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Original Article

Development and In-vitro Characterization of Mucoadhesive Vaginal Tablet

Nakul S. Dhore[1*], Dr. Nishan N. Bobade[2], Dr. Shrikant D. Pande[3], Dr. Vikrant P. Wankhade[4], Dr. Sandeep C. Atram[5], Syed Faizan[6]

[1,2,3,4,5,6]Department of Pharmaceutics, Vidyabharati College of Pharmacy, Amravati 444602 (MH)- India

A R T I C L E I N F O

Keywords:
Mucoadhesive vaginal tablet,
Acyclovir,
HPMC K15M,
Chitosan HCl,
Sustained drug release

A B S T R A C T

Vaginal drug delivery has gained increasing attention due to its ability to bypass first-passmetabolism, provide localized therapy, and reduce systemic side effects. The presence of a mucosal layer necessitates the use of mucoadhesive systems to enhance residence time and drug absorption. Genital herpes, primarily caused by HSV-2, remains a significant global health concern, with high prevalence among women. Conventional oral therapy with acyclovir is limited by low bioavailability (15–30%), justifying the need for an alternative delivery approach. This study aimed to develop and optimize a mucoadhesive vaginal tablet of acyclovir capable of sustaining drug release for 8 hours using a combination of HPMC K15M and chitosan HCl. Tablets were prepared by direct compression and optimized using a 3^2 factorial design, evaluating the influence of polymer concentrations on swelling index, mucoadhesive strength, and drug release.FTIR and DSC studies confirmed compatibility and physicochemical stability of acyclovir with selected excipients. Swelling index ranged from 100.47% to 142.80%, increasing with polymer concentration. Mucoadhesive strength (37.8–53.1 g) and mucoadhesive time (10.20–13.40 h) showed a direct relationship with chitosan content due to its cationic interaction with mucin. Drug content was uniform across formulations (98–101%). In vitro drug release studies demonstrated sustained release up to 8 hours, with lower polymer concentrations showing faster release. Most formulations followed zero-order kinetics, indicating controlled and consistent drug release, while F1 exhibited a Korsmeyer–Peppas mechanism. In conclusion, the combination of HPMC K15M and chitosan HCl exhibited a synergistic effect, balancing mucoadhesion and sustained drug release. The optimized formulation successfully prolonged drug residence time and maintained therapeutic drug levels, offering a promising alternative for effective management of genital herpes with reduced dosing frequency.

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INTRODUCTION

Because of its unique physiological and pharmacological benefits, vaginal medication delivery has piqued the interest of many people throughout history. This method avoids first-pass metabolism, resulting in improved blood flow, less systemic adverse effects, and the potential for long-term drug release. The mucosal layer present in the organ under discussion is an intriguing feature, making formulation mucoadhesiveness a crucial quality. Thus, mucoadhesive polymers are frequently employed to modify the dose form and enable systemic administration through the vaginal mucosa[1].

The vagina, with its extensive network of blood arteries, is a viable target for systemic medication delivery. Its relatively high permeability to numerous drug compounds (including several with high molecular weight) also enables for drug transport across the vaginal mucosa and access into the blood circulation, exhibiting in many cases higher flux levels than those found through intestinal tissues[2].

Mucoadhesive vaginal tablets are still commonly used due to their ease of manufacture and cost-effectiveness, but nanocarriers represent a viable option for more efficient and patient-friendly vaginal drug administration. Vaginal lotions and gels provide lubrication, although they are messy and easy to remove if water soluble. Suspensions and solutions typically disperse unevenly in the vagina[3].Vaginal tablets are designed to melt or disintegrate in the vagina, releasing the drug into the cavity. Vaginal tablets contain all of the same excipients as conventional tablets. The tablets are made using the direct compression method, and effervescent agents can be added to formulations to improve swellability and drug release. Tablets have the advantage of being easy to make and insert. Tablets are more stable and less messy to use than lotions or ointments. [4].

***Corresponding author:**

Mr. Nakul S. Dhore
Department of Pharmaceutics
Vidyabharati College of Pharmacy, Amravati- 444602 (MH) India.
Email: dhorenakul8@gmail.com

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The herpes simplex virus, which has two serotypes, is the cause of herpes. Herpes virus type 1 (HSV-1) often affects the perioral area, whereas herpes virus type 2 (HSV-2) mostly affects the vaginal area. We are concentrating on the latter, which is spread through sexual interaction. According to the World Health Organization's (WHO) most recent data, 491 million individuals between the ages of 15 and 49 had an HSV-2 infection (World Health Organization, 2024). This disease affects more women (313.5 million) than men (178 million), with the highest prevalence found in Africa (102.9 million women and 59.3 million males). The overall number of infected individuals amounts to 13% of the global population.

The Centre for Disease Control and Prevention (CDC) treatment guidelines state that acyclovir, valacyclovir, and famciclovir are currently used as first-line medications. Acyclovir was chosen as the antiviral medication for the formulations created in this investigation. Genital herpes can be effectively treated and prevented with acyclovir, a nucleoside analogue that is active against HSV, varicella zoster virus, Epstein-Barr virus, and CMV. Because of its 15–30% oral bioavailability, the vaginal route is suggested as a substitute to lower the necessary drug dosage and boost the concentration of the active ingredient at the infection site[5].

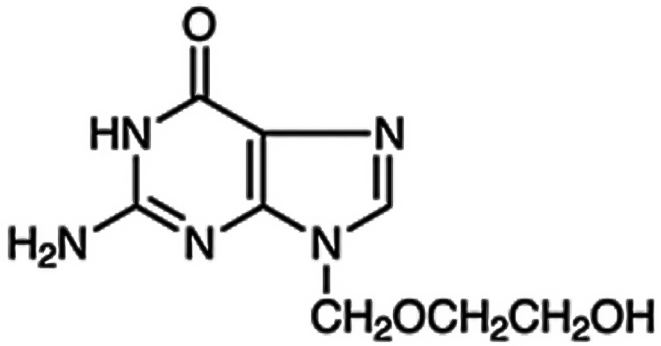


Figure 1: Chemical structure of Acyclovir

Hence this research work study is aimed to overcome the limitations associated with the Drug- Acyclovir and to design a half-a-day mucoadhesive vaginal tablet of Acyclovir to improve adhesion to vagina to prolong residence time and consequently reduce dosing frequency and obtain a long therapeutic concentration at the site of infection, so that a single application offers protection against sexual acquisition of the virus for 8 hours.

This study addresses the possible use of a mixture of HPMC K15M & Chitosan HCLat three different levels withother excipients. The formulated vaginal tablets were evaluated for their mucoadhesion work, in vitro swelling index and in vitro release studies and release kinetics.

2. MATERIALS AND METHOD

Material:Acyclovir was purchased from Dhamtech Pharmaceuticals & Consultants. Polymers and other excipients such as HPMC K15M, Chitosan and Microcrystalline Cellulose, Magnesium stearate, Talc were supplied by the Department of Pharmaceutics, Vidyabharati College of Pharmacy, Amravati. Distilled water has been used in all the operations and procedures along with acetate buffer pH 4.5.

Method:Preparation of Mucoadhesive vaginal tablet was done by Direct Compression Method. It ensures uniform distribution of drug and excipients in the final formulation. The mixture of powder is passed through sieve No. 22 to ensure uniform particle size. The prepared blend was compressed into tablets using a Rotary Tablet Press Machine fitted with a flat bevelled punch. Tablets were characterized to assess their suitability for Drug Release & Mucoadhesion work. Each tablet of 500 mg mass is formulated with a constant amount of Acyclovir (drug) 100 mg; Talc (glidant) 10 mg; Magnesium stearate (lubricant) 5 mg; with variability in mass of HPMC K15M, Chitosan (Polymers) and Microcrystalline Cellulose (diluent).

3.Formulation Optimization & Factorial Design

Mucoadhesive Vaginal Tablets were formulated by using 32 Factorial Design. Two independent variables that affect the drug release pattern and mucoadhesion work of the mucoadhesive vaginal tablet were considered. Each at three levels and experimental trials were carried out at all nine possible combinations/ runs. The HPMC K15M (X1) and the Chitosan (X2) selected as independent variables. The Percentage swelling index, MucoadhesionWork, and Percentage Drug release at 8 hwere selected as the dependent variable[6].

Coded value	Actual value	
	X1 HPMC K15M	X2 Chitosan HCL
-1	60	80
0	75	100
1	90	120

Table 1: Encoded values of independent variables for optimizing formula of 32 factorial batches.

Name of Ingredients	Formulation Code with Their Quantity (Mg)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Acyclovir	100	100	100	100	100	100	100	100	100
HPMC K15 M	60	60	60	75	75	75	90	90	90
Chitosan HCL	80	100	120	80	100	120	80	100	120
MCC	245	225	205	230	210	190	215	195	175
Mg Stearate	5	5	5	5	5	5	5	5	5
Talc	10	10	10	10	10	10	10	10	10
Total	500	500	500	500	500	500	500	500	500

Table 2: Formulation CompositionDesign of Mucoadhesive Vaginal Tablet

Evaluation

Mucoadhesive vaginal tablets were characterized for various Drug parameters like- FTIR & DSC while formulation parameters like Swelling Index (%); Drug Content (%); Mucoadhesive Strength (gm); Mucoadhesive Time (hrs); In-vitro drug release (%).

FTIR

To study the interaction between the drug and excipients of the tablet formulation, the FTIR study was performed. The samples under consideration were subjected to attrition along with KBr, placed in the cell and then finally scanned from 4000 to 500 cm-1 employing FTIR spectrophotometer[7].

DSC

Differential scanning calorimeter was used to conduct DSC. In this procedure a weighed sample of 10 mg was in an aluminium pan. Then the pan was sealed carefully, temperature scanning was carried out between 20 ◦ C and 300 ◦ C by performing a DSC heating/cooling/heating cycle

(1st heating, 1st cooling, and 2nd heating) with a fixed rate of 20 ◦ C/min as the nitrogen gas flows (30 mL/min). Pyris program was used to analyse the heat flow against the temperature by plotting a graph[8].

Drug Content

This test is performed to maintain the uniformity of weight of each tablet which should be in the prescribed range according to the Indian Pharmacopoeia. This test is performed by taking twenty tablets were selected randomly, weighed and powdered. A quantity of powdered tablet equal to 500mg of Acyclovir was dissolved in distilled water in 100ml volumetric flask. This formed sample was diluted and the absorbance was measured at 253 nm using distilled water as blank and the % drug content was estimated[9].

Swelling Index

The swelling behaviour of the tablet is described as the water absorbing capacity determined by using the agar plate. A swelling study was performed on agar gel plate. Mucoadhesive vaginal tablets were weighed individually (W0) and placed in agar gel plate separately. After the schedule of 8 hrs, tables were removed from the Petri plate, wiped with tissue paper, and final weight (Wt) of the swell tablet was noted. The swelling capability is expressed as a swelling index. The following equation calculated it [10].

Swelling Index = (Wt-W0)/W0×100

Mucoadhesive Strength

The ex vivo mucoadhesive strength was determined by a modified balance method using goat vaginal mucosa obtained from the local slaughterhouse. A weighing balance with two pans was used for this study. One vaginal tissue was attached at the base of the left side pan, another vaginal tissue was fixed on a platform and the tissues were hydrated with the AVF pH 4.5. The vaginal tablet was then applied between the mucosa on the platform and the left side pan bearing the vaginal mucosa and then allowed to make the contact so that the tablet formulation was sandwiched between the vaginal tissues. The preload weight of 10 g for 2 min was applied for the close contact. Then the weight was added on the right pan till the detachment of the vaginal tissue was achieved. The mucoadhesive strength (gm) required to detach the vaginal mucosal tissue from the surface of the tablet is determined[11].

Mucoadhesive Time

The goat vaginal tissue was washed with SVF pH 4.5 and attached on a glass slide with adhesive tape. A tablet from each batch was pressed onto the tissue for 30 s. This glass slide was tied to the arm of a USP disintegration test apparatus. It was then given a reciprocating motion in 900 ml of SVF medium at 37 ˚C. It was observed for signs of erosion and detachment periodically. When it was visually confirmed that the entire tablet was eroded or detached, the apparatus was stopped. The time taken for complete erosion or detachment was taken as the mucoadhesion retention time. The average of three readings was taken[12].

In-vitro Drug Release

The in vitro dissolution was performed using USP type II dissolution apparatus (Electrolab, 80AK, Mumbai). The dissolution flasks were filled with artificial vaginal fluid pH 4.5 as dissolution media (900 mL) maintained at 37 ± 0.5°C during the experiment. The revolution of the paddle was adjusted at 50 rpm. The tablets were added in the flasks and the dissolution was carried out for 8 hr. The samples were removed (5 mL) at appropriate time interval (1-8 hr) and the same volume was filled with the AVF pH 4.5. The samples were then filtered and analysed spectrophotometrically at 253 nm. The dissolution profile of all the tablet batches was plotted using the dissolution data[13].

Kinetics of Drug Release

Using an MS- Excel based software program, the release kinetics and curve fitting was performed.

RESULTS AND DISCUSSION

5.1 FTIR

The compatibility and interaction of the drug and polymers were studied through the FTIR spectroscopy. The results of the FTIR study are illustrated in Figure 2. The IR spectrum of drug Acyclovir showed the characteristic peaks of the below functional groups Hydroxyl (O-H) group, Amine NH2 group, Carbonyl (C=O)group, Ether group (-O-), found in the IR region of 3451, 3307, 1705, 1095 cm-1 respectively.

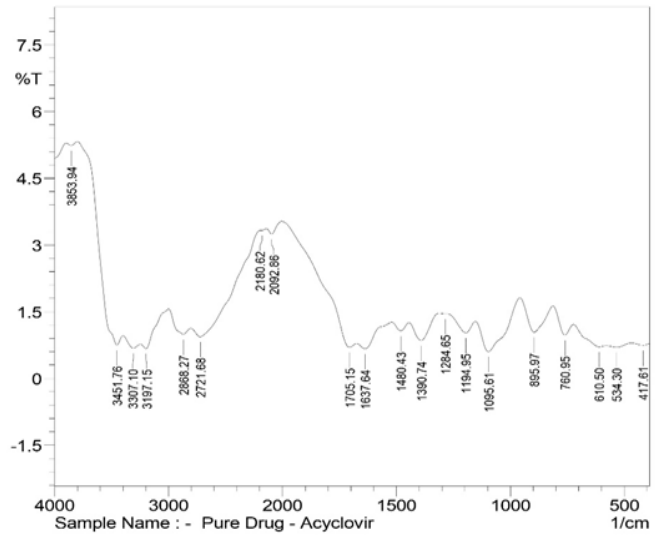


Figure 2: FTIR spectra of Acyclovir Pure Drug sample.

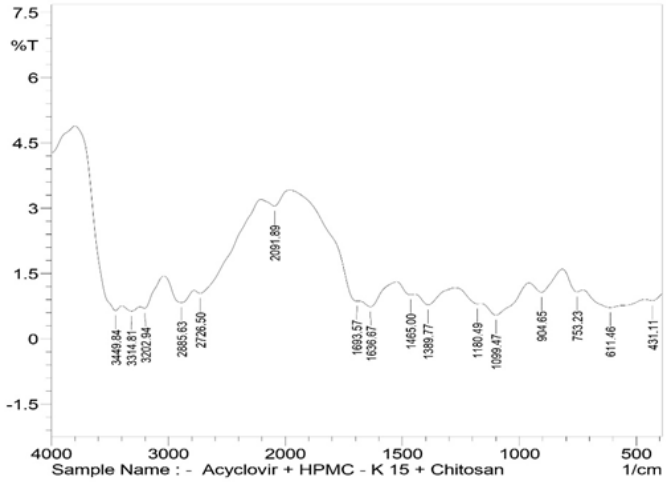


Figure 3: FTIR spectra of physical Mixture of Acyclovir, HPMC K15M, Chitosan HCL.

5.2 DSC

Differential scanning calorimetry allows the quantitative detection of all processes in which energy is required or produced.It was operated in the range between 20-300 ˚C. In the pure drug sample of Acyclovir,the endothermic peak was appeared at 258.58 ºC (Fig: 4) almost very near to that of pure drug 257.00 ºC.

In the physical mixture of drug with polymers of vaginal formulation the endothermic peak of Acyclovir was appeared at 252.75 ºC (Fig: 5). This confirmed the physicochemical stability of drug with the formulation excipients used in the study

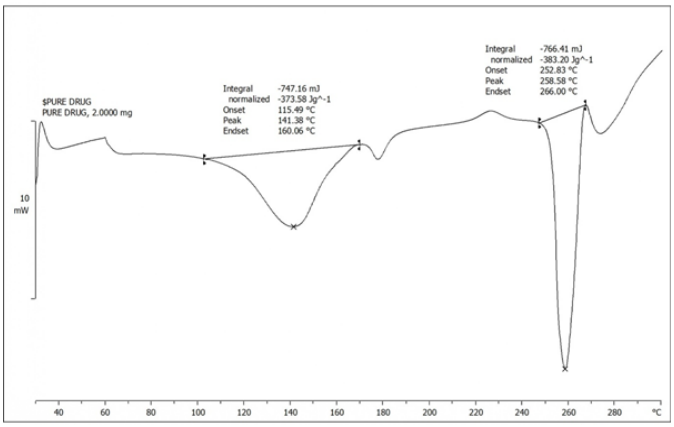


Figure4. DSC thermogram profile of Acyclovir pure drug sample.

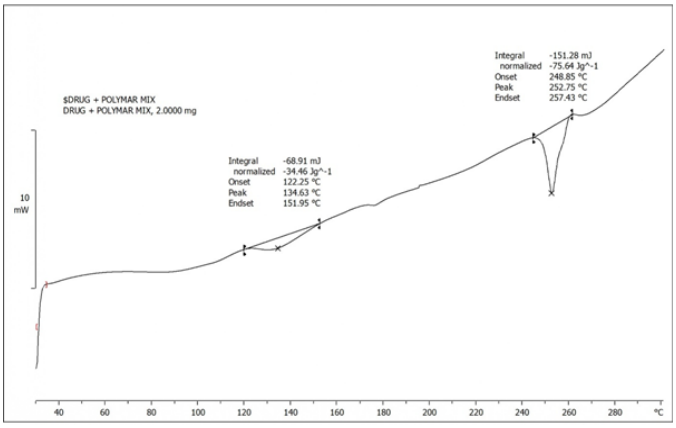


Figure 5. DSC thermogram profile of physical mixture of Acyclovir, HPMC

K15M, Chitosan HCL.

5.3 Swelling Index

It has been found that Percentage of swelling increases with increasing polymer concentration. From the obtained results, it shows that swelling is primarily dependent on one of the variables- HPMC K15M, therefore addition of Chitosan HCL subsequently balances the swelling of tablet. Hence, it is directly proportional to the polymer load. Formulation (F1) has lowest swelling index of 100.04 % of all due to least amount of polymer load, while that of Formulation (F9) is having highest swelling index of 142.80%

1<4<7; 2<5<8; 3<6<9

5.4 Mucoadhesive Strength

Mucoadhesive strength is the parameter which determines overall mucoadhesiveness of the tablet. It has been found under slight acidic conditions it shows good mucoadhesion work. For each set of same quantity of HPMC K15M, the amount of Chitosan is increasing subsequently. Hence it has shown linear increase in mucoadhesive strength as follows,

F1<F2<F3; F4<F5<F6; F7<F8<F9.

5.5 Mucoadhesive Time

Same criteria are followed by the parameter- mucoadhesive time also. Mucoadhesive time is directly proportional to the concentration of Chitosan HCL. It enhances with increasing amount of Chitosan HCL. It is lowest, 10.20 hrs for Formulation (F1) while highest, 13.40 hrs for formulation (F9).

Chitosan HCL has shown good mucoadhesive strength rather than HPMC K15M because of its cationic nature. It strongly binds to negatively charged mucin glycoproteins on mucosal surfaces via electrostatic attraction.

F1<F2<F3; F4<F5<F6; F7<F8<F9.

5.6 Drug Content

The drug content analysis showed that the drug loading is uniform, and there was homogenous drug distribution in the mucoadhesive vaginal tablets. Formulation (F4) showed highest percentage of drug in the formulation of 100.95%. The percent drug content was evaluated by taking the concentration of both standard and sample at 10 mcg/ml at 253 nm wavelength.

Batch Code	Swelling Index (%)	Mucoadhesive Strength (g)	Mucoadhesive Time (hrs)	Drug Content (%)
F1	100.47	37.8	10.20	100.68
F2	111.06	42.7	11.45	99.18
F3	126.90	48.3	12.50	98.22
F4	105.70	39.2	10.55	100.95
F5	121.60	45.5	12.05	100.42
F6	137.51	50.0	13.15	98.00
F7	116.30	40.0	11.15	99.62
F8	132.29	46.9	12.35	99.31
F9	142.80	53.1	13.40	98.87

Table 3: Swelling Index, Mucoadhesion Work and Drug Content of Mucoadhesive Vaginal Tablet

5.7 In-Vitro Drug Release (%)

The in-vitro drug release was performed in the simulated vaginal pH condition of 4.5. The drug release rate of tablet continuously increased up to 8 hrs, in which the Formulation(F1) showed maximum release followed by Formulation (F4) batch in 8 hrs. So, it was found considerable in the factorial design optimization. It has found that release rate of Acyclovir is inversely proportional to the polymer concentration. Higher polymer load of Chitosan HCL in tablet forms dense layer of gel on mucosal surface of vagina while matrix forming ability of HPMC K15M restricts it release in environment and hinders the release rate. The drug release rate of all the formulations F1-F9 has been shown in the figure 6.

Time (hrs)	% In-Vitro Drug Release (Acyclovir)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	11.42	8.63	7.46	9.35	8.18	6.2	8.54	6.38	8.45
2	20.86	17.89	16.09	20.14	20.41	18.52	20.68	16.72	14.92
3	36.25	34.27	31.75	35.26	28.6	26.71	29.41	32.47	25.63
4	44.52	40.83	37.23	43.35	41.73	37.86	46.23	38.31	34.17
5	57.92	53.15	48.74	56.39	49.91	46.22	55.94	50.27	40.73
6	65.399	60.71	55.04	64.49	58.46	53.24	62.78	57.29	55.04
7	82.75	75.19	68.53	79.42	74.38	67.81	75.1	70.87	61.42
8	91.11	83.64	76.08	88.68	81.57	73.92	86.34	78.78	70.23

Table 4: In-Vitro drug release of Mucoadhesive Vaginal Tabletformulations (F1-F9)

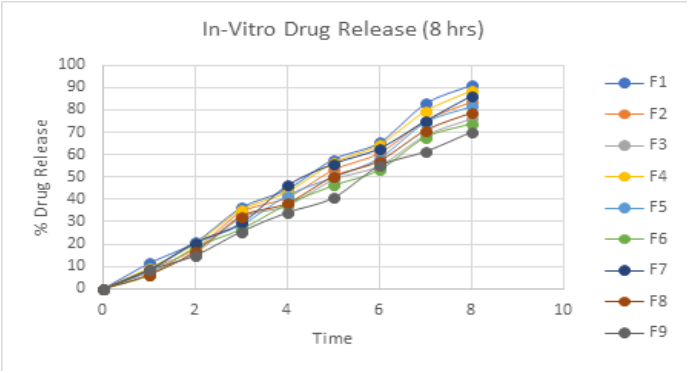


Figure 6: Release profile of mucoadhesive vaginal tablet formulations (F1-F9).

5.8 Kinetics of Drug Release

Kinetics of drug release has been applied over the four models. It has been found that almost all formulations in the study except F1 has obeyed the Zero Order model of drug release.

This indicates the release of drug in sustained and more linear order corresponding to the aim of the study. Formulation F1 has followed Korsmeyer Peppas model of release, indicating mixed release mechanism (both diffusion and polymer swelling/erosion) from the tablet. It has demonstrated in table 5.

Models	Kinetics of Drug Release (R^2)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
First Order	0.8996	0.9443	0.9644	0.9214	0.9427	0.9654	0.9355	0.9614	0.9651
Zero Order	0.9952	0.9946	0.9928	0.9968	0.9955	0.9952	0.9945	0.9935	0.9950
Higuchi	0.9753	0.9811	0.9817	0.9821	0.9765	0.9821	0.9835	0.9849	0.9747
Korsmeyer Peppas	0.9959	0.9930	0.9906	0.9961	0.9951	0.9877	0.9942	0.9866	0.9949

Table 5: Release kinetics of the formulations R^2

6. CONCLUSION

The present research work offered significant development of the mucoadhesive vaginal tablet of the antiviral drug Acyclovir using Chitosan and HPMC K15M as the matrix polymers. The inclusion Of Chitosan HCLin the study improved the permeability of the drug as it is a good permeation enhancer along with mucoadhesive property. Thus, the desired drug concentrations may be achieved with linear pattern. It was concluded that the concentration of Chitosan and HPMC K 15M had synergistic effect on the tablet'smucoadhesion work and swelling behaviour.

But the plot twist observed was that HPMC K15M provides good sustained release pattern due to its matrix forming ability and swelling behaviour subsequently. While Chitosan HCL imparted better Mucoadhesive properties to the formulations with increasing Chitosan content. Higher is the Polymer content, greater is the swelling and mucoadhesion work. While lower is the polymer faster is the drug release from tablet. Hence it has been concluded that HPMC K15M balances swelling and drug release of Chitosan, while Chitosan balances mucoadhesive strength and time of HPMC K15M.

The optimization by 3^2 full factorial design was performed to obtain the optimum batch that could sustain the drug release up to 8 hrs. The drug release mechanism was studied for all the batches by the kinetic models that confirmed the Korsemeyer-Peppas plot& Zero-order model that prompted the drug release to be sustained and both diffusion and polymer swellingmediated. The desired tablet formula was predicted by the software and the same was prepared. The mucoadhesion property would allow increased residence of the drug. The tablet was able to sustain the drug release for 8 hr with maximum drug release and even more at higher polymer concentrations.

Author Contributions:Conceptualization, Mr. Nakul S. Dhore.; methodology, Mr. Nakul S. Dhore.; validation, Dr. Sandip C. Atram and.; investigation, Dr. Nishan N. Bobade; writing—original draft preparation, Mr. Nakul S. Dhore.; writing—review and editing, Mr. Nakul S. Dhore.; visualization, Dr.Shrikant D. Pande; supervision, Dr. Nishan N. Bobade.; project administration, Mr. Nakul S. Dhore.; funding acquisition, Mr. Nakul S. Dhore. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest:

Authors declare no conflict of interest.

Informed Consent:

This study utilized publicly available, anonymized data; therefore, no informed consent was required.

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