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HYDROPHILIC AND HYDROPHOBIC MATRIX SYSTEM ENGINEERED DEVELOPMENT OF EXTENDED-RELEASE TABLETS OF OXYBUTYNIN CHLORIDE

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ABSTRACT: The present aim study is the formulation development and evaluation of extended-release matrix tablets of oxybutynin chloride by using hydrophilic and hydrophobic matrix systems. The pilot-scale batches of nine formulations were prepared using Eudragit RSPO, Eudragit RLPO, Carbopol 971NF, ethylcellulose individually, and in the combination of above polymer and Avicel PH102 by adopting direct compression method. The fabricated matrix tablets were assessed for their physicochemical properties and *in-vitro* drug release study. The drug-excipient interaction was evaluated by Fourier transform infrared spectroscopy, where no such interactions were observed. The F1-F3 formulation batches containing Eudragit RSPO in different proportions showed an effective drug release of nearly 99% at 24 h. The F4-F6 formulation batches contained Eudragit RLPO in the diverse amount presented an impressive drug release of >97%. In batches F7-F9, the combination of Eudragit RSPO and Eudragit RLPO produced a remarkable drug release of 100%. The optimized formulation F3 demonstrated a comparative similarity factor f_2 and less difference factor f_1 with that of the marketed tablet. The formulation F3 also passed the essential attributes needed after short-term accelerated stability study.

INTRODUCTION: Oral drug delivery is the most favored and advantageous selection among all drug delivery system as the oral route gives the greatest dynamic surface area and hence increase the residence time of the drug for absorption [1]. The conventional dosage form produces a wide range of fluctuation in drug concentration in the bloodstream and tissues with resultant undesirable toxicity, and poor efficiency and maintenance of concentration of drug in the plasma within the therapeutic index are very critical for effective treatment. The factors such as repetitive dosing and unpredictable absorption lead to the concept of oral sustained-release drug delivery systems [2].

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The matrix tablets composed of drug and polymer as a release retarding material that offers the simplest approach in developing an extended-release drug delivery system [3]. The matrix systems are the most popular method used in the development of extended-release formulation. Hydrophilic and hydrophobic polymeric matrix systems are widely used in extended drug delivery systems since they make it easier to achieve a desirable drug release profile [4].

An appropriately designed extended-release drug delivery system can be a major advance towards solving problems concerning the targeting of a drug to specific organs or tissue and controlling the rate of drug release for an extended period. The extended-release dosage form is modified that prolongs the therapeutic activity of the drug. It provides prolonged but not a uniform release of drug and reduces the need for repeated dosing [5]. In some disease condition, there is a need to maintain

constant therapeutic blood or tissue level of the drug for an extended period of time, which increases the dosing frequency and results in patient noncompliance. So, the extended-release tablet dosage form will be helpful in maintaining the constant plasma concentration and will reduce the dosing frequency by releasing the drug at an extended period of time [6]. Urinary incontinence is common in elderly patients, particularly elderly women. The clinical symptoms overactive urinary bladder include urge urinary incontinence, urgency, and frequency [7]. The main need for research is to control urinary incontinence and clinical symptoms by using oxybutynin chloride. The drug of choice in this condition is oxybutynin chloride, which has the ability to block acetylcholine release from parasympathetic nerves in the urinary bladder, preventing contraction of the muscle and exerting a direct spasmolytic effect on the bladder [8].

MATERIALS AND METHODS:

Materials: Oxybutynin chloride was obtained from Enaltec Chemistry Applied Ltd., Mumbai. Eudragit RSPO and Eudragit RLPO were procured from Evonik Industries Ltd., Mumbai. Carbopol 971 NF was purchased from Lubrizol India Pvt. Ltd., Mumbai. Ethylcellulose was acquired from Signet Chemical Corporation, Mumbai. Avicel PH-102 magnesium stearate was acquired from Loba Chem Ltd., Mumbai.

Instruments: Tablet Compression machine (Karnawati Mumbai, India), UV-Vis spectrophotometer (UV 1800, Shimadzu, Japan), dissolution test apparatus type II-paddle (Electrolab, India), tablet hardness tester (Monsanto tester, India), electronic balance (Shimadzu AUX 120, Japan), Roche friabilator (Electrolab, India), and Vernier caliper (Mitutoyo, Japan).

Preparation of Oxybutynin Chloride: Matrix embedded extended-release tablets of oxybutynin chloride were prepared by direct compression technique using various concentrations of Eudragit RSPO and RLPO separately and in combination with Carbopol 971, Avicel PH 102, and ethyl cellulose. All the excipients except magnesium stearate were blended in a mortar uniformly; blend passed through sieve #80 to get fine particles. To this, magnesium stearate was added and further mixed for 2-3 min, and finally, the powder blend was compressed into a tablet by using 6 mm diameter punch [9]. The composition of the tablet is given in **Table 1**.

TABLE 1: FORMULATION OF OXYBUTYNIN CHLORIDE EXTENDED RELEASE MATRIX TABLETS

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Oxybutynin chloride	5	5	5	5	5	5	5	5	5
Eudragit RSPO	30	35	45	-	-	-	15	17.5	20
Eudragit RLPO	-	-	-	20	25	30	15	17.5	20
Carbopol 971 NF	45	35	30	50	45	40	45	35	30
Ethyl cellulose	10	15	20	10	15	20	10	15	20
Avicel PH-102	57.5	57.5	52.5	62.5	57.5	52.5	57.5	57.5	52.5
Magnesium Stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5

Evaluation of Pre-Compression Parameters: The pre-parameters were evaluated based on the methods provided by Gangane *et al*., 2018 [10].

Angle of Repose: The frictional force in a loose powder can be measured by the angle of repose (θ). It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. The angle of repose (θ) was calculated using the following formula:

$$\tan \theta = h / r$$

Where; θ = angle of repose,
h = height of the cone, and
r = radius of the cone base.

Bulk Density: The 10 g powder blend introduced into a dry 100 mL cylinder without compacting. The powder was carefully leveled without compacting, and the apparent unsettled volume, Vo, was measured. The bulk density was calculated using the formula:

$$\rho b = M / Vo$$

Where, ρb = apparent bulk density, M = weight of the sample, and Vo = apparent volume of powder.

Tapped Density: After carrying out the procedure as given in the measurement of bulk density, the cylinder containing the sample was tapped using a suitable mechanical tapped density tester. The

cylinder was tapped 500 times initially followed by an additional tap of 750 times until the difference between succeeding measurement was less than 2% and then tapped volume, Vf was measured, to the nearest graduated unit. The tapped density was measure in g/mL, using the formula:

$$\rho tap = M / Vf$$

Where, ρtap = tapped density, M = weight of the sample, Vf = tapped volume of powder.

Compressibility Index: The compressibility index (Carr's Index) is a measure of the flow property of a powder to be compressed. It is determined from the bulk and tapped densities. The compressibility index was calculated using the following formula:

$$\text{Carr's Index} = [(\rho tap - \rho b) / \rho tap] \times 100$$

Where ρb = bulk density and ρtap = tapped density.

Hausner's Ratio: Hausner's ratio is the ratio of tapped density to the bulk density. The lower the values of Hausner's ratio better the flow property. Hausner's ratio was calculated using the following formula:

$$\text{Hausner's ratio} = \text{tapped density} \times 100 / \text{Bulk density}$$

Evaluation of Post-Compression Parameters: The post-compression parameters were evaluated based on the methods provided by Mahajan *et al*., 2017 [11].

Weight Variation Test: Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets were calculated.

The batch passes the weight variation test if not more than two of individual tablet weight deviates from the average weight by more than the percentage limit, as per USP guidelines.

Thickness: The thickness in millimeters (mm) was measured individually for pre-weighed 10 tablets by using a Mitutoyo Digital Vernier Caliper. The average thickness and standard deviation were reported.

Hardness: Hardness indicates the ability of the tablet to withstand mechanical shock while handling. For each formulation, the hardness of the tablet (n=6) was determined by using the Monsanto Hardness tester. It is expressed in kg/cm^2.

Friability: For each formulation, the friability of 20 tablets was determined using the Roche Friabilator (Electro lab). Pre-weighed tablets were placed in the friabilator and rotated at 25 rpm for 4 min (100 rotations). At the end of the test, the tablets were reweighed; loss in the weight is a measure of friability and is expressed in percentage, as per USP guidelines.

$$\% \text{ Friability} = \text{Initial weight - Final weight} \times 100 / \text{initial weight}$$

Swelling Index: Swelling index was determined by placing the tablets in the Petri dish containing phosphate buffer pH 6.8. After every one hr interval and up to 12 h, each Petri dish containing the tablet was withdrawn and blotted with tissue paper to remove the excess water and weighed on the analytical balance.

$$\text{Swelling index (SI)} = W_f - W_i / W_f \times 100$$

Where W_f = weight of tablet after swelling and W_i = initial weight of the tablet

Drug Content: For the determination of drug content, 5 tablets were crushed, and the equivalent weight of powder was dissolved in 100 mL of methanolic HCl. The filtrate further diluted with methanolic HCl was analyzed spectrophotometrically at 220 nm. The drug content was calculated using a standard curve generated using various concentrations of the drug in phosphate buffer [12].

***In-vitro* Drug Release Studies:** *In-vitro* drug release study for the prepared extended-release tablets was conducted for a period of 24 h using a USP type 2 (Paddle) apparatus at 37 °C ± 0.5 °C, 50 rpm speed, and 900 mL media volume. The dissolution studies were carried out in 0.1 N HCl for two hrs and further in phosphate buffer 6.8 up to 24 h under sink condition. At 1 h interval, the sample of 10 mL was withdrawn from the dissolution medium and replaced with a fresh medium to maintain the constant volume [13].

Drug Release Kinetics: In order to determine the mechanism of drug release from the formulation, the *in-vitro* dissolution data were fitted to zero-

order, first-order, Higuchi plot, and Korsmeyer-Peppas plot was drawn for optimized formula, and interpretation of release exponent value (n) was calculated [14].

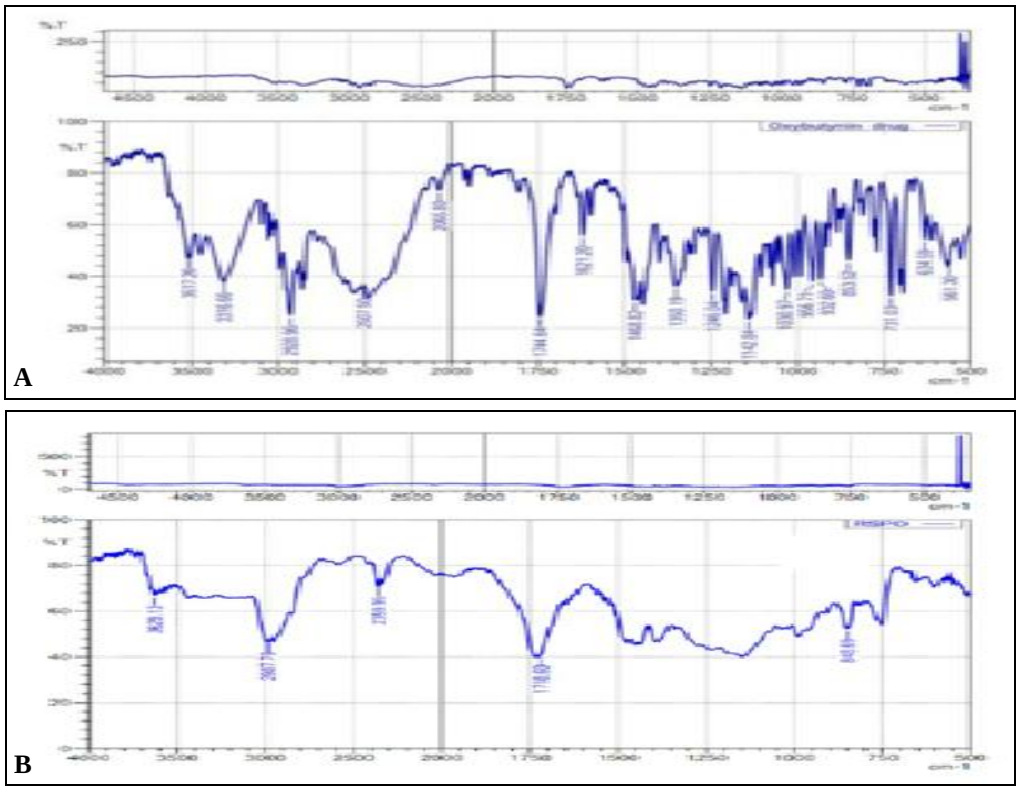
Similarity Index: The similarity factor (*f2*) is an important parameter in fabricating a new formulation. CDER, FDA, and EMEA define it as the logarithmic reciprocal square root transformation of one plus the mean squared difference in percent dissolved between the test and the reference products.

The similarity factor (f2) involves calculation performed in comparison with a reference or with the innovator product to know the possible similarities employing the Pair-wise model-independent approach. It was calculated using PCP Disso v2.08 software [15].

Stability Study: The tablets were kept under accelerated storage conditions 40 ± 2 °C temperature and 75 ± 5% relative humidity, according to ICH guidelines using a stability chamber for a period of three months. The tablets were withdrawn at a pre-determined time interval and evaluated for hardness, drug content, *in-vitro* drug release, and physical parameter [16].

Drug-Interaction Studies: The drug presented prominent peaks (cm^{-1}) at 3517.26, 3316.66, 2928.96, 1744.64, 1621.20, 1468.82, 1350.19, 1246.04, 1142.84, and 853.52. Eudragit RSPO demonstrated characteristic peaks (cm^{-1}) at 3629.13, 2987.79, 2359.95, 1718.60, and 848.69. Eudragit RLPO showed main peaks (cm^{-1}) at 2995.50, 2357.05, 1718.60, 1395.52, 1142.84, and 988.54. In ethyl cellulose sample, peaks (cm^{-1}) at 3488.32, 2975.25, 2362.84, 1748.50, 1375.27, and 919.10 were dominantly seen. Carbopol 971 illustrated peaks (cm^{-1}) at 2360.91, 1715.71, 1449.53, and 797.58. The physical mixture exhibited peaks (cm^{-1}) at 3458.43, 2922.21, 2343.55, 1723.43, 1464.96, and 852.55. From the interpretation of all FTIR spectrum data, it was found that there was no considerable change in the position of characterization absorption bands of drug [3517.26 (3458.43), 2928.96 (2922.21), 1468.82 (1464.96), and 853.52 (852.55)] and bonds of various functional groups present in the physical mixture sample. This spectrum clearly suggests that the drug remains in its normal form with no prominent change in its characteristics, even in its physical mixture. The results of FTIR spectra indicated the absence of any well-defined interaction between the granules **Fig. 1**.

RESULTS AND DISCUSSION:



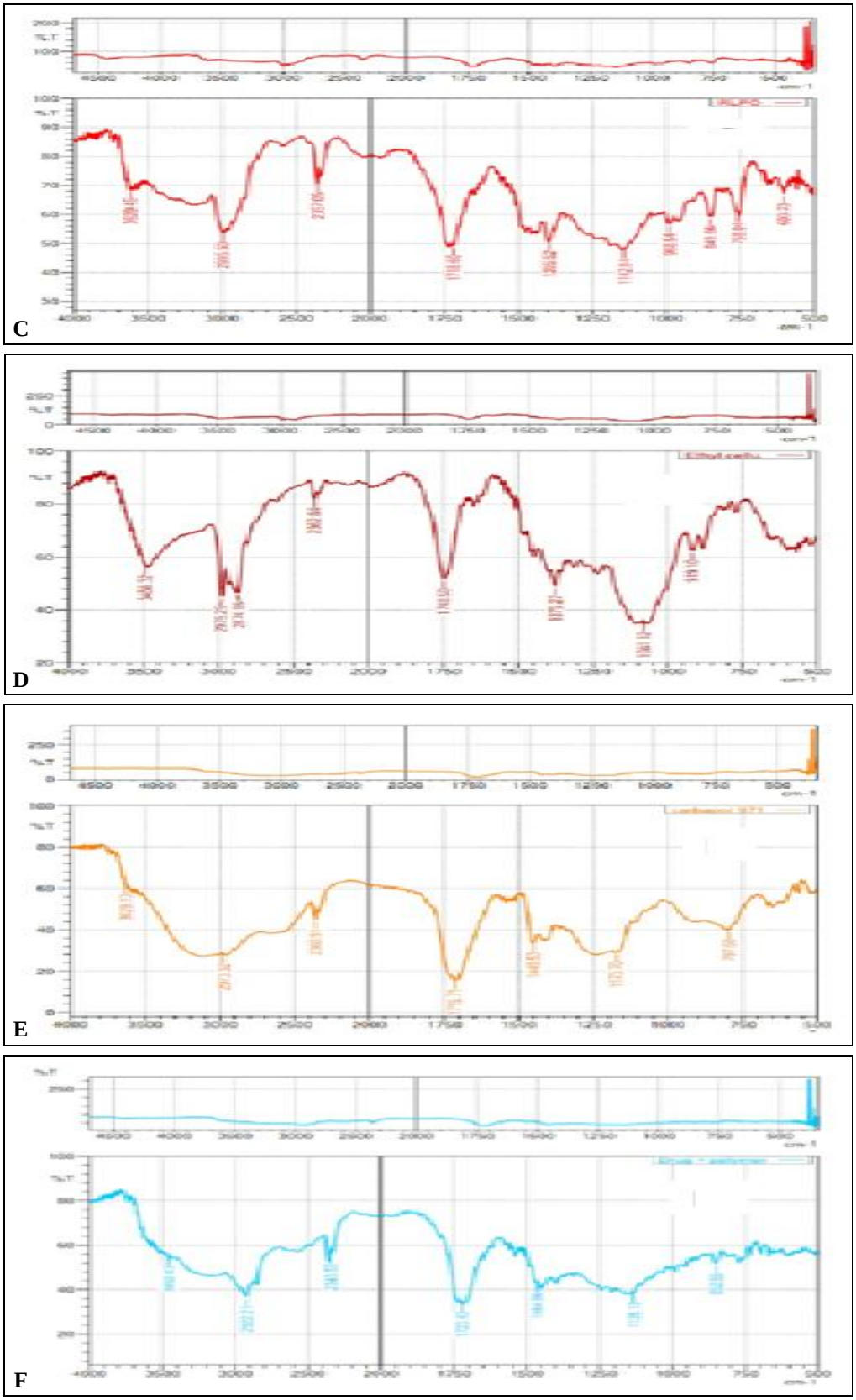


FIG. 1: FT-IR SPECTRA OF (A) OXYBUTYNIN CHLORIDE; (B) EUDRAGIT RSPO; (C) EUDRAGIT RLPO; (D) ETHYL CELLULOSE; (E) CARBOPOL 971 NF; AND (F) PHYSICAL MIXTURE

Micromeritic Properties: The results obtained by evaluating the powder blend of drug and excipients are shown in **Table 2**. The bulk density and tapped density were found in the range of 0.33-0.41 g/mL and 0.47-0.61 g/mL, respectively. The value of angle of repose (θ) was found in the range of 25.26

-37.23 showing that blend of powder mass has good flowing property. The value of Hausner's ratio in the range of 1.33-1.66 indicting that all batches of powder blends were having good compressibility.

TABLE 2: PRE-COMPRESSION PARAMETERS OF POWDER BLEND OF FORMULATION BATCHES

Batch	Bulk density* (g/ml) (mean ± SD)	Tapped Density* (g/ml) (mean ± SD)	Carr index (%)	Hausner's ratio	Angle of Repose (°)
F1	0.33 ± 0.0015	0.56 ± 0.015	32.12	1.66	33.66
F2	0.33 ± 0.0020	0.47 ± 0.0015	29.91	1.42	29.68
F3	0.39 ± 0.0015	0.55 ± 0.001	29.47	1.41	30.96
F4	0.37 ± 0.0015	0.61 ± 0.0015	38.85	1.63	25.26
F5	0.41 ± 0.0015	0.55 ± 0.0015	25.08	1.33	26.56
F6	0.41 ± 0.002	0.59 ± 0.002	31.27	1.45	35.29
F7	0.39 ± 0.0015	0.55 ± 0.002	29.47	1.41	34.68
F8	0.39 ± 0.0015	0.55 ± 0.001	29.49	1.41	37.23
F9	0.36 ± 0.0015	0.51 ± 0.001	29.53	1.41	29.50

*mean ± SD, n=3

The prepared tablets were subjected to different evaluation tests as per USP. The results of the tablet hardness test and friability test showed that the hardness and friability of all formulation were in the range from 5.6-5.9 kg/cm^2 and 0.38% to 0.62%, respectively. The hardness of all formulation was within specified limits. The thickness of all formulation found to be 5.16-4.12 millimeters. The post-compression characteristics of the formulation are given in **Table 3**.

Batch F5 showed least % friability, and Batch F6 showed the highest % friability amongst all formulations, it might be because the difference in concentration of Avicel PH 102 which was in higher concentration in batch F5 as compared to batch F6. The batch F7- F9 shows a slightly high swelling index as compared to other batches, might be due to the combination of two hydrophilic polymers; Eudragit RSPO and RLPO.

TABLE 3: POST-COMPRESSION PARAMETERS OF FORMULATION BATCHES

Batch no.	Average** weight (mg)	Average* Hardness (kg/cm^2)	Thickness* (mm)	Friability** (%)	Swelling index*	Drug content (%)
F1	152.2 ± 0.67	5.5 ± 0.1	4.58 ± 0.09	0.43	212.1 ± 1.050	104.07
F2	151.2 ± 0.54	5.8 ± 0.1	4.58 ± 0.07	0.49	223.2 ± 0.351	97.67
F3	150.7 ± 1.59	5.6 ± 0.1	4.31 ± 0.07	0.50	254.9 ± 1.41	98.84
F4	153.5 ± 2.53	5.6 ± 0.1	4.30 ± 0.07	0.49	185.7 ± 0.2	98.26
F5	152.1 ± 1.32	5,7 ± 0.1	4.82 ± 0.23	0.38	244.5 ± 0.503	100.11
F6	153.3 ± 2.41	5.7 ± 0.1	4.12 ± 0.41	0.62	193.4 ± 0.378	100.58
F7	152.2 ± 0.97	5.7 ± 0.1	4.96 ± 0.13	0.43	259.1 ± 0.264	95.93
F8	154.8 ± 2.58	5.9 ± 0.1	5.16 ± 0.01	0.54	241.4 ± 0.2	98.84
F9	150.9 ± 2.12	5.9 ± 0.1	4.69 ± 0.04	0.47	266.3 ± 1.00	101.16

*mean ± SD, n=3; **mean ± SD, n=10

Dissolution Studies: All the formulations F1-F9 were prepared with different concentrations Eudragit RSPO and Eudragit RLPO, ethylcellulose, and Carbopol 971 NF polymer. In the case of formulation batches, Carbopol 974 was replaced by Carbopol 971, which has low viscosity as compared to Carbopol 974. So, Carbopol 971 retarded the drug release to a greater extent as compared to Carbopol 974. The formulation batches F1-F9 containing the different concentrations of hydrophilic and hydrophobic polymer. F1-F3 Formulation batches contained Eudragit RSPO in different proportion showed the drug release 108.60% (20 h), 95.40% (20 h), and 98.97% (24 h), respectively **Table 4**. Batch F1-F3 contained Eudragit RSPO in different concentrations showed drug release of >95% in 24 h. F4-F6 Formulation batches contained Eudragit RLPO in different proportion showed the drug release 97.091% (14 h), 97.064% (19 h), and 95.409% (18 h), respectively.

TABLE 4: *IN-VITRO* DISSOLUTION STUDY OF FORMULATION BATCHES

Time (in hr)	Marketed Tablet	F1	F2	F3	F4	F5	F6	F7	F8	F9
Media (0.1 N HCl)										
1	0.00	11.51	3.29	1.64	11.51	1.64	3.29	9.87	1.64	3.29
2	1.64	16.45	8.22	1.64	16.45	4.93	4.93	23.03	3.29	3.29
Media (Phosphate buffer pH 6.8)										
3	4.91	29.54	14.77	3.28	27.90	11.48	8.20	27.94	18.01	8.20
4	13.11	39.43	21.35	4.92	41.06	16.42	13.13	37.79	19.73	11.50
5	18.07	47.67	27.93	8.20	59.13	23.00	16.43	46.02	24.65	16.42
6	23.00	57.53	34.51	11.50	69.05	27.94	21.36	60.80	27.95	24.63
7	24.67	69.04	37.82	14.79	80.56	34.51	27.93	73.97	31.24	27.95
8	27.95	77.29	41.11	18.08	90.44	37.82	39.42	83.86	36.17	34.51
9	34.51	85.51	44.40	21.37	93.77	44.39	47.67	87.19	41.10	47.64
10	39.46	93.74	50.97	27.93	95.42	54.24	57.53	93.75	44.40	54.26
11	42.76	95.42	54.28	34.51	95.43	59.20	62.50	88.88	47.70	67.39
12	46.05	97.07	55.93	41.10	97.07	64.14	67.43	101.94	50.99	70.73
13	50.98	97.08	60.85	46.04	98.71	69.08	70.73	103.6	54.28	74.02
14	54.28	95.44	64.15	52.61	97.09	72.38	77.30	103.6	57.57	77.31
15	57.57	88.80	69.08	59.20	-	80.58	83.88	-	60.86	83.88
16	60.86	98.67	75.65	64.14	-	85.53	87.19	-	67.42	87.19
17	64.15	102.00	78.96	72.35	-	90.47	90.48	-	74.00	90.48
18	69.08	105.29	83.89	80.58	-	93.77	95.40	-	77.31	92.13
19	75.65	108.58	90.46	83.90	-	97.06	-	-	80.60	95.41
20	77.32	108.60	95.40	85.55	-		-	-	85.53	97.07
21	80.60	-	-	90.47	-		-	-	93.74	-
22	85.53	-	-	93.77	-	-	-	-	-	-
23	90.47	-	-	95.95	-	-	-	-	-	-
24	97.04	-	-	98.97	-	-	-	-	-	-

In batches F7-F9, the combination of Eudragit RSPO and RLPO in different proportions was present it showed the drug release 103.664% (14 h), 93.745% (21 h), and 97.073% (20 h), respectively **Fig. 2**. The lightly cross-linked polymers, such as Carbopol 971 NF (lower viscosity) tend to be more efficient in controlling drug release than highly cross-linked polymer such as Carbopol 974 NF polymer (higher viscosity). All the formulations F1-F9 were prepared with different concentrations Eudragit RSPO and Eudragit RLPO and ethyl cellulose and Carbopol 971 NF polymers. The above graph showed the comparative drug release of different formulation batches F1-F9.

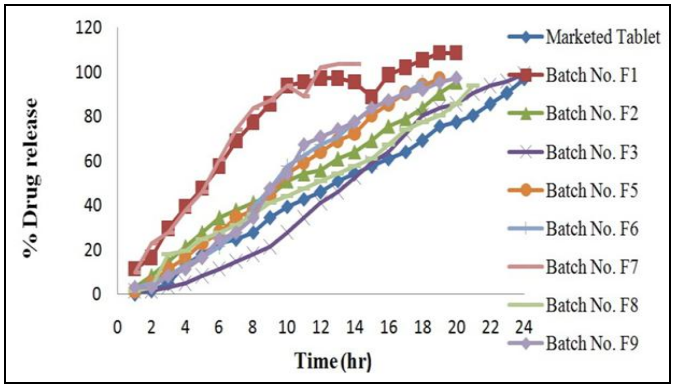


FIG. 2: COMPARATIVE DISSOLUTION STUDY OF MARKETED PRODUCT *vs*. FORMULATED BATCHES

Batch F3 which contains Eudragit RSPO in combination with Carbopol 971 and ethyl cellulose showed similar drug release patterns as compared to the reference product. From *in-vitro* dissolution study, it was found that drug release from extended-release tablets was affected by differences in the rates of hydration and swelling of the polymer hydrogel.

***In-vitro* Drug Release Kinetic Study:** In order to determine the mechanism of drug release from the formulation, the *in-vitro* dissolution data was fitted to zero order, first order, Higuchi plot, and Korsmeyer-Peppas plot was drawn for optimized formula and interpretation of release exponent value (n) was calculated. The result of R^2 for zero-order and the first order for the marketed tablet was found to be 0.996 and 0.773 R^2 for zero-order and the first-order for formulation F3 batch was found to be 0.963 and 0.911 **Table 5**, respectively. The best fit model was zero-order kinetic and Higuchi's model was applied to the *in-vitro* release data, and linearity was obtained with high 'r' value indicating that drug release from extended-release tablet through diffusion. The *in-vitro* release data was further fitted to the Korsmeyer-Peppas model. Good linearity was observed with high 'r' values.

The value of release exponent 'n' is an indication of the release mechanism. The value of 'n' obtained formulation F3 was found to be 1.052 suggesting probable release by super case-II transport (Non-Fickian).

TABLE 5: *IN-VITRO* DRUG RELEASE KINETIC STUDY

Batch	Zero-order	First-order	Higuchi's plots	Korsmeyer-Peppas plot		Best fit Model	Drug release mechanism
	R^2	R^2	R^2	R^2	n		
Marketed tablet	0.996	0.733	0.928	0.206	0.479	Zero order	Non- Fickian
F3 formulation	0.963	0.911	0.819	0.550	1.052	Zero order	Non-Fickian

Similarity Factor: Two fit factors, the similarity factor (f_2) and the difference factor (f_1) that compare the dissolution profile formulation of F3 and marketed formulation were applied to the dissolution data. Formulation F3 showed more comparative similarity factor (f_2) and less difference factor (f_1) with the marketed tablet, so it was selected as an optimized batch.

Accelerated Stability Study: Accelerated stability study for 3 months was performed for optimized batch F3 formulation and further evaluated for weight hardness drug content and *in-vitro* drug release. There was no significant change observed in physical appearance, average weight, hardness, drug content, and cumulative drug release after a three-month stability study, which results indicated that formulation is stable at test temperature and humidity condition **Table 6**.

TABLE 6: ACCELERATED STABILITY STUDIES OF THE OPTIMIZED FORMULATION

Parameters	Initial (0 months)	After 3 months
Physical appearance	White	White
Average weight (mg)	150.9 ± 0.52	149.2 ± 0.51
Hardness kg/cm^2	5.6 ± 0.1	5.6 ± 0.1
Drug content (%)	98.84	97.11
Cumulative drug release (%)	98.97 ± 0.06	98.89 ± 0.06

CONCLUSION: The extended-release matrix tablet by using hydrophilic and hydrophobic polymer in individual and combination in different concentrations of the polymer was formulated and evaluated. The compatibility study of pure drug and all excipients mixture was confirmed by FTIR studies. All pre-compression parameters, including bulk density, tapped density, compressibility index, and Hausner's ratio and post-compression parameters like weight variation, hardness, swelling index, drug content, and *in-vitro* dissolution was shown satisfactory result. The tablets were formulated by using the Eudragit RSPO, Eudragit RLPO, ethylcellulose, and Carbopol 971 NF. Among all batches, the F3 batch showed the expected drug release for an extended period of time (24 h). The lightly cross-linked polymers, such as Carbopol 971 NF polymer (lower viscosity) tend to be more efficient in controlling drug release than highly cross-linked polymer such as Carbopol 974 NF polymer (higher viscosity). Batch F4-F6 contained Eudragit RLPO in different proportion showed 97% drug release within 19 h. Formulation batches F7-F9 contained both Eudragit RSPO and Eudragit RLPO in different proportion showed maximum drug release within 20 h.

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