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FORMULATION AND EVALUATION OF SILODOSIN BUCCAL FILM

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ABSTRACT

Objective: The objective of this research work was to formulate and evaluate buccal film containing Silodosin by enhancement of Permeability by preparing inclusion complex of Silodosin with β-CD and to increase patient compliance which is useful in the treatment of Hyperplasia. **Materials and Methods**: In this research, the method used to prepare buccal films was solvent casting. β-CD inclusion complex with silodosin in 1:1 ratio to increase permeability of drug. 3^2 Full Factorial design was used for optimization by selecting two independent factors – concentration of film forming agent (HPMC E5)-X I and concentration of plasticizer (Propylene glycol)-X II and their effect on Disintegration time- (R I), and % drug release- (R II). Optimization of factorial batches was done using Design Expert 13 software. **Result**: Best results were obtained in Batch F1 in which HPMC E5 was 150mg and Propylene glycol was 1ml with 31.4 seconds of disintegration time and 99.1 % cumulative drug release at 15 minutes. Check point batch shows 34.74 seconds of disintegration time 97.09 % cumulative drug release. A 1 month accelerated Short term stability study was done on prepared films and it is stable for 1 month. **Conclusion**: Buccal film containing Silodosin were formulated using HPMC E5 as a film forming and Propylene glycol as a plasticizer by solvent casting method. Hence, from the results it was concluded that faster disintegration and faster drug release can be achieved by the buccal film of Silodosin.

KEYWORDS: Buccal films, HPMC E5, Propylene glycol, PEG 4000, solvent casting, design expert.

I. INTRODUCTION

Benign prostatic hyperplasia (BPH) belongs to the most frequent diseases in ageing men. In the 4th decade of life, BPH is demonstrable in 30-40% of men, and its prevalence increases almost linearly to 70-80% in those older than 80 years.[1] Silodosin is BCS class Ⅲ drug with high solubility and low permeability.[2] Silodosin is the most selective alpha-1A adrenergic receptor blocker, leading to better efficacy in improving lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). Silodosin relieves the symptoms of benign prostatic hyperplasia by relaxing the muscles of bladder and prostate.[3] Buccal films are superior flexibility which enhances comfort, in addition to a customizable size. Such films are comprised of multiple layers and are predominantly indicated for prolonged drug release within the oral cavity. buccal film technology can be utilised to deliver quality, efficacious and safe therapy.[4] A 3^2 full factorial design involves 2 factors each tested 3 levels creating 9 unique treatment combination to study main effect and interactions.[5]

II. MATERIALS AND METHOD

Silodosin is provided as a gift sample BROOKLYN pharmaceutical Pvt. Ltd. And excipients were HPMC E5, HPMCK4M, Propylene Glycol, PEG 4000, β- CD, sucrose and Peppermint oil was provided by oxford lab fine chem. LLP and water.

Preformulation Studies

Organoleptic Characteristics of Silodosin[6]

The Silodosin drug sample was checked for basic properties like colour, odour, taste, and appearance.

Melting point determination[7]
Capillary melting point is the most widely used technique for determining the melting point. The melting point of a sample is determined by observing the temperature ranges across which it melts in melting point apparatus.

Solubility study of Silodosin[7]
The solubility of Silodosin in different solvent was determined by shake flask method, in this method an excess amount of Silodosin is added into 250ml conical flask containing different types of solvents such as methanol, water, pH 6.8 phosphate buffer. The shaking was carried for 24hrs on incubator water bath. Then dissolved drug solution is filtered through Whatman filter paper and drug concentration was determined using UV spectrophotometer. Finally, measure the absorbance of each diluted sample at 269 nm and plot Absorbance vs. Concentration curves determine the solubility of Silodosin.

Determination of Absorbance Maxima of Silodosin[8]
Standard stock solution of silodosin prepared by dissolving 10mg of silodosin in solvent to produce a conc. of 1000µg/ml 1ml of this stock solution was taken then diluted up to10ml by using solvent Give a solution 100µg/ml. A UV-Visible Spectrophotometer was utilized to scan a range of solutions with varying concentrations, measuring between 200 and 400 nm.

Drug-excipient compatibility study by using FTIR study[9]
For identification of drug-polymer compatibility by using FTIR (Fourier transform Infra-red). Silodosin was subjected to an FT-IR analysis using a Shimadzu.

Preparation of β-CD inclusion complex with silodosin
Silodosin and β-CD were combined in 1:1, 1:2, and 1:3 molar weight ratio. A Methanol was used as the solvent system. Initially, 50% of the solvent was taken in a mortar, and the calculated amount of polymer was added.

Differential scanning calorimetry[DSC][10]
DSC (Differential Scanning Calorimetry) study was carried out using DSC instrument. The instrument comprises of calorimeter, flow controller, thermal analyzer and operating software. The drug was heated in sealed aluminum pans under airflow (30ml/min) at a scanning rate of 20ºC/min from 50-300ºC. Empty aluminum pan was used as a reference. The heat flow as a function of temperature was measured for the sample.

Method of preparation of buccal film[11]
The film-forming polymer is dissolved in a water, and thoroughly mixed to ensure complete dissolution. Then Silodosin+permeation enhancer, plasticizers, other excipients (such as flavouring and Permeation enhancer) are added to the polymer solution, with continuous stirring to ensure a uniform mixture. The resulting homogeneous solution is poured onto a flat surface or to achieve the desired film thickness. The cast solution is dried at a controlled temperature to evaporate the solvent, solidifying the film.

Selection of Factors, Levels and Responses of 3^2 Full-Factorial Designs
It is best to create pharmaceutical products with minimal amounts of labor and ingredients, but this requires effective product development. The One Factor at a Time (of AT) design was utilized in the past, but it takes a long time to complete and is only capable of checking the effects of interactions. Full factorial design is used to optimize the Buccal film of Silodosin. The table below illustrates the factors & levels. The two factors that were chosen as independent variables were: XI (concentration of HPMC E5, a film-forming agent) and XII (concentration of Propylene glycol, a plasticizer). For each criteria, three levels have been chosen: -1, 0, +1. The responses, or dependent variables, were: Y1: disintegration time (sec), Y2: In vitro drug release at 15 min.

The impact of factors (independent variables) on dependent factors (responses) was examined using the Design Expert 13 programme.

Table 1: Layout of 3^2 full factorial designs.

Independent variables					
XI			**XII**		
HPMC E5 (concentration) (mg) (film forming polymer)			**Propylene glycol(concentration)(ml) (plasticizer)**		
-1	0	+1	-1	0	+1
145	150	155	0.5	1	1.5
Dependent variables					
Y1			**Y2**		
Disintegration time (sec)			In vitro drug release at 15min		

Table 2: Final formulation table for factorial batches.

Ingredients (mg/ml)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Silodosin + β-cyclodextrin	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.3
HPMC E5	145	145	145	150	150	150	155	155	155
Propylene glycol	0.5	1	1.5	0.5	1	1.5	0.5	1	1.5
Sucrose	20	20	20	20	20	20	20	20	20
Peppermint oil	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Water	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15	q.s upto 15

Evaluation parameter of film[12-14]

- **Film Thickness**

To assess the thickness of the buccal film, a micrometer screw gauge is used at multiple critical points across the strip. Consistency in thickness directly relates to uniformity in drug dosage, as there is a proportional relationship between strip thickness and drug content.

- **Strip Weight**

The individual weights of the films are measured using an analytical balance. The average weight is then calculated to ensure uniformity. Consistent strip weight indicates proper formulation and dosage precision.

- **Moisture Content**

To determine residual moisture, the film is weighed and stored in a desiccator for 24 hours. The process continues until the weight stabilizes, indicating that the moisture has been effectively removed. The difference in weight is used to calculate the moisture percentage.

- **pH Measurement**

To evaluate pH, the strip is immersed in distilled water for approximately one hour. After soaking, the pH of the resulting solution is measured using a calibrated pH meter. This test ensures the formulation's compatibility with oral tissues.

- **Disintegration Time**

Disintegration time is an essential parameter for buccal films. Though no specific pharmacopoeial standard exists for these films, a benchmark of 30 seconds used for buccal tablets is commonly applied. A standard disintegration test apparatus may be employed, with typical disintegration times ranging from 5 to 60 seconds.

- **Folding Endurance**

This parameter evaluates the film's flexibility and resistance to mechanical stress. The film is repeatedly folded at a 180° angle until it tears. The number of successful folds before rupture is recorded as the folding endurance value.

- **In Vitro Dissolution Study**

The dissolution profile is assessed using a beaker containing 125 ml of phosphate buffer (pH 6.8) as the dissolution medium. The film is affixed to the beaker wall using adhesive tape. A magnetic stirrer operates at 200 rpm, and samples of 5 ml are withdrawn at intervals of 3,5,7,9,12 and 15 minutes. Each sample is replaced with fresh buffer. Drug release is analyzed spectrophotometrically by measuring absorbance at a specific wavelength.

Generating of Quadratic Model for 3^2 FFD (Full Factorial Design)

A quadratic polynomial model was used for assess the influence of independent factors on dependent variables. From the acquired data of disintegration time and percent (%) drug release, a quadratic model equation was generated using polynomial regression analysis. The process of finding the polynomial equation that best fits a set of data is known as quadratic regression.

Selection of optimized batch

The final formulation was selected based on the lowest disintegration time and highest drug release at 15 min. According to desirability value, the optimized levels of HPMC E5 concentration and Propylene glycol concentration. According to the selected levels using the same methodology Silodosin containing buccal film were prepared.

Short term Stability Study

Stability study aims to ascertain how different environmental factors, including temperature, humidity, and light, affect the quality of therapeutic substances or medication formulations over time. An "accelerated stability study" was carried out on prepared films at 40°C±2°C/75 percent RH 5% (percent) RH, in accordance with the ICH Q1A guideline. The "ICH Q1A guideline" governs the stability assessment of innovative pharmaceutical compounds and products. An expedited stability study should last at least six months, according to the ICH Q1A standard, but due to scheduling constraints, the study only lasted one month. A month later, the films were examined for a number of characteristics, including fold-through durability, disintegration time, drug percentage content, and percentage CDR.

RESULT AND DISCUSSION

Organoleptic Properties and Melting Point of Silodosin

The drug sample of silodosin was assessed for organoleptic properties, including color, odor, taste, and

appearance, under controlled conditions to ensure accuracy. Observations were compared with reference standards to confirm identity and suitability for formulation development. The result is as per table 3.

Table 3: Organoleptic Properties of Silodosin.

Properties	Observation
Appearance	Amorphous powder
Taste	Bitter
Colour	White to pale yellowish
Odour	Odourless

Melting point determination

The melting point of silodosin was determined using a capillary tube method. A small sample was placed in a sealed capillary tube and gradually heated in a melting point apparatus. The temperature range at which the substance transitioned to a liquid was recorded, ensuring precise measurement. The melting point of drug is determined as shown in table 4.

Table 4: Melting Point Determination.

Parameter	Observation
Melting point(℃)	107ºC

Absorption maxima of Silodosin(λ_{max})

The maximum absorption of drug in phosphate buffer at 269 nm which is shown in table 5 and fig.1 and on it's based we form the calibration of Benfotiamine which is shown in fig.2.

Table 5: Determination of absorption maxima of drug (λ_{max})

Solvent	λ_{max} (nm)
6.8 pH Phosphate buffer	269

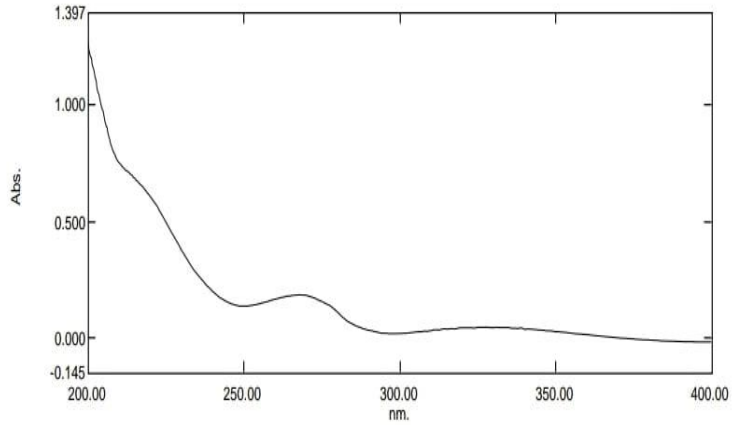

Fig. 1: Absorption maxima of Silodosin.

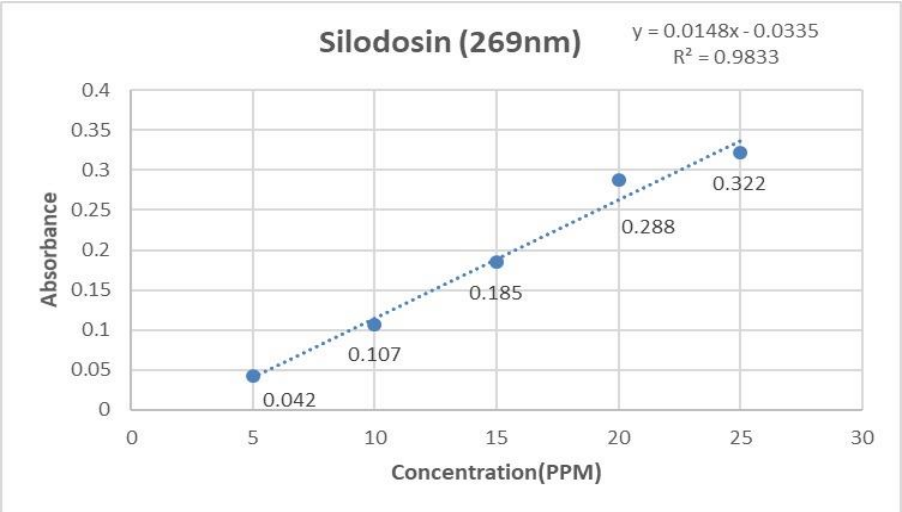

Fig. 2: calibration curve of silodosin.

FTIR Study

Infrared spectroscopy was conducted using FT-IR spectrophotometer and the spectrum was recorded in the wave number region of 4000 to 400 cm-1. The procedure consisted of dispersing the sample (drug alone, mixture of drug and excipients and the optimized formulation) in Potassium bromide and compressed into discs by applying a pressure of 5 tons for 5 minutes in a hydraulic press. The pellet was placed in the light path and the spectrum was recorded which is shown in fig.3.

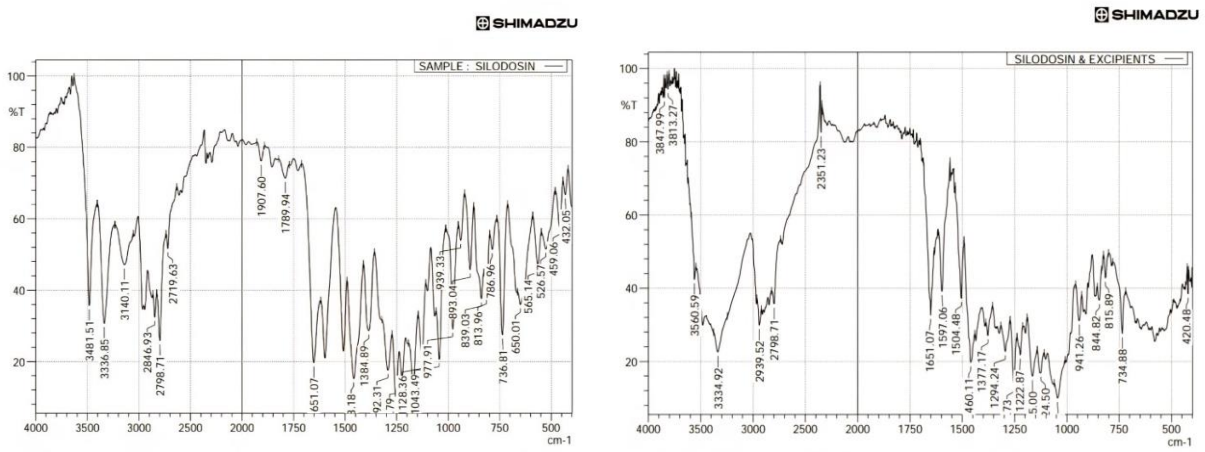

Fig. 3: FTIR of Silodosin and FTIR of Silodosin + excipients.

Result of solubility of β-CD inclusion complex with silodosin

Silodosin and β-CD were combined in 1:1, 1:2, and 1:3 molar weight ratio. A Methanol was used as the solvent system the result is as per table 6.

Table 6: Solubility of β-CD inclusion complex with silodosin.

Formulation	Ratio	Solubility(µg/ml)
Silodosin + β-CD	**1:1**	**62.3**
Silodosin+ β-CD	1:2	42.9
Silodosin+ β-CD	1:3	35.65

(n=3±SD)

Result of DSC (Differential scanning calorimetry)

DSC (Differential Scanning Calorimetry) study was carried out using DSC instrument. The instrument comprises of calorimeter, flow controller, thermal analyzer and operating software. The drug was heated in sealed aluminum pans under airflow (30ml/min) at a scanning rate of 20ºC/min from 50-300ºC. Empty aluminum pan was used as a reference. The heat flow as a function of temperature was measured for the sample**.** The graphical representation of DSC is shown in fig 4.

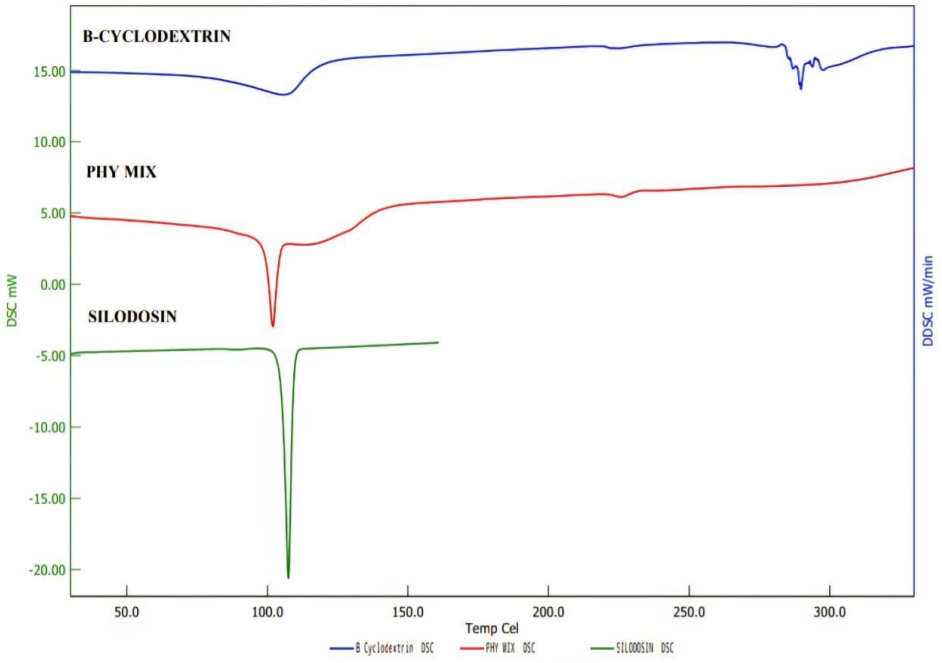

Fig. 4: Overlay DSC of Physical Mixture.

Evaluation of factorial batch

As we discuss the method and the equations of evaluation parameter in method and material section we find out the result as per table 7 and 8.

Table 7: Evaluation of factorial batch.

Factorial batches	Appearance	Smoothness	peel ability	Disintegration time (sec)	Thickness
F1	**Translucent**	**Smooth**	**Good**	**31.04±0.81**	**0.36±0.05**
F2	Translucent	Smooth	Good	33.83±0.53	0.32±0.11
F3	Translucent	Smooth	Good	36.28±0.65	0.42 ±0.2
F4	Translucent	Smooth	Average	36.9±0.68	0.36±0.2
F5	Translucent	Smooth	Average	38.2±0.91	0.31±0.03
F6	Translucent	Smooth	Average	42.93±0.18	0.38±0.12
F7	Translucent	Smooth	Good	62.23±0.63	0.41±0.05
F8	Translucent	Smooth	Average	71.08±1.95	0.42±0.02
F9	Translucent	Smooth	Poor	77.12±0.85	0.36± 0.02

n=3±SD

Table 8: Evaluation of factorial batch.

Factorial batches	Folding endurance	Surface pH	Weight variation (mg)	Drug content (%)	% Moisture content
F1	**150±3.41**	**7.2±0.21**	**75±1.13**	**98.26±0.21**	**1.864±0.029**
F2	179±5.25	7.1±0.21	74±2.24	99.21±0.45	1.547±0.010
F3	145±4.13	6.9±0.19	74±3.15	99.14±0.36	1.613±0.042
F4	146±3.25	6.6±0.16	73±2.32	99.32±0.45	1.691±0.021
F5	158±2.12	6.7±0.14	74±2.23	99.21±0.36	1.681±0.059
F6	164±3.15	6.7±0.52	73±1.13	98.75±0.38	1.439±0.052
F7	156±2.36	7.4±0.9	76±2.36	99.78±0.98	1.549±0.064
F8	169±4.36	6.4±0.12	76±3.36	99.71±0.31	1.846±0.073
F9	171±2.14	7.1±0.24	75±1.23	99.65±1.54	1.794±0.039

n=3±SD

In-vitro dissolution of factorial batches

The graphical representation of in vitro study is shown in fig.5.

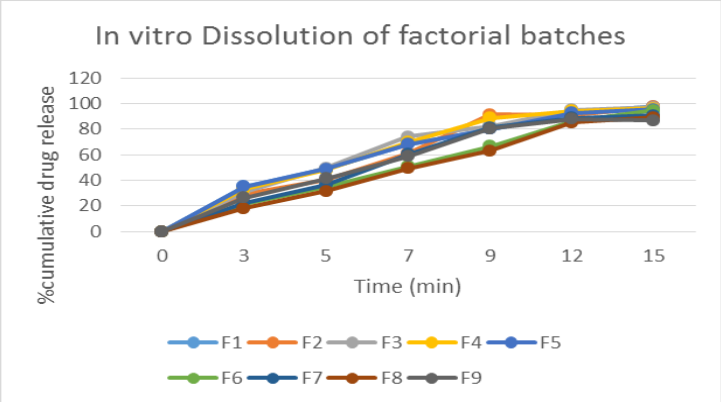

Fig. 5: In-vitro dissolution of factorial batches(F1-F9).

Photos of buccal film of Silodosin

The formulation of buccal film is shown in fig 6.

Fig. 6: Buccal film of silodosin.

Generation of Quadratic Model 3^2 [FFD] Full Factorial Design

Contour plots were generated for each independent variable to visualize their individual effects on the selected responses, such as percentage yield, entrapment efficiency and particle size. These plots displayed constant contours (z-slices), enabling a two-dimensional representation of the three dimensional response surface. Additionally, 3D surface quadratic plots were created for each variable, providing a deeper insight into their interaction with the responses and highlighting the influence of different factor levels. The 3D plots are shown from fig.7.

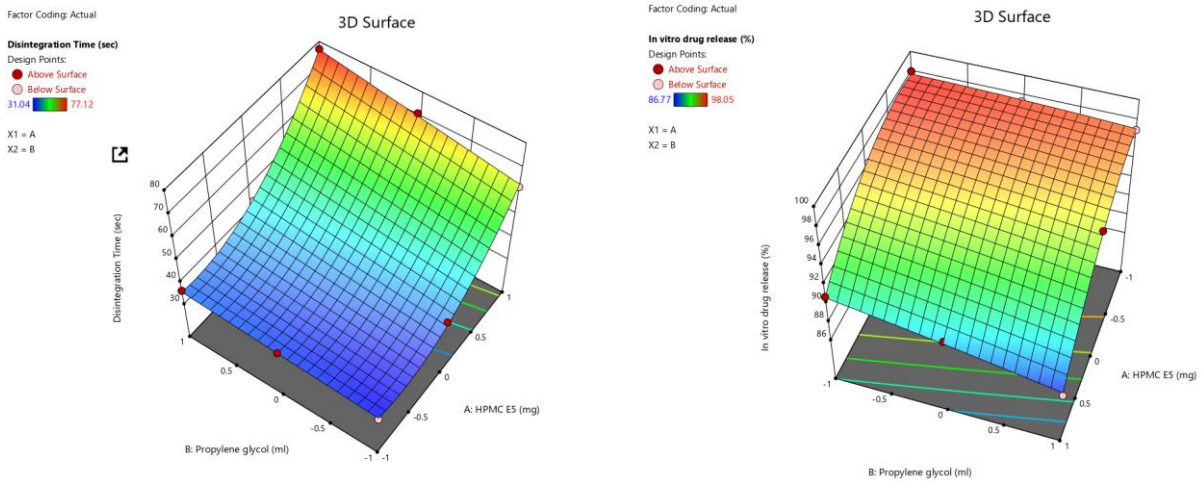

Fig. 7: 3D surface plot of R1 R2.

Selection of optimized batch

To validate the accuracy of the design model, a check point batch was selected from the overlay plot for evaluation which is shown in fig.8. This batch was formulated and tested within the experimental domain to ensure model reliability. The observed experimental values of the response parameters were quantitatively compared to the predicted values, and the percentage bias was calculated to assess the deviation between them. The close agreement between experimental and predicted values confirmed the adequacy of the model, ensuring the reliability of the optimization process.

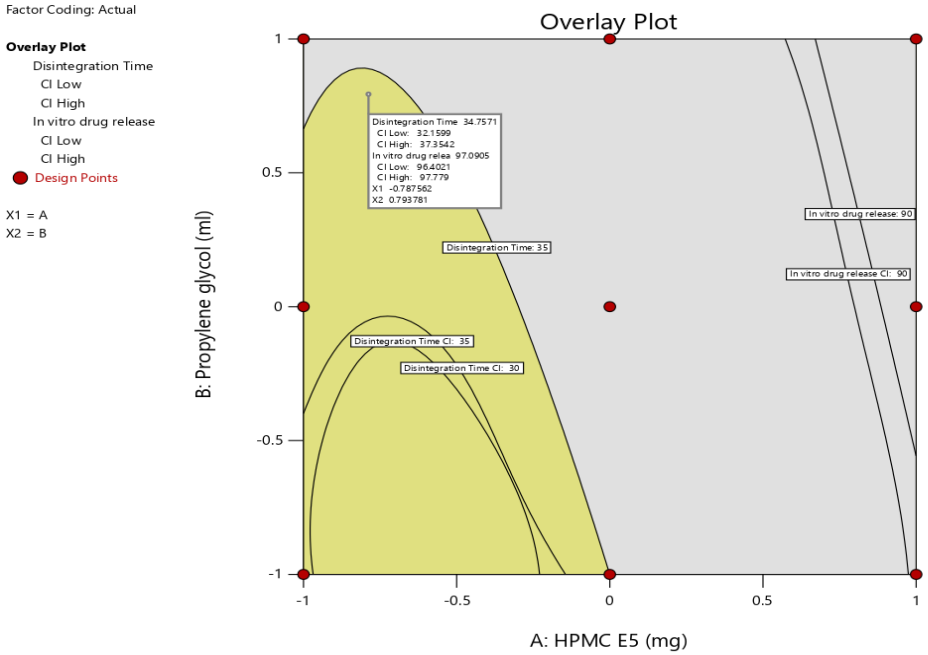

Fig. 8: Overlay plot and Check point batch.

Short term stability study of optimized batch

A stability study was conducted to assess the stability profile of the developed formulation under accelerated conditions (40°C ± 2°C / 75 ± 5% RH). The condition of drug is shown in table.9.

Table 9: Short term stability of optimized batch.

Condition	**40°C ± 2 °C and 75% RH ± 5% RH**	
Evaluation	Initial observation	After a Month
Appearance	Translucent	Translucent
% Drug content	98.26±0.21	97.21± 0.23
Disintegration time(sec)	31.04±0.81	33± 0.56
Folding Endurance	150±3.41	148± 0.63
%CDR at 15 min	98.05±0.4	96.4 ±0.45
±SD n =3		

CONCLUSION

Buccal film containing Silodosin were formulated using HPMC E5 as a film forming agent and Propylene glycol as a plasticizer by solvent casting method. Hence, from the results it was concluded that faster disintegration and faster drug release can be achieved by the buccal film of Silodosin by oral route.

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