation batch.

j) Impact of hardness on Buoyancy Lag Time (BLT) or Floating Lag Time (FLT):[17]

Formulation F2 was selected to study the effect of hardness on buoyancy lag time. The tablets of batch F2 were compressed at 3 completely different compression pressures to get the hardness of 5kg/cm2, 7kg/cm2 and 9kg/cm2. The tablets were evaluated for Buoyancy Lag Time.
The methodology followed is same as that of Buoyancy test.

k) In-vitro Dissolution Study:-[16]

In-vitro release studies were carried out exploitation USP XXIII dissolution test equipment. 900ml of zero.1N HCl (pH one.2) was filled in dissolution vessel and the temperature of the medium was set at370C±0.10C. For the study ring/meshassembly was used. The tablet was put within the ring assembly and placed within the dissolution vessel. The speed was set at fifty revolutions per minute. 1ml of sample was withdrawn at preset time intervals for eight hours and same volume of recent medium was replaced. The samples were analyzed for drug content against zero.1N HCl as a blank atʃmax 203nm exploitation U.V. spectrophotometer.

l) Curve fitting analysis:

The mechanism of cefadrin released from the matrix system was studied by fitting the dissolution data obtained to following equation using PCP DISSO V2 software package.

i) Korsmeyer – Peppas equation ii) Zero order equation

iii) Higuchi square root equation

Result

Table No. 5: Standard Calibration Curve of cefadrin

CONCENTRATION	ABSORBANCE
0.5	0.098
1	0.165
2	0.289
3	0.459
4	0.562
5	0.781

Figure No 1: Standard calibration curve of Cefadrin

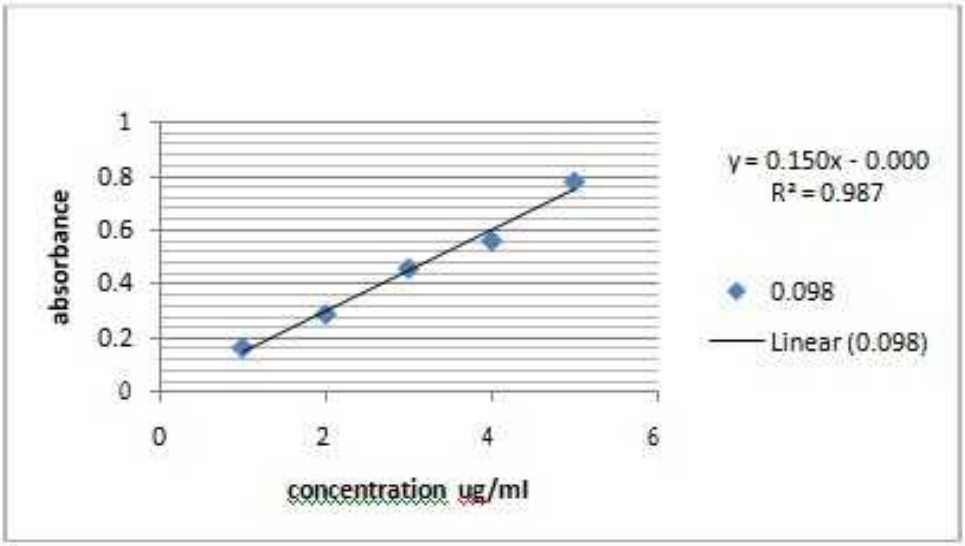

Table No.6: Angle of Repose, Compressibility Index

Batch	Angle of repose(degree)	Compressibility Index
F1	24	12.30
F2	26	15.67
F3	25	14.48
F4	28	16.34
F5	29	15.41

Table No.7: Physical Properties of Tablets of Batch F1 to F5

Batches	Diameter (mm)	Thickness (mm)	Hardness (Kg/cm²)	Friability (%)	Weight Variation (mg)	Drug content uniformity (mg)
F1	12.99 +0.040	5.16 +0.010	4.5 +0.47	0.96	800.65 +1.29	97.01
F2	12.98 ±0.006	5.14 ±0.012	4.4 ±0.32	0.72	801.50 ±1.74	99.5
F3	12.99 ±0.067	5.12 ±0.06	4.1 ±0.54	0.91	799.55 ±1.18	98.01
F4	12.98 ±0.070	5.16 ±0.011	4.3 ±0.42	0.86	800.05 ±1.37	97.4
F5	12.98 ±0.056	5.18 ±0.012	4.5 ±0.35	0.79	801.65 ±1.49	98.1

Table No. 8: Tablet Density, Buoyancy Lag Time, Total Floating Time

Batch	Tablet Dancy	Buoyancy Lag Time	Total Floting Time
F1	0.93	62 sec	>12 hrs
F2	0.92	49 sec	>12 hrs
F3	0.89	55 sec	>12 hrs
F4	o.99	134 sec	>12 hrs
F5	0.97	102 sec	>12 hrs

Table No.9: Swelling Index of Tablets of Batch F1 to F5

Time	Swelling index (%)				
	F1	F2	F3	F4	F5
1 hr	80	82	79	76	76

2 hr	129	135	130	120	125
3 hr	148	162	156	140	142
4 hr	168	185	172	161	163
5 hr	185	207	189	170	179

Table No.10: Effect of Hardness on Buoyancy Lag Time of Batch F2

Hardness in kg/cm^2	Buoyancy Lag Time (sec)
$4kg/cm^2$	49
$5kg/cm^2$	102
$7kg/cm^2$	480
$9kg/cm^2$	650

Table No.11 Cumulative % Drug Released from Tablet Formulations F1 to F5 and Marketed Product

Time (hrs)	**F1**	**F2**	**F3**	**F4**	**F5**	**Marketed Product**
1	22.5	20.7	21.6	25.2	23.8	24.3
2	32.4	31.5	33.3	48.6	38.7	34.2

3	49.5	46.8	47.7	59.0	57.6	48.6
4	58.5	53.1	56.7	67.5	61.2	59.4
5	70.2	62.1	64.8	81.9	71.1	66.6
6	75.6	68.4	69.0	97.2	77.4	74.7
7	80.1	73.8	76.0	_	81.5	77.9
8	83.7	78.3	79.0	_	88.2	81.9
9	91.8	84.3	87.0	_	92.7	90.7
10	93.6	89.4	91.0	_	96.3	92.3

Table No. 12 Model Fitting of the Release Profiles using Three Different Models (r-values)

Batch no	Mathematical Models				
	Zero order	Higuchi Matrix	Peppas	'n'	Best Fit Model
F1	0.9356	0.9868	0.9914	0.6885	Peppas
F2	0.9517	0.9862	0.9949	0.6842	Peppas
F3	0.9403	0.9897	0.9948	0.6736	Peppas
F4	0.9777	0.9770	0.9906	0.7612	Peppas
F5	0.9109	0.9870	0.9914	0.6476	Peppas

Discussion

Hydrodynamically balanced tablets of cefadrin were ready and evaluated for his or her use as gastroretentive drug delivery systems to increase its local action and bioavailability In the gift work total 5 formulations were ready and complete composition of all batches

shown in Table no 5. The tablets were then characterised for varied physicochemical parameters.

I. Standard calibration curve:

Standard standardisation curve of cefadrin was drawn by plotting absorbance V/s concentration. The ʃ max of cefadrin in zero.1N HCL decided to be 203 nm as shown in Fig.11. The absorbance values square measure tabulated in Table 6.

Ii. Compatibility study:

Compatibility studies were performed using IR photometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studiedThe characteristic absorption peaks of cefadrin were obtained at 1373.95cm-1, 1691.72cm-1, 2978.17cm-1, 3469.42cm-1. The peaks obtained in the spectras of every formulation correlates with the peaks of drug spectrum. This indicates that the drug is compatible with the formulation components.

Evaluation of hydrodynamically balanced tablets:

1. Pre-compression Parameters:

a. Angle of Repose (θ):- The values obtained for angle of repose for all formulations square measure tabulated in Table seven. The values were found to be in the vary from 240.88' to 29.30'. This indicates smart flow property of the powder mix.

b.Compressibility Index:- compressibility index price ranges between 12.30% to 16.34% indicating that the powder mix have the required flow property for direct compression.

2. Post-compression Parameters:

a) shape of the tablet:-

Microscopic examination of tablets from every formulation batch showed circular form with no cracks.

b) Tablet dimensions:-

The dimensions determined for developed tablets were tabulated Table four.

Tablets mean thickness (n=3) were nearly uniform in all the 5 formulations and were found to be in the vary of 5.12mm to 5.18mm. The diameter of the tablet ranges between 12.98mm to 12.99mm..

c) Hardness test:-

The measured hardness of tablets of every batch ranged between four.1 to 4.5kg/cm2 (Table 8). This ensures smart handling characteristics of all batches.

d) Friability Test:-

The values of breakableness take a look at were tabulated in table in result. The worries friability was but one hundred and twenty fifth all told the formulations ensuring that the tablets were automatically stable.

e) Tablet density:-

To offer smart floating behavior in the abdomen, the density of the device ought to be less than that of the gastric contents (1.004g/cm3). All the batches showed density below than that of gastric fluid (1.004). The values square measure shown in Table.When tablet contacts the test medium, tablet swollen (because of swellable polymers) and there was liberation of greenhouse gas gas (because of effervescent agent, NaHCO3). The density minimized due to this enlargement and upward force of greenhouse gas gas generation. This plays an vital role in guaranteeing the floating capability of the dose type.

f) Weight Variation Test:-

The share weight variation for all formulations was shown in Table above. All the tablets passed weight variation test because the the burden variation was within the pharmacopoeial limits of ±5% of the weight. The weight of all the tablets was found to be uniform with low variance values.

g) Buoyancy Study:-

On immersion in 0.1N HCl resolution pH (1.2) at 370C, the tablets floated, and remained buoyant without disintegration. Table nine shows the results of Buoyancy study and it shows Buoyancy character of ready tablet. From the results it will be over that the batch containing solely HPMC polymers showed smart Buoyancy lag time (BLT) and Total floating time (TFT). Formulation F2 containing HPMC K15M showed smart bacon-lettuce-tomato sandwich of forty nine sec, whereas the formulation containing chitosan alone and together with HPMC K15M showed highest bacon-lettuce-tomato sandwich, and TFT of less than twelve hrs. this might be due to the quantity of chemical compound and gas generating agent, that were unbroken constant in the gift study. The gas generated cannot be entrapped within the jellylike layer.

h) Swelling Study:- Swelling magnitude relation describes the quantity of water that is contained among the gel at associate degree equilibrium and is a function of the network structure, hydrophilicity and ionization of the practical teams. Swelling study was performed on all the batches for five hour. The results of swelling index is given in Table 9.From the results it was over that swelling will increase as the time passes as a result of the chemical compound bit by bit absorb water due to hydrophilicity of chemical compound. The outer deliquescent chemical compound hydrates and swells and a gel barrier is shaped at the outer surface. As the gelatinous layer increasingly dissolves and/or is distributed, the association swelling unleash method is repeated towards new exposed surfaces, so maintaining the integrity of the dose type. In the gift study, the upper swelling index was found for tablets of batch F2 containing HPMC K15M having nominal consistence of 15,000 cps. Thus, the consistence of the chemical compound had major influence on swelling method, matrix integrity, as well as floating capability, thus from the on top of results it will be over that linear relationship exists between swelling method and consistence of chemical compound.

i) Drug Content Uniformity:-

The share of drug content was found to be between ninety seven.4% to 99.5 of cefadrin that was among acceptable limits. Table four shows the results of drug content uniformity in every batch.

j) Effect of hardness on Buoyancy Lag Time:-

The result of hardness on buoyancy lag time for batch F2 was studied. The results of floating lag time of tablet having hardness of 5kg/cm2, 7kg/cm2 and 9kg/cm2 were 102, 480 and 650 sec severally as tabulated in Table eleven. The plot of floating lag time (sec) V/s hardness (kg/cm2) is represented. Batch F2 was elite for the study as a result of it showed buoyancy lag time of forty nine sec at hardness of 4kg/cm2. Buoyancy of the tablet was ruled by each the swelling of the hydrocolloid particle on surface once it contacts the gastric fluid that in flip ends up in a rise within the bulk volume and also the presence of internal void area within the dry center of the tablet (porosity). On increasing the hardness of the tablets ends up in accumulated buoyancy lag time that would possibly be due to high compression ensuing in reduction of consistency of the tablet and what is more, the compacted substance particles on the surface of the tablet cannot hydrate rapidly once the tablet reaches the stomachal fluid and as a result of this, the capability of the tablet to float is considerably reduced.

k) In-vitro Dissolution Study:-

The in-vitro drug unleash profile of tablet from every batch (F1 to F5) were shown in Table no 12. For in-vitro dissolution study ring mesh device was used as shown in Figures. The reason is that once paddle equipment is used, the tablets would rise and eventually stick to the rim of the rotating shaft leading to partial surface occlusion. In case of basket equipment, it ensures full exposure of all surfaces of deliquescent swelling tablets that might stick to bottom of dissolution vessel if paddle equipment was used. However, it was discovered that once 5-7 hour the tablets had swollen to such associate degree extent that they were utterly constricted by the radius of the basket and utterly stuffed the bottom of the basket. Once the dose forms utterly fills the basket, tablet is unable to swell more and move in unobstructed fashion leading to restricted drug unleash.

From the in-vitro dissolution knowledge it was found that formulation F4 containing chitosan alone discharged ninety seven.2% of drug among half-dozen hour of the study indicating that the polymer quantity is not adequate to management the drug release. Formulation F5 containing chitosan on with HPMC K15M showed higher management of drug unleash than chitosan alone, and discharged ninety six.3% drug at the top of ten hour. tablet of batch F1, F2 and F3 contained same quantity of chemical compound of various grades viz. HPMC K4M, HPMC K15M and combination of HPMC K4M and K15M that showed drug unleash rate of ninety three.6%, 89.4% and 91.8% severally. Out of all the 5 formulations batch F2 showed higher management over drug unleash indicating that the discharge was minimized once the consistence of the polymer was accumulated.*l)* .

Curve Fitting Analysis:-

The results of dissolution information fitted to numerous drug release kinetic equations. Peppas model was found to be best fitted in all dissolution profile having higher correlation constant (r value) followed by Higuchi model and zero Order unharness equation. The kinetic values obtained for totally different formulations square measure tabulated in Table thirteen. Korsemeyer-Peppas model indicates that release mechanism is not accepted or a lot of than one sort of release phenomena may be concerned. The 'n' value could be used to characterize totally different release mechanisms as:

N	Mechanism
0.5	Fickian
0.5 < n < 1	Non- fickinian diffusion
1	Case II transport

The results are reported in Table nine and in the gift study 'n' price ranges between 0.64 to 0.76 for all 5 batches. It ranges between zero.5 to 1, thus it was terminated that the drug unleash occurred via non-Fickian diffusion, that shows that the unleash from at first dry, deliquescent glassy polymers that swell once additional to water and become rubbery show abnormal diffusion as a result of the arranging of organic compound chains.

Conclusion

From the findings obtained, it is terminated that:- Hydro dynamically Balanced Tablets of associate bactericide drug Cefadrin will be developed as associate approach to increase gastric residence time and thereby improve its bioavailability. Among the polymers used to improve the stomachal residence, cellulose polymers HPMC K4M, HPMC K15M showed higher management over drug unleash compared to saccharide compound Chitosan. Developed tablets gave satisfactory results for varied chemistry analysis for tablets like tablet dimensions, Hardness, Friability, Weight variation, tablet density, Swelling index and Content uniformity Overall, tablets of batch F2 possessed fast buoyancy lag time and sensible total floating time. Variation on hardness on tablet of batch F2 was found to impact the floating lag time of the tablet as hardness increased .In-vitro unleash rate showed that the drug unleash was higher controlled in formulation F2 followed by F3, F1, F5 and F4. Developed floating tablets best fitted to Peppas model followed by Higuchi model and zero order rate dynamics. Formulation F2 has higher controlled drug unleash in comparison to marketed product Clarithro ER. this work is continuing any to prove its stability throughout period, in-vivo gastric residence time by using gamma scintigraphy and institution of in vitro – in vivo correlation

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