



## Development and Evaluation of Gastroretentive Film of Gabapentin

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### ABSTRACT

Gabapentin is among others, is an anticonvulsant medication primarily used to treat neuropathic pain and also for partial seizures of epilepsy. The research work aims to formulate and evaluate the Gastro retentive mucoadhesive film of Gabapentin using polymers like HPMC K15M, PVA, MD and Propylene Glycol (PG) as a plasticizer by solvent casting method for treatment of partial seizures of epilepsy. Prepared gastro retentive mucoadhesive films were evaluated for various parameters such as in-vitro unfolding behaviour of film, Folding endurance, Percent swelling, Drug content and *in-vitro* drug release studies. The release rate of the gastro retentive mucoadhesive films of Gabapentin was found to obey Korsmeyer Peppas kinetics. After analysis of different evaluation parameters and drug release kinetics. Formulation code F4 was selected as a promising formulation for delivery of Gabapentin as a mucoadhesive Gastro retentive film with required in-vitro parameters 99.10% drug release at 12th h.

**Keywords:** Gabapentin, Gastro retentive mucoadhesive film and solvent casting technique.

### INTRODUCTION

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration leads to high level of patient compliance. The oral route is problematic because of the swallowing difficulty for paediatric and geriatric Patients who be afraid of choking. Patient convenience and compliance-oriented research have resulted in bringing out safer and newer drug delivery systems. Recently, fast dissolving drug delivery systems have started gaining popularity and acceptance as one such example with increased consumer choice, for the reason of rapid disintegration or dissolution, self-administration even without water or chewing<sup>1</sup>. Fast dissolving drug delivery systems were first invented in the late 1970s as to overcome swallowing difficulties associated with tablets and capsules for pediatric and geriatric patients. Buccal drug delivery has lately become an important route of drug administration. Various bioadhesive mucosal dosage forms have been developed, which includes adhesive tablets, gels, ointments, patches, and more recently the use of polymeric films for buccal delivery, also known as mouth dissolving films<sup>2</sup>.

### Advantages

- ❖ Oral films have some special advantages over other oral dosage forms given as follows:
- ❖ Rapidly dissolved and disintegrated in the oral cavity because of large surface area which lowers dosage interval, improves onset of action, efficacy and safety profile of therapy<sup>3</sup>.

- ❖ Oral films are more flexible, compliant and are not brittle as ODTs.
- ❖ Easily handled, storage and transportation<sup>4</sup>.

### METHODOLOGY

- I) Drug Polymer Compatibility Studies Using FTIR
  - II) Construction of Calibration Curve
  - III) Preparation of Films and filled in Empty Capsule shell
  - IV) Evaluation of Films filled in Empty Capsule shell
- 1) In-vitro Unfolding Behavior of the Film
  - 2) Folding Endurance of Film
  - 3) Drug Content
  - 4) Swelling Index
  - 5) In-vitro Dissolution Studies

### Selection of the drug:

The Gabapentin which has significantly different pharmacokinetic profiles. Gabapentin is a Neurontin among others, is an anticonvulsant medication. Primarily used to treat neuropathic pain and also for partial seizures of epilepsy. It is a commonly used medication for the treatment of neuropathic pain caused by diabetic neuropathy, postherpetic neuralgia, and central pain. It is moderately effective: about 30–40% of those given gabapentin for diabetic neuropathy or postherpetic neuralgia have a meaningful benefit Gabapentin was soluble in water and in solvents. Gabapentin was stable at salivary pH.



**Construction of calibration curve for Gabapentin:****Determination of  $\lambda_{max}$** 

Gabapentin  $\lambda_{max}$  was determined by spectrophotometer using pH 6.8 buffer medium. First dissolve 10mg of pure drug in 10ml of 6.8 buffer medium. From this 10 $\mu$ g/ml solution was prepared by using 6.8 buffer. 10 $\mu$ g/ml solution absorbance was measured at 200-400 nm range by spectrophotometrically using 6.8 buffer as reference solution.

**Preparation of calibration curve:**

1. Primary stock solution: Standard calibration curve of Gabapentin in 6.8 buffer were prepared. First dissolve 10mg of pure drug in 10ml of 6.8 buffers this is primary stock solution.

2. Second stock solution: From the above primary stock solution pipette out 1ml of Solution and again make up to 10ml this is secondary stock solution. From this secondary stock solution different concentrations of Gabapentin (5, 10, 15, 20, And 25  $\mu$ g/ml) in 6.8 buffer were prepared and absorbance of these solutions Measured at 265 nm by spectrophotometrically using 6.8 buffer as reference solution.

**Preparation of mouth dissolving films****1. Solvent casting**

In this method water soluble polymer is dissolved in suitable solvent to make Homogenous viscous solution. In this other excipient (plasticizer and sweetener) including Drug resinate complex were dissolved under stirring. Then the solution is degassed by keeping it in the sonicator. The resulting bubble free solution poured into Petri plate and was kept in oven. Dried film is then cut into the desired shape and size for the intended Application. Preparation of blank films using different polymers

**Procedure:**

- Accurately weighed quantity of polymer was dissolved in specific quantity of Water.

**Formulation of Gabapentin oral Gastro-retentive films****Table 1:** Composition of Gabapentin Gastro-retentive films

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Gabapentin	100	100	100	100	100	100	100	100	100
Polyvinyl alcohol	25	50	75	-	-	-	-	--	-
Maltodextrin	-	-	-	25	50	75	-	-	-
Propylene glycol	-	-	-	-	-	-	25	50	75
HPMC K15M	100	200	300	100	200	300	100	200	300
D.W	qs	qs	qs	qs	qs	qs	qs	qs	Qs
Citric Acid	10	10	10	10	10	10	10	10	10
Cross Povidone	15	15	15	15	15	15	15	15	15
Mannitol	15	15	15	15	15	15	15	15	15
Total weight	100	100	100	100	100	100	100	100	100

- The dissolved polymer was made to a uniform dispersion using a Homogenizer.
- During stirring other excipients (plasticizer and sweetener) were added.
- Then the solution is degassed by keeping it in the Sonicator.
- The bubble free solution poured into Petri plate and was kept in oven.
- Then the dried films were used to select the best film forming polymers.

**Selection of best film forming polymer**

The polymer employed should be non-toxic, non-irritant and devoid of leachable impurities. It should have good wetting and Spreadability property. The polymer should exhibit sufficient peel, shear and tensile strengths. The polymer should be readily available and should not be very expensive. Film obtained should be tough enough to avoid the damage while handling or during transportation. Different Polymers Used for Trails PVA ; MD ;PG Preparation of oral Gastro-retentive films.

The Gastro-retentive films of Gabapentin were prepared by solvent casting technique.

The Gastro-retentive films were prepared using different polymers like PVA, MD, Propylene Glycol (PG). Propylene Glycol (PG) and HPMC K15M was used as plasticizer. The calculated amount of polymer was dispersed in the solvent with continuous stirring using magnetic stirrer and the homogenous solution is formed. Then add 4 ml of plasticizer. Then the sweetener and flavor were added to drug mixed polymeric solution. Then the solution was kept in sonicator for degassing. Then the bubble free solution was casted on to Petri plates and was kept in hot air oven. Then the obtained films were cut into required dimensions (4 cm  $\times$  2 cm) and folded in accordion pattern, and inserted into a 00-size capsule, and are evaluated.

## RESULTS AND DISCUSSION

### Analytical Method Development for Gabapentin Construction of Calibration Curve:

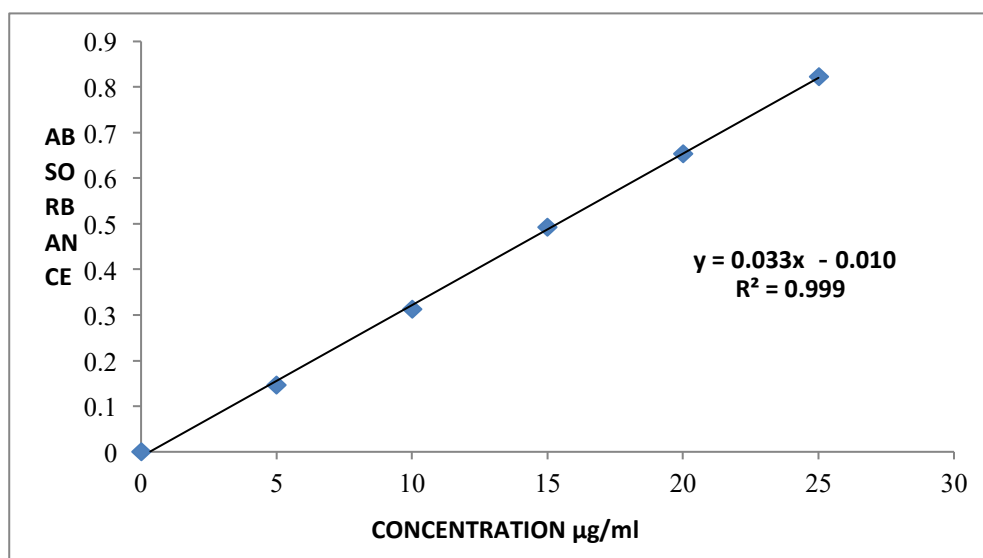
Gabapentin  $\lambda_{\max}$  was determined by spectrophotometer using pH 6.8 buffer medium. First dissolve 10 mg of pure drug in 10 ml of 6.8 buffer medium. From this 10  $\mu\text{g/ml}$  solution was prepared by using 6.8 buffer. 10  $\mu\text{g/ml}$  solution absorbance was scanned at 200 to 400 nm range by spectrophotometrically using 6.8 buffer as reference solution and  $\lambda_{\max}$  was observed at 265 nm. A standard graph of pure drug in suitable medium was prepared by plotting the concentration ( $\mu\text{g/ml}$ ) on X-Axis and absorbance on Y-Axis. An excellent correlation co-efficient ( $R^2=0.999$ ) was observed.

*In vitro* dissolution study of formulations F1-F9 shown good drug release respectively up to 12hours. Among the all

formulations F4 showed good dissolution property. F4 batch contains Maltodextrin and HPMC K15M as film forming polymer.

**Table 2:** Calibration Curve values of Gabapentin in phosphate buffer pH 6.8 at  $\lambda_{\max}=265\text{nm}$

Concentration ( $\mu\text{g/ml}$ )	Absorbance $\lambda_{\max}=265\text{ nm}$
0	0
5	0.147
10	0.313
15	0.492
20	0.654
25	0.823



**Figure 1:** Calibration curve of Gabapentin in pH 6.8 phosphate buffer at  $\lambda_{\max}=265\text{ nm}$

### *In-vitro* tests of film:

**Table 3:** *In vitro* evaluation results for all formulations:

Code	Visual Appearance	<i>In vitro</i> unfolding behavior (min) Mean $\pm$ S.D (n=3)	% Drug content Mean $\pm$ S.D (n=3)	Folding endurance (times $\pm$ S.D) (n=3)	Swelling index (%) Mean $\pm$ S.D (n=3)
F1	Transparent	15 $\pm$ 0.57	98.8 $\pm$ 0.23	179 $\pm$ 0.26	104.1 $\pm$ 0.16
F2	Transparent	14 $\pm$ 0.12	99.3 $\pm$ 0.69	180 $\pm$ 0.14	95.3 $\pm$ 0.28
F3	Transparent	17 $\pm$ 0.36	97.1 $\pm$ 0.46	181 $\pm$ 0.62	98.1 $\pm$ 0.30
F4	Transparent	14 $\pm$ 0.47	99.9 $\pm$ 0.16	178 $\pm$ 0.96	100.0 $\pm$ 0.41
F5	Transparent	15 $\pm$ 0.61	98.3 $\pm$ 0.93	178 $\pm$ 0.40	99.9 $\pm$ 0.65
F6	Transparent	12 $\pm$ 0.92	99.1 $\pm$ 0.77	184 $\pm$ 0.62	98.2 $\pm$ 0.44
F7	Transparent	15 $\pm$ 0.44	96.6 $\pm$ 0.90	182 $\pm$ 0.13	96.4 $\pm$ 0.29
F8	Transparent	18 $\pm$ 0.39	98.7 $\pm$ 0.14	185 $\pm$ 0.42	101.3 $\pm$ 0.42
F9	Transparent	16 $\pm$ 0.20	97.6 $\pm$ 0.36	181 $\pm$ 0.82	102.2 $\pm$ 0.22

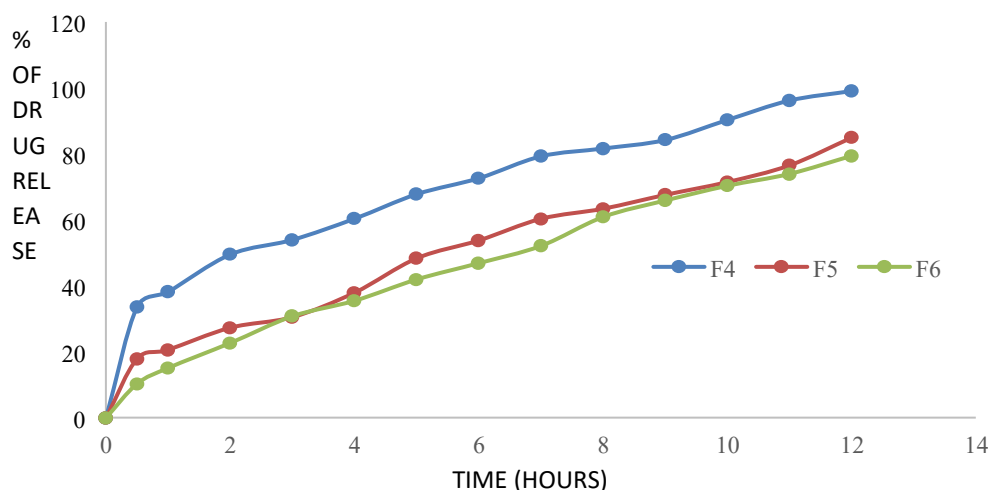
### *In-Vitro* dissolution studies

Dissolution profiles from films of Gabapentin were carried out in USP dissolution apparatus-II. The results are reported in the table 4.



**Table 4:** *In vitro* drug releases for F1 to F9 formulations

Time (H)	Cumulative Percent Drug Released								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	35.6	15.9	25.6	33.60	17.86	10.31	12.2	9.3	8.5
1	52.8	25.6	36.7	38.19	20.62	15.10	22.3	12.3	14.5
2	69.4	35.6	48.5	49.52	27.31	22.68	33.4	32.1	18.4
3	78.3	52.8	52.3	53.96	30.53	30.78	53.6	44.6	23.4
4	88.4	69.4	69.4	60.37	37.94	35.48	73.8	53.6	28.2
5	96.6	78.3	78.4	67.82	48.36	41.94	88.2	68.5	32.1
6		88.4	87.3	72.65	53.78	46.87	97.4	74.5	44.6
7		96.6	92.5	79.29	60.33	52.10		83.2	53.6
8			95.2	81.66	63.39	60.87		89.3	68.5
9			98.3	84.25	67.59	65.85		92.3	74.5
10				90.33	71.48	70.32		98.2	83.2
11				96.21	76.55	73.92			89.3
12				99.10	84.95	79.40			98.3



**Figure 2:** Comparison curve of *In vitro* drug release for F4- F6 formulations

**Table 5:** Release kinetics of optimized formulation.

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG ( T )	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	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
33.6	0.5	0.707	1.526	-0.301	1.822	67.200	0.0298	-0.474	66.4	4.642	4.049	0.592
38.19	1	1.000	1.582	0.000	1.791	38.190	0.0262	-0.418	61.81	4.642	3.954	0.688
49.52	2	1.414	1.695	0.301	1.703	24.760	0.0202	-0.305	50.48	4.642	3.696	0.946
53.96	3	1.732	1.732	0.477	1.663	17.987	0.0185	-0.268	46.04	4.642	3.584	1.058
60.37	4	2.000	1.781	0.602	1.598	15.093	0.0166	-0.219	39.63	4.642	3.409	1.232
67.82	5	2.236	1.831	0.699	1.508	13.564	0.0147	-0.169	32.18	4.642	3.181	1.461
72.65	6	2.449	1.861	0.778	1.437	12.108	0.0138	-0.139	27.35	4.642	3.013	1.629
79.29	7	2.646	1.899	0.845	1.316	11.327	0.0126	-0.101	20.71	4.642	2.746	1.895
81.66	8	2.828	1.912	0.903	1.263	10.208	0.0122	-0.088	18.34	4.642	2.637	2.004
84.25	9	3.000	1.926	0.954	1.197	9.361	0.0119	-0.074	15.75	4.642	2.507	2.135
90.33	10	3.162	1.956	1.000	0.985	9.033	0.0111	-0.044	9.67	4.642	2.130	2.511
96.21	11	3.317	1.983	1.041	0.579	8.746	0.0104	-0.017	3.79	4.642	1.559	3.082
99.1	12	3.464	1.996	1.079	-0.046	8.258	0.0101	-0.004	0.9	4.642	0.965	3.676



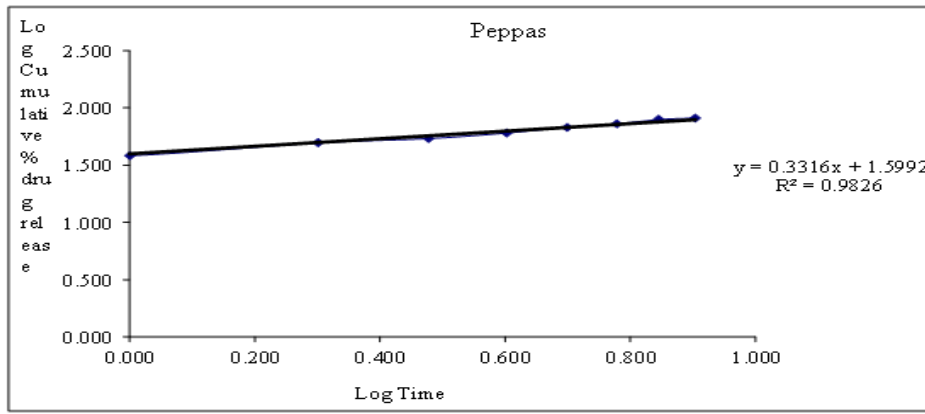


Figure 3: Peppas release kinetics

The prepared F4 optimized were subjected to the drug release kinetics and release mechanism. The formulations were studied by fitting the drug release time profile with the various equations such as Zero order, First order, Higuchi and Korsmeyer pappas. The optimized formulation F4 was analyzed for the drug release mechanism. The best correlation coefficient value (0.9826) indicates the best release mechanism (Peppas release).

**Drug-Excipient Compatibility (FTIR studies):**

IR spectral analysis was carried out using FT-IR and the results showed that there were no interactions between drug and Excipients.

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.

Gabapentin is also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

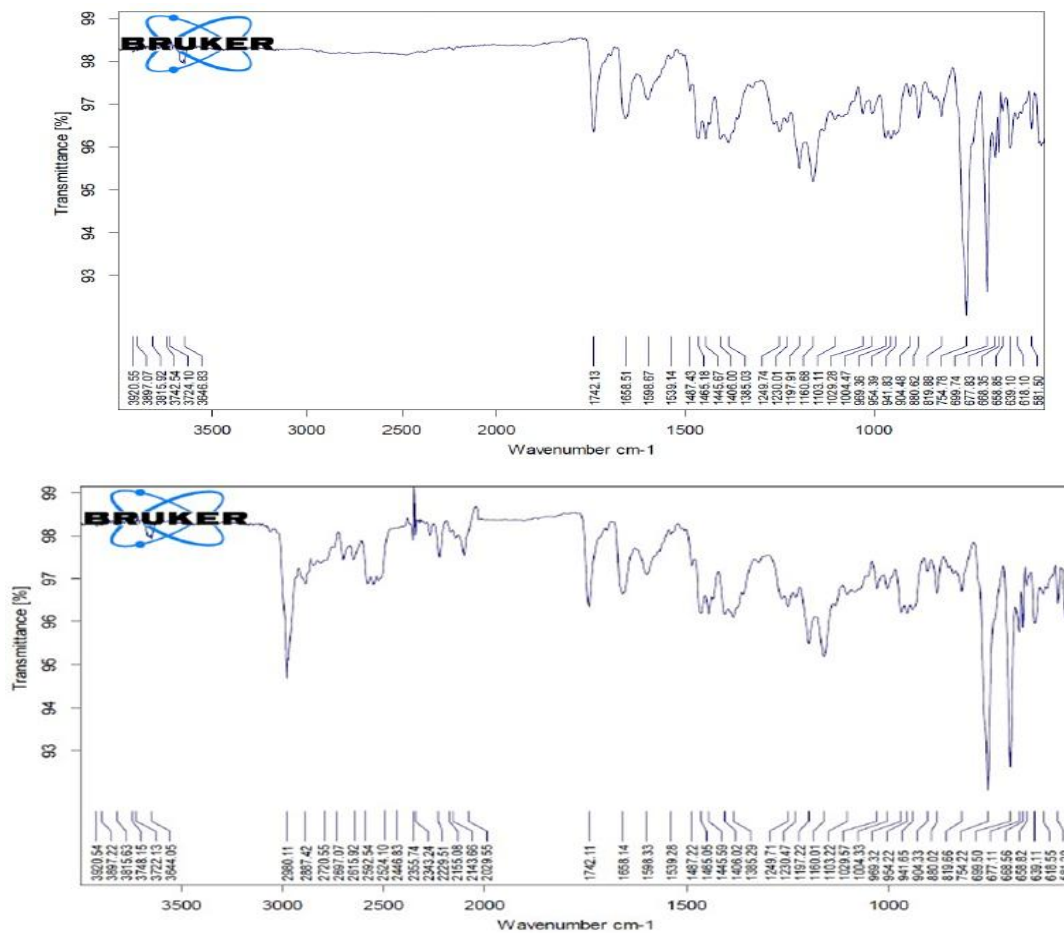


Figure 4 and 5: Drug-Excipient Compatibility (FTIR studies) Gabapentin

## DISCUSSION

Analytical method development for Gabapentin  $\lambda$  max determination  $\lambda$  max determination of Gabapentin pH 6.8 phosphate buffer was determined by using UV Spectrophotometer at 265 nm.

### Development of standard graph

Standard plot of Gabapentin pH 6.8 phosphate buffer was plotted to concentration vs absorbance at 265 nm and the slope value and  $R^2$  value were found to be 0.999.

The Gastro retentive mucoadhesive film was prepared by solvent casting method, by trial-and-error method. Several ratios of Gabapentin: Polyvinyl alcohol, Maltodextrin and Propylene glycol ranges from 25 to 75mg was performed, and ratios range were fixed based on the thickness of the film. Based on the above selection criteria, 3 ratios were fixed and the above ratios of films were cast and optimized. *In vitro* parameters of all the formulations (F1-F9) such as folding endurance was found to be in the range of  $178 \pm 0.96$  times, drug content in the range of 96.6% - 99.9%, and the swelling index was found to be in the range of 104.1 - 95.3% and *in vitro* unfolding behavior was found to be within 14-18 seconds for all the formulations, *in-vitro* maximum drug release was found to be in the range of 4 h – 12

## CONCLUSION

The Gabapentin oral films could be promising one as they, increase bioavailability, minimize the dose, reduce the side effects and improve patient compliance and also Gabapentin might be a right and suitable candidate for oral delivery. Low dose of drug can be suitable for oral films with low density of polymers. From the present investigation it can be concluded that Gastroretentive films formulation can be a potential novel drug dosage form for pediatric, geriatric and also for general population. The prepared Gabapentin oral films were characterized based upon their physiochemical characteristics like *In-vitro* Unfolding Behavior of the Film, Folding Endurance of Film, Drug Content, Swelling Index and *In-vitro* Dissolution Studies. All the results were found to be found to be within the pharmacopeia limits.

Based on the results F4 was the best one when compared to other. Based on Dissolution Studies the Gastro-retentive

films formulation F4 has drug release up to 12hours. So Gastro-retentive films formulated with Maltodextrin and HPMC K15M Polymer F4 is best formulation.

From the above results, the present research work revealed that the gastro retentive mucoadhesive is an advanced alternative to traditional gastro retentive dosage forms.

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