Formulation Design and Development of Mucoadhesive Tablets of Cefixime Trihydrate

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ABSTRACT :

Mucoadhesive tablets of Cefixime trihydrate were prepared using Carbopol 940P, HPMC K15M and Polyox WSR 303 as a mucoadhesive polymers and β-cyclodextrin as a solubility enhancer. Nine formulations were developed using 3^2 factorial designs. Carbopol 940P is used as a primary polymer because of its excellent mucoadhesive property and secondary polymers like HPMC K15M & polyox were used. The formulations were tested for in-vitro drug release, mucoadhesive strength, swelling studies, residence time and surface pH. Formulation F3 showed maximum release of 23.03% in 7 hrs. Formulation F5 showed maximum mucoadhesive strength and force of adhesion. Formulation F9 showed maximum swelling index of 83.76%. Formulation F5 and F4 showed maximum residence time. All formulation follows the Koresmeyer-Peppas model. Studies show that there is no evidence of interaction between drug and polymers.

Keywords: Mucoadhesive tablets, Cefixime trihydrate, mucoadhesive strength, direct compression.

INTRODUCTION:

Recently pharmaceutical industry have seen a steady shift in research from the development of new chemical entities to the development of Novel Drug Delivery System of existing drug molecules to maximize their effectiveness in terms of therapeutic action and patient protection. Mucoadhesive drug delivery system prolongs the residence time of the dosage form at the site of application or absorption and facilitate an intimate contact of the dosage form with the underline absorption surface and thus contribute to improved and better therapeutic performance of the drug . The localization of mucoadhesive delivery systems within a certain GI-segment, ideally where the drug has its absorption window, would lead to a tremendous improvement in the oral bioavailability of these drugs.

Cefixime is an antibacterial agent of the cephalosporin class. It is used in various infections like Otitis, Sinusitis and Pharyngitis. Like other cephalosporins, Cefixime exerts antibacterial activity by binding to and inhibiting the action of penicillin-binding proteins involved in the synthesis of bacterial cell walls. This leads to bacterial cell lysis and cell death. Cefixime trihydrate is a BCS class-IV drug. Therefore the bioavailability of Cefixime trihydrate is very poor. The absolute oral bioavailability of Cefixime is in the range of 22-54 %. Because of poor bioavailability there is a need to increase its bioavailability by forming a mucoadhesive dosage forms. The half life of Cefixime trihydrate is about 3-4 Hrs. Hence, Cefixime trihydrate is a suitable drug for mucoadhesive dosage form and may provide a better therapeutic profile.

In the present work, mucoadhesive tablets of Cefixime trihydrate were prepared using polymers like Carbopol 940P, HPMC K15M, Polyox WSR 303, β-cyclodextrin and tween 80. A full 3^2 factorial design was used, where the amounts of Carbopol 940P (X^1) and HPMC K15M (X^2) were selected as factors. The levels of the two factors were selected on the basis of preliminary studies carried out before implementing the experimental design.

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MATERIALS AND METHOD

Cefixime trihydrate was provided as gift sample from Medley Lab, Mumbai. Carbopol 940P and β-cyclodextrin was obtained as gift sample from Microlabs, Bangluru. Hydroxypropyl methyl cellulose (HPMC K15M) was gifted by Wockhardt Ltd., Aurangabad. Polyox WSR 303 was obtained from Colorcon India Pvt. Ltd., Goa. All other excipients and chemicals used were of analytical grade.

Preparation of Mucoadhesive Tablets:

Table-3 enlists the composition of different mucoadhesive formulations prepared using varying amounts of polymers (CP 940P and HPMC K15M). Polyox WSR 303 was added as one of the mucoadhesive polymer to increase the mucoadhesive strength of tablets. β-cyclodextrin were added as a solubility enhancer and tween 80 were used as permeation enhancer because Cefixime trihydrate is a BCS class-IV drug. PVP K30 was used as a binder, magnesium stearate as lubricant and Avicel PH101 was used as diluent. 3^2 factorial design was used for the formulation of mucoadhesive tablets of Cefixime trihydrate, where the amounts of Carbopol 940P ($X^{1)}$ and HPMC K15M (X^2) were selected as factors. Factor combination as per chosen experimental design and translation of code levels in actual units shown in Table-1 and Table-2 respectively. The drug and excipients were homogenously blended and subsequently compressed into flat faced tablets (500 mg, 11 mm diameter), using 12-station Karnavati tablet compression press. Tablets were compressed by direct compression method.

Evaluation of Formulation:

Assay of Cefixime trihydrate

Required quantity of blends of batches F1 to F9 were weighed and dissolved in 50 ml of 0.05 M monobasic potassium phosphate buffer solution of pH 7.2. From this 0.5 ml of solution was pipetted and diluted to 10 ml using 0.05 M monobasic potassium phosphate buffer solution of pH 7.2 The absorbance of the final solution was taken by using UV-Visible spectrophotometer at λmax of 284 nm.

Study of Drug-Polymer Interaction

Drug polymer interaction was studied by Infrared spectroscopy. 1 mg of blend mixed with potassium hydroxide and pellets were prepared by using hydraulic pressure and subjected to IR spectroscopy. The spectrum was recorded using Schimadzu FTIR spectrophotometer.

Pre-compression Study

Determination of Bulk Density and Tapped Density

20 g of the mixed blend (W) was introduced into a 100 ml measuring cylinder, and the Initial volume was observed. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 sec intervals. The tapping was continued until no further change in volume was noted. The bulk density, and tapped density were calculated using the following formulae;

$$Bulk\ density = W/Vo\ ;\quad Tapped\ density = W/Vf$$

Where; W = weight of the granules, Vo= initial volume of the granules and Vf = final volume of the granules

Determination of Angle of Repose

Angle of repose is an indication of the frictional forces existed between granule particles. It is the maximum angle possible between the surface of the pile of granules and the horizontal plane. The angle of repose was calculated using the following formula;

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

Where; θ = angle of repose, h = height of the powder heap, r = radius of the powder heap

Compressibility Index (Carr's Index)

Compressibility index is an important measure that can be obtained from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. A material having values of less than 20% has good flow property. Carr's Index was calculated using the following formula;

$$\text{Carr's index: } (\text{Tapped density-Bulk density/Tapped Density}) \times 100$$

Hausner's Ratio

It indicates the flow properties of the granules and is measured by the ratio of tapped density to the bulk density. Hausner's ratio was calculated using the following formula;

$$\text{Hausner's ratio} = \text{Tapped density/Bulk density}$$

Post-Compression Study

Tablet hardness, thickness, diameter, friability test, weight variation tests were performed as per the provisions of Indian Pharmacopoeia.

Tablet Hardness

Hardness of five randomly chosen tablets of each batch was checked by using Monsanto hardness tester. The hardness was measured in terms of kg/cm^2.

Friability Test

Percentage friability was calculated by using the formula;

$$\%\ friability = (Initial\ weight\ of\ the\ tablet - Final\ weight\ of\ the\ tablet / Final\ weight) \times 100$$

Tablet Thickness

Thickness was measured using Vernier Calipers.

Uniformity of Drug Content

From individual batch five tablets were powdered in glass mortar and powder equivalent to 20 mg of drug was placed in 50 ml volumetric flask. The powder was dissolved in 50 ml 0.05 M monobasic potassium phosphate pH 7.2 buffer solution this solution was sonicated to dissolve the drug completely. From this 0.5 ml of solution was pipetted out and diluted to 10

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ml using 0.05M monobasic potassium phosphate pH 7.2 buffer solution. The absorbance of final solution was taken by using UV-Visible spectrophotometer at λmax of 284 nm.

In-Vitro Drug Release Studies

The dissolution study was carried out in USP XXIII tablet dissolution test apparatus-II, employing paddle stirrer at 100 rpm and 900 ml of 0.05 M monobasic potassium phosphate buffer pH 7.2 maintained at 37±0.5^{0}C. Three tablets from each batch were taken for dissolution study. At different time intervals as 0.5 hr, 1 hr up to 7 hrs, 5ml sample was withdrawn and replaced with fresh medium to maintain sink condition. Samples were filtered and analyzed for Cefixime trihydrate by using UV-Visible Spectrophotometer at λmax of 284 nm. The cumulative percent drug release (CPDR) was calculated by using following formula

$$\%\ CPDR = Amount\ drug\ release \times 100 / Dose$$

Determination of Swelling Index

Three tablets were individually weighed (W1) and placed separately in petri plates with 10 ml of 0.05 M monobasic potassium phosphate buffer of pH 7.2. At the time interval of 0.5 hr, 1 hr, 2 hr upto 6 hr. Tablet was removed from the petri plates and excess water was removed carefully using the filter paper. The swollen tablet was then reweighed (W2) and the swelling index was calculated using the following formula;

$$Swelling\ Index = (W2 - W1)/W1 \times 100$$

Where; W1 = Initial weight and W2 = Final weight

Determination of Mucoadhesive Strength:

Bioadhesion test apparatus employed for the purpose was a modification of the apparatus reported by Gupta *et al* (1992) that involved a modified double beam physical balance. Both the pans of the physical balance were removed. The right hand pan was replaced with the lighter plastic pan and on the left hand side of the balance a flat round pan was placed, height of it was adjusted in such a way that it was just 5 mm above the stand which was placed below it to keep the mucosa. The two sides of the balance were balanced.

Sheep intestinal mucosa was used as a model membrane for the measurement of bioadhesive strength. The mucosal membrane was excised by removing the underlying connective tissue. After washing thoroughly with 0.05 M monobasic potassium phosphate buffer pH 7.2, it was kept on the stand which is below to left hand side pan and the mucosa was tied to it using a thread. Another cleaned piece of intestinal mucosa was tied to left hand side pan using a thread. Before carrying out the investigation, the two sides of the balance were equilibrated. The tablet was hydrated by using 0.05 M monobasic potassium phosphate buffer pH 7.2 and then placed on stand between both intestinal mucosa. The assembly was kept undisturbed for 3 min and sand was slowly added to the plastic pan on the right hand side till the tablet detached from the membrane surface. The excess weight on the right hand side i.e. total weight in gm was taken as a measure of the bioadhesive strength.

Determination of Surface pH

A combined glass electrode was used for this purpose. The tablets were allowed to swell by keeping them in contact with 1 ml of distilled water (pH 6.5 ± 0.1) for 2 hr at room temperature and pH was noted by bringing the electrode in contact with the surface of the tablet, allowing it to equilibrate for one minute.

Determination of Residence Time

The mucoadhesive property of tablets was evaluated using sheep intestinal mucosa tissue. The dissolution apparatus was used for this purpose. The time taken for the mucoadhesive tablet to detach from the mucosal section in a well-stirred beaker was used to assess the mucoadhesive performance. The fresh cut tissue was fixed to the one side glass slide by using thread. Before addition of the buffer, tablets were attached to intestinal mucosal tissue by applying light force for 20 sec. The beaker was then filled with 250 ml 0.05M monobasic potassium phosphate buffer pH 7.2 and kept at a temperature of 37 °C. A stirring rate of 100 rpm was maintained to simulate the intestinal movement. The time for the tablets to detach from the mucosal tissue was recorded up to 8 hr. The average values were reported after repeating the experiments three times for individual batch.

RESULTS

The results of bulk density and tapped density were found in the range of 0.40-0.47 g/cm3 and 0.58 - 0.66 g/cm3. The compressibility index was found between 27.69-34.42%. Hausner's ratio was found within the range of 1.41-1.52. The angle of repose was range of 21.30°-40.69°. The precompressional results are shown in table-4. The assay result of the blend was found between 73.25-91.80 %, the result is shown in table-5. Hardness of all the tablets prepared by direct compression method was maintained within the range of 4.1±0.1 kg/cm2 to 4.5±0.1 kg/cm2. In all the formulations the hardness test indicates good mechanical strength. The mean thickness was almost uniform in all the formulations and values of tablets prepared were ranged from 4.4 ± 0.2 mm to 5.0 ± 0.2 mm. The standard deviation values indicated that all the formulations were within the range. The results of thickness for tablets were shown in table-6. The friability was found in all formulations in the range 0.00 to 0.422% to be well within the approved range (<1%) which indicates the tablets had good mechanical resis-

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tance. The weight variation was found in the range of 497-503 mg. The weight variation results revealed that average percentage deviation of 20 tablets of each formula was less than ± 7.5% i.e. in the Pharmacopoeial limits, which provide good uniformity in all formulations. The uniformity drug content of each batches were determined. The drug contents were in the range of 86.05 % to 92.76%. The post-compressional results are shown in table-6.

The batches F1 to F9 were evaluated for water uptake study and the results are shown in table-8. The results of mucoadhesive strength and force of adhesion are shown in table- 9 and 10. The results for surface pH and residence time are shown in table-11 and 12. The cumulative % drug release of batches F1 to F9 are shown in table-7. The comparative performance of all batches with reference to mucoadhesive strength, force of adhesion, surface pH and residence times is shown in figure 1-4. The in-vitro release obeyed Koresmeyer-Peppas model of kinetics with mechanism of release was diffusion followed by Non-Fickian diffusion due to more hydrophilic nature of polymer.

Trial Bach	Coded factor levels	
	X_1	X_2
F1	-1	-1
F2	-1	0
F3	-1	+1
F4	0	-1
F5	0	0
F6	0	+1
F7	+1	-1
F8	+1	0
F9	+1	+1

Table 1: Factor combinations as per the chosen experimental

Factors	Coded level		
	-1	0	+1
Carbopol 940P (X1)	10	20	30
HPMC K15M (X2)	80	100	120

Table 2: Translation of code levels in actual units

Formulation Table (weight of all ingredients in mg for one tablet)									
Ingredients/ Batches	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cefixime	200	200	200	200	200	200	200	200	200
Carbopol 940	10	10	10	20	20	20	30	30	30
HPMC K 15 M	80	100	120	100	80	120	80	100	120
β – Cyclodextrins	25	25	25	25	25	25	25	25	25
Polyox	20	20	20	20	20	20	20	20	20
PVP K-30	25	25	25	25	25	25	25	25	25
Magnesium stearate	5	5	5	5	5	5	5	5	5
Avicel pH 101	110	90	70	80	100	60	90	70	50
Tween 80	25	25	25	25	25	25	25	25	25
Total wt. of tablet (mg)	500	500	500	500	500	500	500	500	500

Table3: Formulation table of tablets

Formulation Code	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index	Hausner's ratio	Angle of repose (°)	Flow rate (sec)
F1	0.45±0.006	0.66±0.006	30.76	1.47	23.74	21.67±0.58
F2	0.40±0.006	0.58±0.006	29.82	1.43	40.69	36.67±0.58
F3	0.40±0.006	0.62±0.006	34.42	1.53	27.27	27.33±0.58
F4	0.43±0.006	0.60±0.006	28.33	1.41	23.26	28.33±0.58
F5	0.43±0.006	0.63±0.012	31.74	1.48	29.68	24.67±0.58
F6	0.40±0.006	0.61±0.012	34.42	1.52	22.78	29.67±0.58
F7	0.44±0.006	0.66±0.006	32.3	1.50	21.30	9.67±0.58
F8	0.47±0.006	0.66±0.006	27.69	1.41	24.22	4.33±0.58
F9	0.45±0.012	0.66±0.006	31.81	1.46	23.74	13.67±0.58

Table 4: Pre-compression parameter results of blend Cefixime trihydrate

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
% Purity	86.05	74.30	90.25	77.60	81.30	91.80	73.25	74.30	83.00

Table 5: Percentage purity of blends of mucoadhesive tablets of Cefixime trihydrate

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Formulation	Hardness (kg/cm^2)	Thickness (mm)	Diameter (mm)	% Friability	Weight variation (mg)	% Purity
F1	4.4 ± 0.1	4.6 ± 0.2	11 ± 0	0.000	498 ± 8.64	87.23
F2	4.26 ± 0.1	4.6 ± 0.2	11 ± 0	0.223	497 ± 9.9	86.02
F3	4.4 ± 0.1	4.7 ± 0.2	11 ± 0	0.000	499 ± 6.22	90.25
F4	4.4 ± 0.1	5.0 ± 0.2	11 ± 0	0.195	500 ± 9.20	90.13
F5	4.4 ± 0.1	4.6 ± 0.2	11 ± 0	0.000	496 ± 6.76	86.91
F6	4.4 ± 0.1	4.4 ± 0.2	11 ± 0	0.000	497 ± 6.11	92.76
F7	4.4 ± 0.1	4.4 ± 0.2	11 ± 0	0.422	500 ± 4.25	89.73
F8	4.4 ± 0.1	4.6 ± 0.2	11 ± 0	0.000	503 ± 9.92	87.23
F9	4.4 ± 0.1	4.6 ± 0.3	11 ± 0	0.000	501 ± 6.73	89.86

Table 6: Post-compression parameter results Cefixime trihydrate tablets

Time in (hr)	% Cumulative Drug Release								
	Formulation Code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	3.92	3.79	3.77	3.9	3.74	4.47	2.84	2.92	2.57
1	6.59	6.50	6.46	6.14	5.99	5.38	4.4	4.79	4.19
2	10.70	10.70	10.61	10.02	9.72	10.09	7.32	8.26	6.74
3	16.02	14.74	11.09	14.94	12.37	11.66	10.14	10.53	9.45
4	17.59	16.05	18.61	16.32	15.47	15.08	12.43	13.27	11.8
5	21.55	20.02	17.90	18.09	17.46	15.7	13.66	15.05	13.46
6	21.91	21.01	21.58	20.56	19.18	17.69	15.4	16.29	14.11
7	22.42	21.77	23.02	21.86	22.4	19.58	15.47	17.22	15.18

Table 7: *In-vitro* drug release studies

Time (hr)	Batch								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	21.01	18.42	22.50	22.33	22.53	22.66	24.15	19.88	19.6
1.0	28.88	25.10	27.49	31.38	33.80	29.72	31.08	33.00	25.74
2.0	36.56	33.60	38.24	37.02	39.03	39.50	39.80	40.55	37.22
3.0	37.77	37.44	42.23	41.04	47.68	53.84	43.96	51.29	49.3
4.0	41.01	40.28	55.17	43.25	50.30	58.62	50.49	57.85	59.8
5.0	44.44	43.52	59.56	47.88	57.14	65.58	60.00	74.75	73.86
6.0	54.14	48.78	68.32	57.54	64.58	75.05	65.94	82.10	83.76

Table 8: % Swelling index

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
Mucoadhesive strength	16.52	24.46	15.09	64.19	64.69	47.11	32.95	42.04	30.54

Table 9: Observation for mucoadhesive strength

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
Force of Adhesion	0.161	0.239	0.147	0.629	0.633	0.461	0.322	0.411	0.299

Table 10: Force of adhesion of mucoadhesive tablets

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
pH	4.37	4.37	3.89	4.15	4.08	4.63	4.70	4.17	4.22

Table 11: Surface pH of mucoadhesive tablets

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
Residence time	4.1	4.5	4.0	7.1	7.1	6.1	5.2	5.7	5.3

Table 12: Residence time of mucoadhesive tablets

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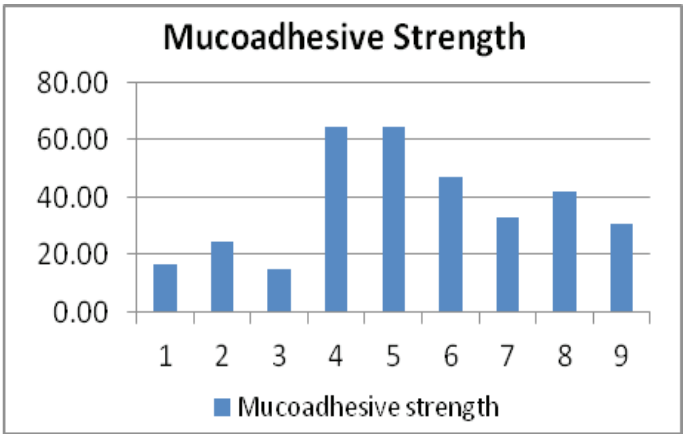

Fig.1: Graph for Mucoadhesive Strength

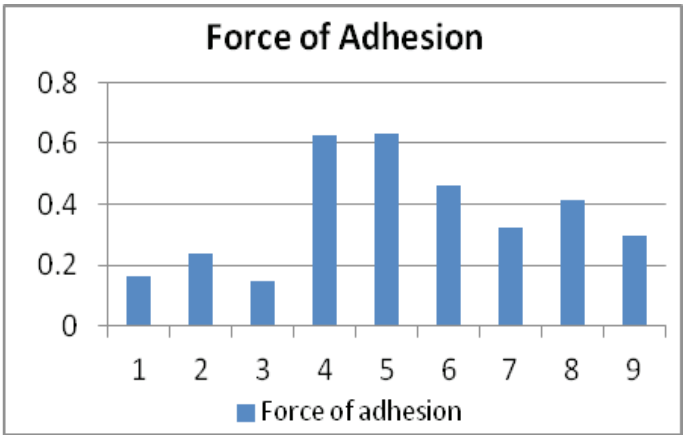

Fig.2: Graph for Force of Adhesion

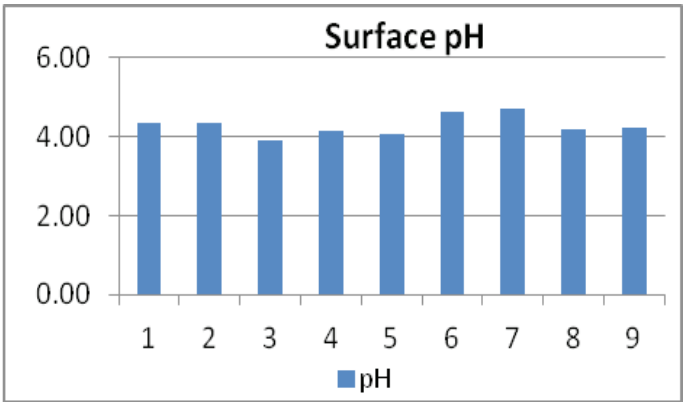

Fig.3: Graph for the Surface pH

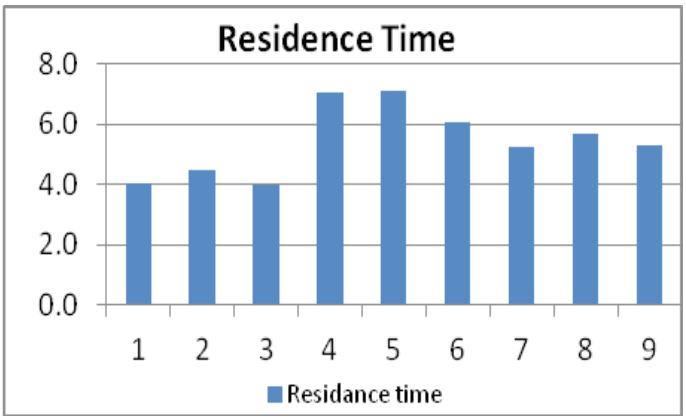

Fig.4: Graph for the Residence Time

DISCUSSION AND CONCLUSION

The mucoadhesive tablets of Cefixime trihydrate could be prepared using polymers with combination like Carbopol 940P and HPMC K15M by direct compression method. The IR study suggested that there was no drug-polymer interaction. All the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability and drug content as per Pharmacopoieal specification. The surface pH of prepared mucoadhesive tablets was not in the range of strong acidic pH or strong basic pH it was found to be near to neutral pH, suggested that prepared tablets could be used without risk of mucosal irritation. In-vitro release of mucoadhesive buccal tablets of Cefixime trihydrate was extended up to 7 hrs. Tablets containing CP 940P 30 mg and HPMC K 15M 120 mg (batch F3) showed the maximum release whereas formulations containing high concentration of CP 940P showed minimum release. Therefore it is concluded that as the concentration of CP 940P increases the release rate decreases. As the concentration of HPMC K15M increases the release rate is also increases. The in-vitro release obeyed Koresmeyer-Peppas model of kinetics with mechanism of release was diffusion followed by non-Fickian diffusion due to more hydrophilic nature of polymer. The increase in concentration of Carbopol 940P did not significantly ($p>0.05$) affect the in vitro release of Cefixime trihydrate. The mucoadhesive tablets showed good swelling up to 6 hrs in 0.05 M monobasic potassium phosphate buffer pH 7.2 maintaining the integrity of formulation which is required for bioadhesion. As the concentration of Carbopol 940P and HPMC K15M increases the swelling is also increases. The formulation containing maximum concentration of Carbopol 940P and HPMC K15M i.e. batch F9 showed maximum swelling index. All the tablets showed good mucoadhesive strength of 15.09 to 64.69 gm with high force of adhesion. The mucoadhesive strength was enhanced by the addition of secondary polymers like HPMC K15M, Polyox WSR 303. All the tablets showed good force of adhesion of 0.1478 to 0.6339 which shows good attachment to mucosal membrane. All the tablets showed good residence time of 3.50 to 6.50 hrs, indicated good adhesive capacity of polymers used.

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