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Research

Formulation Development And In Vitro Characterisation Of Deflazacort Extended Release Matrix Tablets

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Abstract

The aim of the present study was to develop Extended release formulation of Deflazacort to maintain constant therapeutic levels of the drug for over 12 hrs. HPMC K100M, HPMC (K4M) and Carbopol 71G were employed as polymers. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F6) showed better and desired drug release pattern i.e., 98.85% in 12 hours. It contains the HPMC (K4M) as Extended release material. It followed peppas release kinetics mechanism.

Keywords: Deflazacort, HPMC K100M, HPMC (K4M), Carbopol 71 G and Extended release system.

INTRODUCTION

The oral route is the most popular route used for administration of drugs, which is due in part to the ease of administration and to the fact that gastrointestinal physiology offers more flexibility in dosage form design than most other routes. The terms Sustained release, prolonged release, modified release, extended release or depot formulations are used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. [1,2]

There are several reasons for attractiveness of these dosage forms: provides increased bioavailability of drug product, reduction in the frequency of administration to prolong duration of effective blood levels, reduces the fluctuation of peak trough concentration and side effects and possibly improves the specific distribution of the drug. If one were to develop an ideal drugdelivery system, two pre-requisites would be required: Firstly single dose for the

duration of treatment whether for days or weeks as with infection, diabetes orhypertension. Second it should deliver the active entity directly to the site of action minimizing the side effects.

There are certain considerations for the preparation of extended release formulations: If the active compound has a long half-life, it is sustained on its own, If the pharmacological activity of the active is not directly related to its blood levels, If the absorption of the drug involves an active transport and If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose. The above factors need serious review prior to design.[3]

Extended release formulations make the drug available over extended time period after oral administration. The extended release product will optimize therapeutic effect and safety of a drug at the same time improving the patient convenience and compliance. By incorporating the dose for 24 hrs into one tablet/capsule from which the drug is released slowly. This formulation helps to avoid the side effects associated with low and high concentrations. The ideal drug delivery system should show a constant zero-order release rate and maintain the constant plasma concentrations.

It is desirable to maintain a therapeutic blood concentration in order to achieve the desirable pharmacological effects. To maintain a narrow range of therapeutic blood concentration it is desirable to have a dosage form that can deliver the drug in a more sustainable or controlled way to achieve the desired results. Extended release tablets and capsules are commonly taken once or twice daily, compared with counterpart conventional forms that may have to be taken three or four times daily to achieve the same therapeutic effect. Typically, extended release products provide an immediate release of drugs that promptly produces the desired therapeutic effect, followed by gradual release of additional amount of drugs to maintain this effect over a predetermined period. The sustained plasma drug levels provided by extended release products often eliminate the need for night dosing, which benefits not only the patient but the patient but the caregiver as well.[4]

Rationale of Extended Drug Delivery[5]

The main objective to formulate an API in an extended drug delivery system is related to its pharmacokinetics parameters. An appropriate formulation can make the absorption, distribution, metabolism and elimination (ADME) profile of a drug much more favourable. This change of the ADME can have a profound impact on many aspects of the clinical use of the drug from patient compliance and convenience to its very efficacy, tolerance and safety parameters.

Pellets

Pelletization is an agglomeration process, that converts fine powder blend of drug(s) and excipients into small, free flowing, spherical units, referred to as pellets. Rationale of extended release pellets Pellets provide the development scientist with a high degree of flexibility during the design and development of oral dosage forms. They can be divided into desired dose strengths without formulation or process changes, and can also be blended to deliver incompatible bioactive agents simultaneously or particles with different release profiles at the same site or at different sites within the gastrointestinal tract.

Mechanism

A matrix system consists of active and inactive ingredients, which are homogeneously dispersed and mixed in the dosage form. According to the materials used, the matrix systems have different mechanisms toward the controlled action. The release from matrix type formulations is governed by Fick's first law of diffusion.

Types of matrix systems

1. Slowly Eroding Matrix
2. Inert plastic Matrix

There are two types of matrix systems which are as follows

It consists of materials or polymers which erode over a period of time such as waxes, glycerides, Stearic acid, cellulosic materials etc. The Portion of drug intended to have extended action is combined with lipid or cellulosic material and then granulated. Untreated drug granulated both mixed. The rate controlling release ingredients of hydrophilic matrix are polymers which act by swelling when it contact with aqueous solution and form a gel layer on the surface of the system. Swelling or dissolution can be the effective factor for a specific type of polymers, in most cases drug release kinetics is a result of a combination of these two mechanisms.

Limitations of Matrix System

Matrix systems have lack of flexibility in adjusting to constantly change dose levels as needed by clinical study outcome. Therefore new dosage strength is necessary. Furthermore, for some products that require unique release profiles (dual release or delayed plus extended release), more complex matrix based technologies such as bilayer tablets are required.

Factors Affecting Extended Release Formulation[7,8]

Physicochemical Properties of Drug

Aqueous Solubility

Generally drugs are weak acids or weak bases, since the unchanged form of a drug preferentially permeates across lipid membranes, drugs aqueous solubility will be decreased by conversion to an unchanged form. Drugs with low water solubility will be difficult to incorporate into extended release mechanism. The lower limit on solubility for such product has been reported 0.1 gm/ml. Drugs with extreme water solubility are equally difficult to incorporate in extended release system because it is difficult to control release of drug from dosage form. pH dependent solubility, particularly in the physiological pH range, would be another problem because of the varied pH of gastro intestinal tract, which ultimately gives variation in dissolution profile. e.g.: Aspirin, which is less soluble in stomach, but more soluble in intestine.

Partition coefficient

Partition coefficient is generally defined as the fraction of drug in an oil phase to that of an adjacent aqueous phase. As biological membrane is lipophilic in nature through which the drug has to pass though, so partition co-efficient of drug influence the bioavailability of drug very much. Drug having lower partition coefficient values less than the optimum activity are undesirable for oral ER drug delivery system, as it will have very less lipid solubility and the drug will be localized at the first aqueous phase it come in contact e.g. Barbituric acid. Drug having higher partition co-efficient value greater than the optimum activity are undesirable for oral ER drug delivery system because more lipid soluble drug will not partition out of the lipid membrane once it gets in the membrane. The value of partition co-efficient at which optimum activity is observed is approximately 1000:1 in 1-octanol/water system.[8]

Drug pKa and Ionization at Physiological pH

As we know only unionized drugs are well absorbed and permeation of ionized drug is negligible, since its rate of absorption of ionized drug is 3 to 4 times less than that of the unionized drug. pKa range for acidic drug where ionization is pH sensitive is around 3.0 to 7.5 and pKa range for basic drug whose ionization is pH sensitive is around 7.0 to 11.0 are ideal for optimum positive absorption. Drug shall be non-ionized at the site to an extent 0.1 – 5.0%. Drugs existing largely in ionized form are poor candidates for oral ER drug delivery system. e.g.:- Hexamethonium.[9]

Drug stability

Drugs when administered orally can undergo both acid/base hydrolysis and enzymatic degradation. The degradation will proceed at the reduced rate for drugs in the solid state. For the drugs that are unstable in stomach, formulation systemsthat prolong delivery to the entire GI tract are beneficial. Compounds that areunstable in the small intestine may demonstrate decreased bioavailability when administered in extended release dosage form. This is happening due to the fact that a greater quantity of drug is delivered in small intestine and is being subjected to more degradation.

Molecular size and diffusivity

With large molecular size are poor candidate for oral extended release (ER) where it is 1st time drug delivery system because the ability of the drug to diffuse polymeric membrane is a function of its diffusivity (or diffusion co-efficient). Diffusivity depends on size shape of the cavities of the membrane. The diffusion co-efficient of intermediate molecular weight drug is 100 to 400 Daltons; through flexible polymer range is 10-6 to 10-9 cm2 /sec. For drugs having molecular weight > 500 Daltons, the diffusion coefficient in many polymers are very less i.e. less than 10-12 cm2 /sec. The examples of drugs which are difficult to control release rate of medicament from dosage form are proteins and peptides.

Protein binding

The Pharmacological response of drug depends on unbound drug concentration rather than total concentration and almost all drugs bind to some extent to plasma and or tissue proteins. Protein binding plays a significant role in its therapeutic effect regardless the type of dosage form as extensive binding to plasma increase

biological half life and thus sometimes ER drug delivery system is not required for this type of drug[10].

Biological Properties of Drug[11,12]

Absorption

The absorption behavior of a drug can affect its suitability as an extended release product. The aim of formulating an extended release product is to place a control on the delivery system. It is essential that the rate of release is much slower than the rate of absorption. If we assume the transit time of most drugs and devices in the absorptive areas of GI tract is about 8-12 hours, the maximum half-life for absorption should be approximately 3-4 hours. Otherwise the device will pass out of absorptive regions before drug release is complete. Therefore the compounds with lower absorption rate constants are poor candidates for extended release systems. Some possible reasons for a low extent of absorption are poor water solubility, small partition co-efficient, acid hydrolysis, and metabolism or its site of absorption.

Distribution

The distribution of drugs in tissues can be important factor in the overall drug elimination kinetics. Since it not only lowers the concentration of circulating drug but it also can be rate limiting in its equilibrium with blood and extra vascular tissue, consequently apparent volume of distribution assumes different values depending on time course of drug disposition. Drugs with high apparent volume of distribution, which influence the rate of elimination of the drug, are poor candidate for oral ER drug delivery system e.g. Chloroquine. For design of extended release products, one must have information on disposition of the drug.

MATERIALS AND METHODS

Materials

Deflazacort-Procured From Neon Laboratories Ltd, Provided by SURA LABS, Dilsukhnagar, Hyderabad, HPMC K100M-Merck Specialities Pvt Ltd, Mumbai, India, HPMC (K4M)-Merck Specialities Pvt Ltd, Mumbai, India, Carbopol 71 G-Merck Specialities Pvt Ltd, Mumbai, India, PVP K 30-Merck Specialities Pvt Ltd, Mumbai, India, MCC102-Merck Specialities Pvt Ltd, Mumbai, India, Mg. stearate-Merck Specialities Pvt Ltd, Mumbai, India, Talc-Merck Specialities Pvt Ltd, Mumbai, India.

Methodology

Analytical method development

Determination of absorption maxima

100mg of Deflazacort pure drug was dissolved in 15ml of Methanol and make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with 100 ml by using 0.1 N HCL (stock solution-2 i.e 100µg/ml).From this 10ml was taken and make up with 100 ml of 0.1 N HCL (10µg/ml). Scan the 10 10µg/ml using Double beam UV/VIS spectrophotometer in the range of 200 – 400 nm.

Preparation calibration curve

100mg of Deflazacort pure drug was dissolved in 15ml of Methanol and volume make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCl (stock solution-2 i.e 100µg/ml). From this take 1, 2, 3, 4 and 5 ml of solution and make up to 10ml with 0.1N Hcl to obtain 10, 20, 30, 40 and 50 µg/ml of Deflazacort per ml of solution. The absorbance of the above dilutions was measured at 244nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Formulation development of Extended release Tablets

All the formulations were prepared by direct compression method. The compositions of different formulations are given in Table 7.1. The tablets were prepared as per the procedure given below and aim is to prolong the release of Deflazacort.

Procedure

1) Deflazacort and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.

3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

Table 1: Formulation of Extended release tablets

INGREDIENTS	FORMULATION CODE								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Deflazacort	6	6	6	6	6	6	6	6	6
HPMC K100M	4	8	12	-	-	-	-	-	-
HPMC (K4M)	-	-	-	4	8	12	-	-	-
Carbopol 71 G	-	-	-	-	-	-	4	8	12
PVP K 30	10	10	10	10	10	10	10	10	10
MCC102	76	72	68	76	72	68	76	72	68
Mg. stearate	5	5	5	5	5	5	5	5	5
Talc	3	3	3	3	3	3	3	3	3
Total Weight (mg)	100	100	100	100	100	100	100	100	100

RESULTS AND DISCUSSION

The present work was designed to developing Extended tablets of Deflazacort using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Analytical Method

Standard graph of Deflazacort in 0.1N HCl

The scanning of the 10µg/ml solution of Deflazacort in the ultraviolet range (200-400 nm) against 0.1 N HCl blank gave the λ_{max} as 244 nm. The standard concentrations of Deflazacort (10-50 µg/mL) prepared in 0.1N HCl showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer-Lamberts law.

Table 2: Standard curve of Deflazacort in 0.1N HCl

Concentration (µg/ mL)	Absorbance
0	0
10	0.119
20	0.234
30	0.345
40	0.461
50	0.572

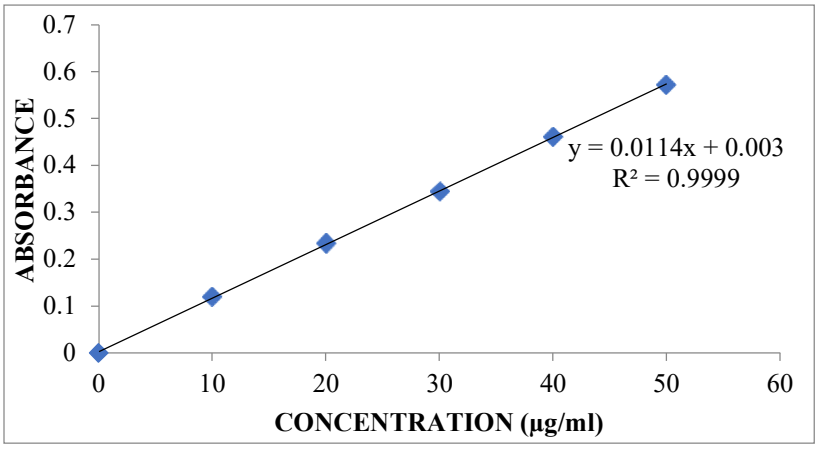

Fig 1: Calibration curve of Deflazacort in 0.1 N HCl at 244nm

Standard Curve of Deflazacort in Phosphate buffer pH 6.8

The scanning of the 10µg/ml solution of Deflazacort in the ultraviolet range (200-400nm) against 6.8 pH phosphate buffer as blank gave the λ_{max} as 244nm. The standard concentrations of Deflazacort (10-50µg/ml) prepared in 6.8 pH phosphate buffer showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer--Lamberts law.

Table 3: Standard curve of Deflazacort in Phosphate buffer pH 6.8

Concentration (µg / ml)	Absorbance
0	0
10	0.131
20	0.254
30	0.385
40	0.512
50	0.629

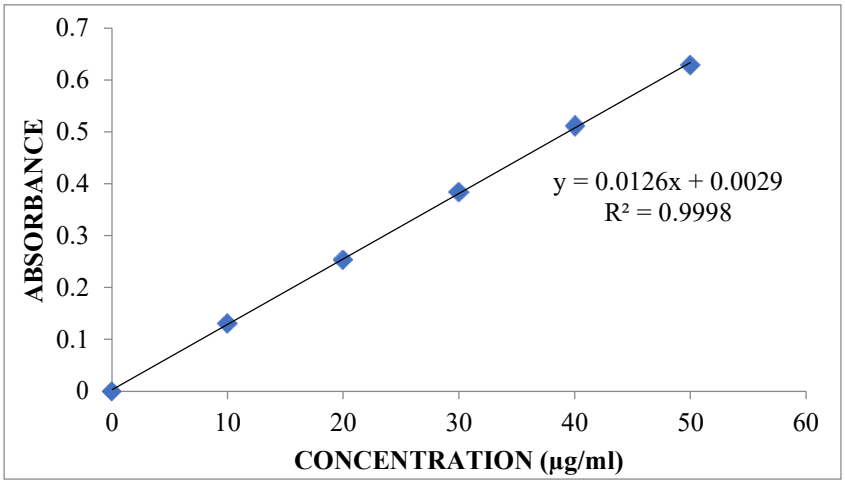

Fig 2: Calibration of Deflazacort in Phosphate buffer pH 6.8

Evaluation parameters

Pre-compression parameters

Table 4: Pre-compression parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/cm^3)	Tapped density (gm/ cm^3)	Carr's index (%)	Hausner's Ratio
F1	25.01	0. 59	0.57	14.03	1.16
F2	26.8	0. 46	0.67	16.41	1.19
F3	27.7	0. 32	0. 54	18.75	1.23
F4	25.33	0.54	0.64	15.62	1.18
F5	25.24	0.52	0.65	18.46	1.22
F6	28.12	0. 46	0. 56	15.15	1.17
F7	27.08	0.58	0.69	15.94	1.18
F8	25.12	0.48	0.67	15.78	1.18
F9	26.45	0.54	0.65	16.92	1.25

Tablet powder blend was subjected to various pre-compression parameters. The angle of repose values was showed from 25.01 to 28.12; it indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.32-0.59 (gm/cm^3) showing that the powder has good flow properties.

The tapped density of all the formulations was found to be in the range of 0.54-0.69 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging from 14.03 to 18.75 which showed that the powder has good flow properties. All the formulations were showed the hausner ratio ranging from 1.16 to 1.25 indicating the powder has good flow properties.

Post Compression Parameters For tablets

Table 5: Post Compression Parameters of Tablets

Formulation codes	Weight variation (mg)	Hardness (kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	98.62	5.9	0.52	3.16	96.35
F2	96.35	**5.1**	0.34	3.56	99.61
F3	99.21	5.6	0.62	3.41	98.52
F4	97.49	5.2	0.41	3.22	97.42
F5	95.32	5.8	0.26	3.61	97.12
F6	99.58	5.1	0.39	3.25	99.33
F7	97.96	5.7	0.65	3.42	98.64
F8	99.67	5.9	0.73	3.13	95.78
F9	98.32	5.5	0.15	3.24	96.41

Weight variation and thickness

All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown in table 8.4. The average tablet weight of all the formulations was found to be between 95.32 to 99.67**.** The maximum allowed percentage weight variation for tablets weighing >100.5 mg is 1.5% and no formulations are not exceeding this limit. Thus all the formulations were found to comply with the standards given in I.P. And thickness of all the formulations was also complying with the standards that were found to be between 3.13 to 3.61.

Hardness and friability

All the formulations were evaluated for their hardness, using monsanto hardness tester and the results are shown in table 8.4. The average hardness for all the formulations was found to be between **(**5.1 to 5.9**)** Kg/cm^2 which was found to be acceptable.

Friability was determined to estimate the ability of the tablets to withstand the abrasion during packing, handling and transporting. All the formulations were evaluated for their percentage friability using roche friabilator and the results were shown in table 8.4. The average percentage friability for all the formulations was between 0.15 and 0.73, which was found to be within the limit.

Drug content

All the formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown in table 7.4. The drug content values for all the formulations were found to be in the range of **(**95.78 to 99.61**).** According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the FDT formulations comply with the standards given in IP.

***In Vitro* Drug Release Studies**

The formulations prepared with different natural polymers by wet granulation method. The tablets dissolution study was carried out in paddle dissolution apparatus using 0.1N HCl for 2 hours and 6.8 pH phosphate buffers for remaining hours as a dissolution medium.

Table 6: Dissolution Data of Deflazacort Tablets Prepared With HPMC K100M In Different Concentrations

Time (hr)	Cumulative percent drug released		
	F1	F2	F3
0	0	0	0
0.5	25.32	20.04	18.63
1	34.53	27.56	21.63
2	49.90	34.35	28.52
3	54.96	43.52	31.31
4	59.14	48.75	38.25
5	62.85	52.54	45.78
6	73.92	59.26	50.17
7	80.41	65.95	57.79
8	89.61	70.14	62.27
9	93.17	73.45	69.64
10	96.33	81.57	74.87
11		98.18	84.10
12			98.64

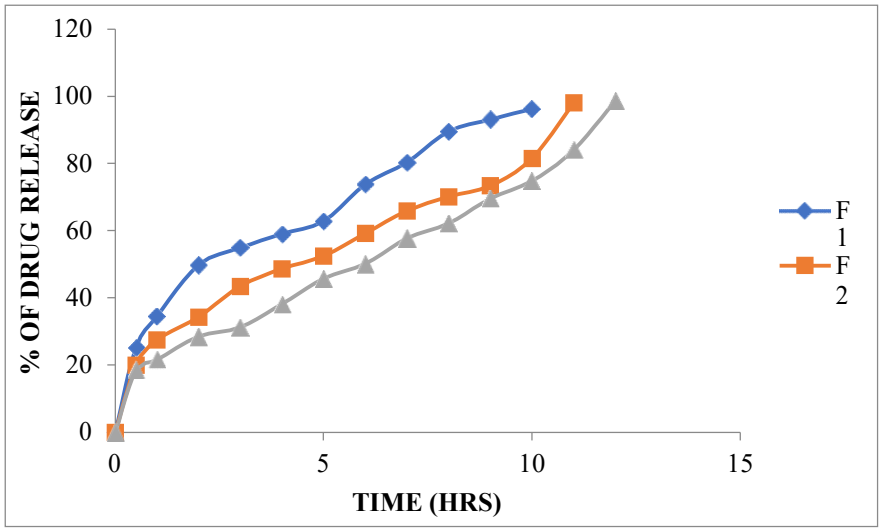

Fig 3: Dissolution study of Deflazacort Extended tablets (F1 to F3)

Table 7: Dissolution Data of Deflazacort Tablets Prepared With HPMC (K4M) in Different Concentrations

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED		
	F4	F5	F6
0	0	0	0
0.5	15.17	13.90	10.49
1	22.12	19.45	16.63
2	36.64	25.02	27.55
3	42.20	31.31	33.21
4	48.56	37.82	40.96
5	55.43	43.47	45.11
6	58.01	50.74	55.28
7	67.57	54.05	61.71

8	73.91	57.93	67.34
9	79.41	63.26	74.98
10	83.72	75.45	80.74
11	86.02	80.36	86.12
12	90.14	95.47	98.85

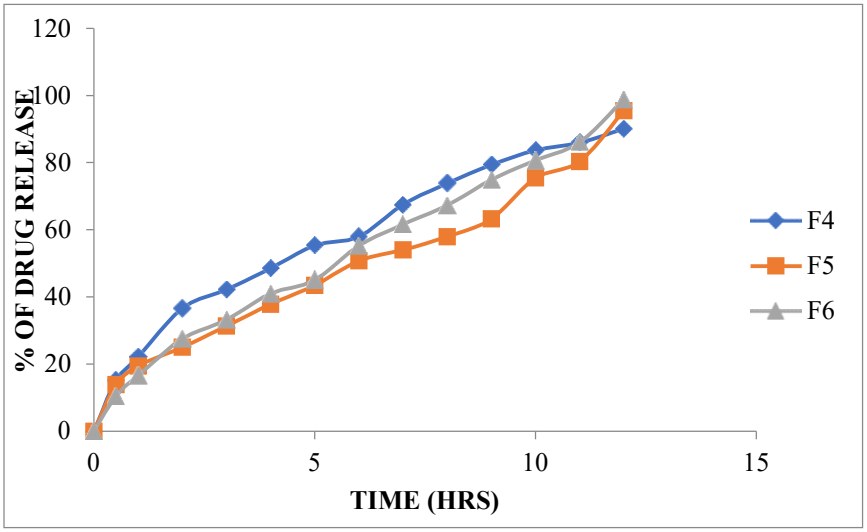

Fig 4: Dissolution study of Deflazacort tablets (F4 to F6)

Table 8: Dissolution Data of Deflazacort Tablets Prepared With Carbopol 71 G in Different Concentrations

TIME	CUMULATIVE PERCENT DRUG RELEASED		
(hr)	**F7**	**F8**	**F9**
0	0	0	0
0.5	20.56	17.58	10.62
1	26.45	23.20	15.28
2	31.23	27.35	20.95
3	40.54	34.14	25.51
4	49.73	39.75	29.32
5	56.46	43.09	33.96
6	58.12	46.16	39.78
7	62.59	55.75	44.35
8	71.41	60.11	50.62
9	78.98	64.67	56.43
10	83.24	68.34	60.02
11	89.72	76.40	64.10
12	90.14	85.18	70.16

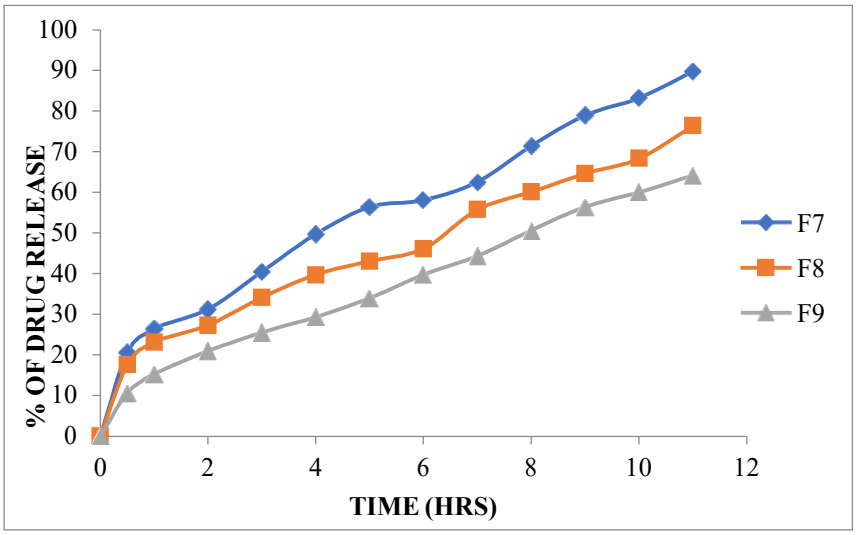

Fig 5: Dissolution study of Deflazacort tablets (F7 to F9)

From the dissolution data it was evident that the formulations prepared with HPMC K100M as polymer were retarded the drug release more than 12 hours. Whereas the formulations prepared with higher concentration of HPMC (K4M) retarded the drug release up to 12 hours in the concentration 12 mg. In lower concentrations the polymer was unable to retard the drug release. The formulations prepared with Carbopol 71G showed very less retardation capacity hence they were not considered. Hence from the above dissolution data it was concluded that F6 formulation was considered as optimised formulation because good drug release (98.85%) in 12 hours.

Application of Release Rate Kinetics to Dissolution Data

Data of *in vitro* release studies of formulations which were showing better drug release were fit into different equations to explain the release kinetics of Deflazacort release from Extended tablets. The data was fitted into various kinetic models such as Zero, First order kinetics; Higuchi and Korsmeyer peppas mechanisms and the results were shown in below table

Table 9: Release kinetics data for optimised formulation (F6)

CUMULATIVE (%) RELEASE	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	**0**	0			2.000				100	4.642	4.642	0.000
10.49	**0.5**	0.707	1.021	-0.301	1.952	20.980	0.0953	-0.979	89.51	4.642	4.473	0.168
16.63	**1**	1.000	1.221	0.000	1.921	16.630	0.0601	-0.779	83.37	4.642	4.369	0.273
27.55	**2**	1.414	1.440	0.301	1.860	13.775	0.0363	-0.560	72.45	4.642	4.169	0.473
33.21	**3**	1.732	1.521	0.477	1.825	11.070	0.0301	-0.479	66.79	4.642	4.057	0.584
40.96	**4**	2.000	1.612	0.602	1.771	10.240	0.0244	-0.388	59.04	4.642	3.894	0.748
45.11	**5**	2.236	1.654	0.699	1.739	9.022	0.0222	-0.346	54.89	4.642	3.800	0.841
55.28	**6**	2.449	1.743	0.778	1.651	9.213	0.0181	-0.257	44.72	4.642	3.550	1.092
61.71	**7**	2.646	1.790	0.845	1.583	8.816	0.0162	-0.210	38.29	4.642	3.371	1.271
67.34	**8**	2.828	1.828	0.903	1.514	8.418	0.0149	-0.172	32.66	4.642	3.196	1.445
74.98	**9**	3.000	1.875	0.954	1.398	8.331	0.0133	-0.125	25.02	4.642	2.925	1.717
80.74	**10**	3.162	1.907	1.000	1.285	8.074	0.0124	-0.093	19.26	4.642	2.681	1.961
86.12	**11**	3.317	1.935	1.041	1.142	7.829	0.0116	-0.065	13.88	4.642	2.403	2.238

98.85	**12**	3.464	1.995	1.079	0.061	8.238	0.0101	-0.005	1.15	4.642	1.048	3.594

Drug and Excipient Compatability Studies

FTIR study

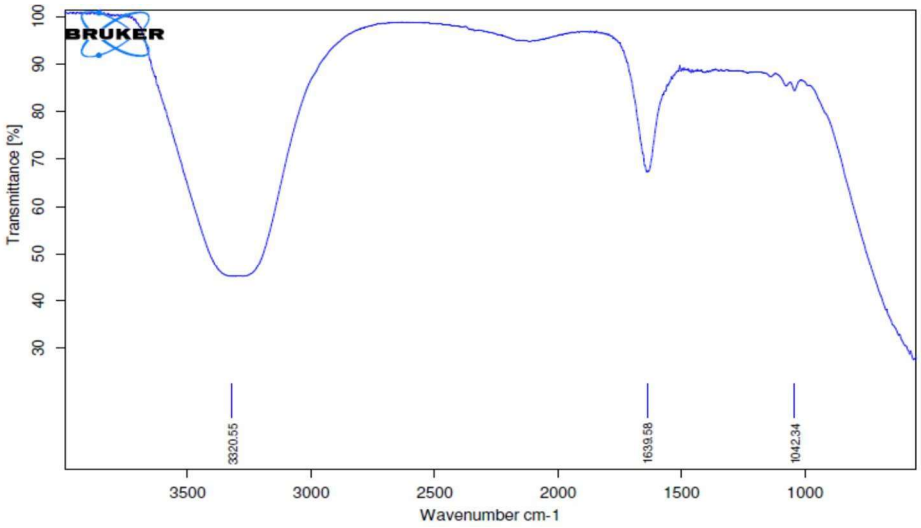

Fig 6: Ftir Graph Of Pure Drug Of Deflazacort

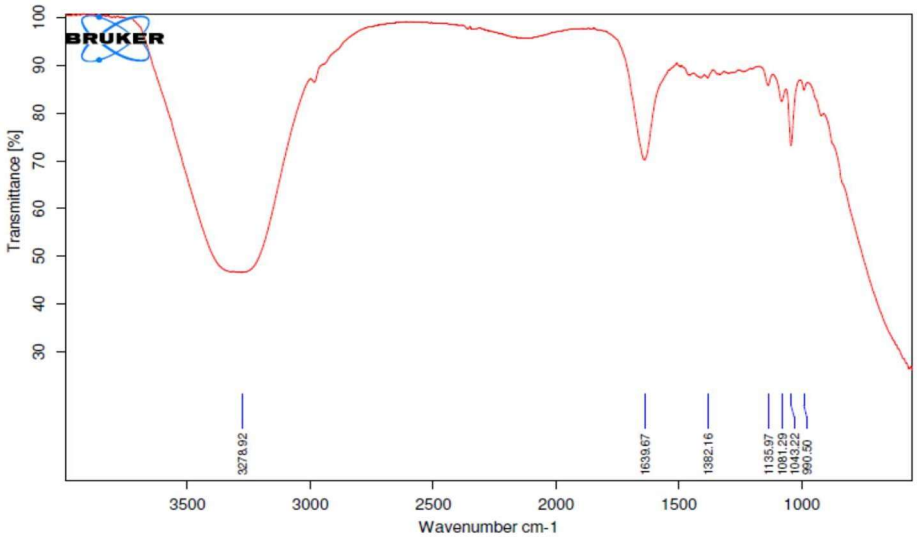

Fig 7: Ftir Graph Of Pure Drug Of Deflazacort Optimised Graph

There is no incompatibility of pure drug and excipients. There is no disappearence of peaks of pure drug and in optimised formulation.

Summary

Development of Extended release tablets is one of the alternative routes of administration to prolonged extended release of drug. Extended release tablets of Deflazacort were prepared by direct compression method using various natural and synthetic polymers like HPMC K100M, HPMC (K4M) and Carbopol 71 G in different concentrations. The formulated Extended release tablets were evaluated for different parameters such as drug excipient compatability studies, weight variation, thickness, hardness, content uniformity and *In vitro* drug release. *In vitro* drug

release studies performed in pH 1.2 and phosphate buffer pH 6.8 for 12hrs in standard dissolution apparatus. The data was subjected to zero order, first order, Zero and First diffusion models. The following conclusions could be drawn from the results of various experiments. FTIR studies concluded that there was no interaction between drug and excipients. The physico-chemical properties of all the formulations prepared with different polymers like HPMC K100M, HPMC (K4M) and Carbopol 71 G were shown to be within limits. Properties and from the results, it was concluded that the *in vitro* drug release of the optimized formulations is suitable for Extended drug delivery system.

CONCLUSION

The present study concludes that Extended drug delivery of Deflazacort tablets can be a good way to prolong duration of action of drug by reducing the frequency of dosing of Deflazacort. Present study concludes that extended drug delivery system should be a suitable method for Deflazacort administration. The optimised formulation was found to be F6 formulation.

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