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FORMULATION AND EVALUATION OF SOLIFENACIN SUCCINATE SUBLINGUAL TABLETS

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ABSTRACT

The aim of present investigation was formulation and development of Solifenacin Succinate Sublingual tablets. The Study started from the Preformulation study of the drug. Drug belonged to BCS class-II and had good solubility properties. The flow properties of API were found to be good enough, hence direct compression technique was used for tablet preparation. While studying IR spectrum, it was concluded that there was no interaction between drug and other excipients. Initially feasibility trials were taken to optimize three superdisintegrants namely Crospovidone, Croscarmellose sodium and Sodium starch glycollate. Tablets were found acceptable in physical parameters evaluation. After preliminary screening, it was concluded that Crospovidone showed fastest rate of drug release. Based on that P2 batch was found satisfactory and considering for further factorial screening. 32 factorial design was applied by taking Crospovidone and Mannitol as independent factors. Factorial batch F1-F9 prepared by using direct compression method. Physical and chemical evaluation was done for all batches. Finally, from overlay plot Checkpoint batch (S1) was prepared and post compression parameters were evaluated and compared with optimised factorial batch F2 and found satisfactory. F2 batch was also compared with marketed formulation for rate of drug release in phosphate buffer pH 6.8. Finally optimized factorial batch F2 was loaded for stability study for 1 month and evaluation was done and found acceptable. Hence, F2 was the optimized formulation.

Keywords: Solifenacin succinate, Sublingual tablets, Crospovidone, Croscarmellose sodium and Sodium starch glycollate

INTRODUCTION

The oral route of drug administration was most preferred and widely accepted route of administration for variety of drugs and nutraceuticals **[1]**. It offers numerous advantages such as, ease of administration, greater flexibility in dosage form and design space along with rapid mass production with high degree of automation and low manufacturing cost. The parenteral route of administration is important in case of medical emergencies, while topical route is mainly employed to deliver drugs to systemic circulation via epidermis **[2]**. Almost 90% of the prescribed drugs are administered by oral route for their obvious advantages over other route of administration and hence have become the most popular route of administration. The dosage form available for oral administrations are solutions, suspensions, powders, tablets and capsules **[3]**. The drugs administered by oral route are versatile, flexible in dosage strength, relatively stable, present lesser problem in formulation and packaging and are convenient to manufacturer, store, handle and use. Solid dosage forms provide best protection to drugs against temperature, light, oxygen and stress during transportation **[4]**. Most commonly employed solid oral dosage forms are tablet and capsule. Many pharmaceutical dosages are administered in the form of pills, granules, powders, and liquids. Generally, a pill design is for swallowing intact or chewing to deliver a precise dose of medication to patients. However, some patients, particularly pediatric, geriatric, bedridden, psychiatry and traveling patients have difficulty for swallowing or chewing solid dosage forms **[5]**. These patients develop unwilling tendency to take these solid preparations due to fear of choking and unavailability of water duringtraveling. One study shows that an estimated 50% of the population suffers from dysphagia problem **[6]**. It shows need for a new dosage form that can improve patient compliance. Sublingual drug delivery system is a type of oral mucosal drug deliverywhere in dosage form is placed beneath the patient's tongue mucosal tissue where it rapidly disintegrates, dissolves and absorbed through highly vascularised sublingual mucosa and drug reaches into systemic circulation Sublingual drug delivery comprises various types of dosage forms such as films, tablet, spray, solution and powder **[7]**. These all-dosage form when given sublingually reaches into systemic circulation. Major advantages of this dosage form is that it bypasses hepatic first pass metabolism and increase bioavailability of poorlybio available drug and faster onset of

action of drug compared to conventional oral route. Water is not required for such dosage forms, which is a convenient feature for patients who are travelling and do not have immediate access to water **[8]**. The presence of saliva ensures faster wetting of the dosage form as the dosage form is submerged into it followed by faster disintegration, dissolution and finally absorption. Flushing of saliva occurs so to overcome its effect on dosage form, mucoadhesive sublingual dosage form can be incorporated which can retain at the site of action for longer period of time exhibiting its action **[9]**.

MATERIALS AND METHODS

Materials

Solifenacin Succinate, Crospovidone, Sodium Starch Glycolate, Croscarmellose Sodium, Aspartame, Magnesium Stearate, Talc, Avicel pH 102, MCC

Methods

Physical Characterization

Solifenacin succinate was evaluated for organoleptic characteristics like colour, odor andtaste.

Preformulation Studies

Preformulation testing is defined as investigation of physical and chemical properties of a drug substance alone and when combined with excipients. It gives information needed to define the nature of the drug substance and provide framework for the drug combination with pharmaceutical excipients in the dosage form.

Bulk Density

Apparent bulk density was determined by pouring pre-sieved drug excipient blend into a graduated cylinder and measuring the volume and weight “as it is”. It is represented in gm/mL and is given by,

$$Db = M/V0$$

where, M is mass of powder,

V**0** is Bulk volume of the powder.

Tapped Density

It was determined by placing a graduated cylinder, containing a known massof drug-excipient blend, on mechanical tapping apparatus. Take the powder to constant volume. The tapped volume was measured by tapping. It expressed in gm/mL and is given by,

$$Dt = M / Vt$$

Where, M is the mass of powder,

Vt is the tapped volume of the powder .

Carr’s Index

It is expressed in percentage and is expressed by

$$CI = Dt - Db/Dt$$

Where, Dt is the tapped density of the powderDb is the bulk density of the powder.

Table 1: Relationship between Carr's Index and compressible property

Carr's Index	Compressible property
5-15	Excellent
1-16	Good
18-21	Fairly Acceptable
23-35	Poor
33-38	Very poor
<40	Very very poor

Hausner's ratio:

Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following formula.

H= Dt / DbWhere, Dt is the tapped density of the powder Db is the bulk density of the powder.

Lower Hausner's ratio (< 1.25) indicate better flow properties than higher ones (>1.25).

Angle of Repose.

The frictional forces of a loose powder can be measured by using angle of repose.It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane.

$\tan(\theta) = h / r\theta = \tan^{-1}(h / r)$

Where,θ is the angle of repose. h is the height in cmsr is the radius in cms.

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). Angle of repose was calculated by measuring the tallness and radius of the heap of powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel. Relationship between angle of repose and powder flow property is given as:

Table 2: Angle of repose as an indication of powder flow properties

Angle of repose	Flow
<25	Excellent
25 – 30	Good
30 – 40	Passable
>40	Very poor

Formulation development

Sublingual tablets containing 5 mg of model drug were prepared with a total tablet weight of 100 mg. Considering the preformulation studies and the literature survey conducted, the excipients were selected and an attempt to produce sublingual tablets with ideal mouth feel maintaining the basic tablet properties was made.

Selection of superdisintegrants:

Short disintegration time with good dispersibility is the most important characteristics of a sublingual or mouth dispersible tablets. The necessity of a Sublingual tablet is to disintegrate within seconds, in limited amount of the water available in the form of saliva. Different

superdisintegrants like croscarmellose sodium, crospovidone, Sodium starch glycollate were used which act as disintegrating agents used at various concentrations and a comparative study was carried out.

Method of formulation

Direct compression method.

The model drug (Solifenacin succinate) was thoroughly mixed with the superdisintegrants, and then other excipients were added to the mixture and passed through the sieve (#40). Collected the powder mixer, blended with magnesium stearate (pre-sieved), and subjected the blend for tablet compression.

Evaluation of tablets

Hardness test:

The hardness of the tablets was determined by diametric compression using a Hardness testing apparatus. A tablet hardness of about 4-5 kg is considered adequate for mechanical stability. Determinations were made in triplicate.

Friability:

The friability of the tablets was measured in a Roche friabilator. Tablets of a known weight (W0) dedusted in a drum for a fixed time (100 revolutions) and weighed (W) again. Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1 %.

Measurement was calculated using the following formula:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final we}}{\text{Initial weight}}$$

In- vitro Disintegration Time:

Disintegration times for sublingual tablets were determined using USP tablet disintegration apparatus with saline phosphate buffer of pH 6.8 as medium. Maintained the medium temp at 37± 2° C. The time in seconds taken for complete disintegration of the tablets with no palatable mass remaining in the apparatus was measured.

Wetting Time:

A piece of tissue paper folded twice was placed in a small Petri dish (ID = 6.5 cm) containing 6 mL of simulated saliva pH, a tablet was put on the amaranth powder containing paper the time required for upper surface of the tablet for formation of pink color was measured.

In-vitro Dissolution studies:

Dissolution of the tablet of each batch was carried out using USP dissolution type II apparatus (ELECTROLAB) using paddles at 50 rpm. As per the official recommendation of IP, 900mL of phosphate buffer of pH 6.8 was used as dissolution medium and the temperature of the medium was set at 37 ± 0.5°C. 5 mL of sample was withdrawn at predetermined time interval of 2, 4, 6, 8, 10, 12, 14 and 16 min and same volume of fresh medium was

replaced. The withdrawn samples were analyzed by an UV-visible spectrophotometer at 259 nm using phosphate buffer of pH 6.8 as blank solution.

Stability Studies:

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage conditions, re-test periods and shelf-lives. Generally, the observation of the rate at which the product degrades under normal room temperature requires a long time. To avoid this undesirable delay, the principles of accelerated stability studies areadopted.

ICH specifies the length of study and storage conditions.

Long-Term Testing: 25^0 C ± 2^0 C / 60% RH ± 5% for 12 Months

Accelerated Testing: 40^0 C ± 2^0 C /75% RH± 5% for 6 Months/ 3 months/ 1 month

Stability studies were carried out at 40^0C ± 2^0C /75% RH ± 5% for all the optimized formulation for a period of 1 month.

The selected formulations were closely packed in aluminum foils and then stored at 40^0 C ± 2^0 C /75% RH ± 5% in stability chamber for 1 month and evaluated for their physical appearance, drug content and *in-vitro* drug release studies after 1 month.

RESULT:

Physical Characteristics-

Solifenacin succinate is White Amorphous powder, having no distinct odour and is found to be bitter in taste.

Literature review also reveals the acceptance of physical characteristics and is foundto be matching with test results of the drug **(Table 3)**.

Table 3: Physical Characteristics

Appearance	**White Amorphous Powder**
Odour	**Odourless**
Taste	**Bitter**

Identification of drug-

Solifenacin succinate was identified by UV-visible spectrophotometry, and found that the λmax observed in the spectrum was found to be 220 nm in distilled water which matches exactly with the reported λmax of the pure drug. The match confirms that the drug sample is Solifenacin succinate. The calibration curve was prepared in phosphate buffer pH 6.8, because the *in-vitro* drug release studies was to be carried out in simulated salivary fluid which isphosphate

buffer pH 6.8.The Absorption maxima (λ_{max}) in phosphate buffer pH 6.8 was found to be 259 nm.The absorbance of the concentrations made was found to be increasing linearly with the increase in the concentration of drug. The R^2 value was found to be 0.9913 which states that linearity was observed in relationship of concentration and absorbance. In the current investigation, analytical method obeyed beer-lamberts law in the concentration range of 10-100 µg/mL and it was suitable for the estimation solifenacin succinate using phosphate buffer of pH 6.8. The value of correlation coefficient (r) for the linear regression equation was found to be more than 0.99 which indicates a positive correlation between the concentration of drug and corresponding absorbance values.

Drug-Excipients Compatibility Studies-

Chemical interactions between drug and excipients were carried out FTIR spectrophotometric studies.

Both Pure drug as well as drug-excipient mixture (blend) of optimized formulation was scanned and the bond stretching was compared and matched with that of pure drug.

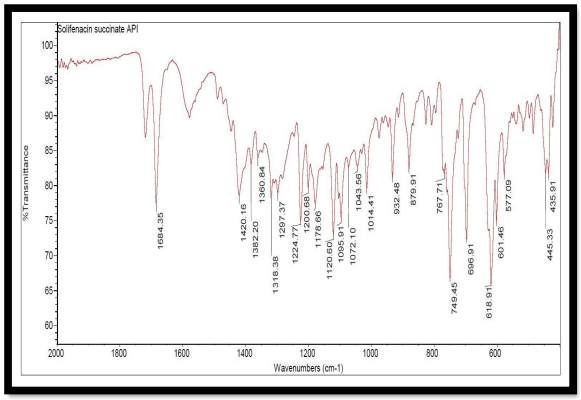

Figure 1: FTIR Spectra of pure drug Solifenacin Succinate

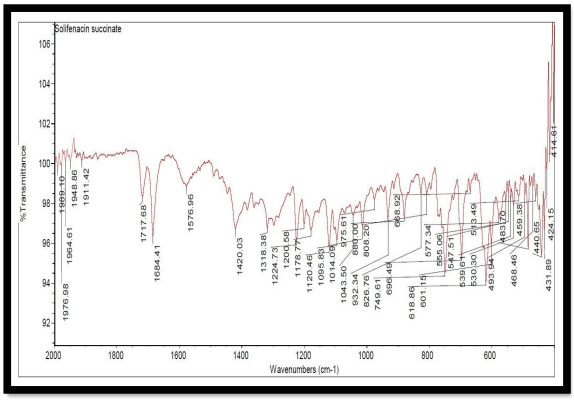

Figure 2: FTIR Spectra of Drug and Excipients (Blend)

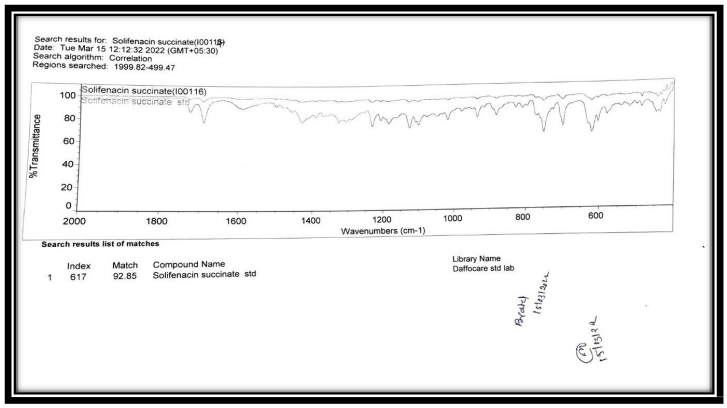

Figure 3: Comparison of FTIR spectra of pure drug and Blend

FTIR data obtained from spectra of pure drug (API) and Blend were compared and the comparison of FTIR data of Blend and API was found to be 92.85 % match, which states that API as well as excipients both are chemically compatible and it proves that there is no chemical interaction between API and excipients.

Melting point-

Table 4: Results of Melting point

Drug	Observed Melting point range	Standard melting point range
Solifenacin Succinate	132-135˚C	134-136 ˚C

Precompression studies of Preliminary Batches-

Table 5: Precompression parameters of Preliminary batches

Formulation	Bulk Density (gm/mL)	Tapped Density (gm/mL)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (θ)
P1	0.49±0.06	0.61±0.04	19.67±0.01	1.24±0.07	24.55˚
P2	0.47±0.10	0.50±0.02	6.00±0.04	1.06±0.05	22.33˚
P3	0.50±0.07	0.54±0.06	7.41±0.04	1.08±0.03	22.98˚
P4	0.48±0.03	0.58±0.01	17.24±0.08	1.21±0.02	26.22˚
P5	0.46±0.10	0.66±0.03	30.30±0.06	1.430.06	29.19˚
P6	0.43±0.08	0.62±0.03	30.65±0.08	1.44±0.09	30.61˚
P7	0.51±0.10	0.54±0.09	5.56±0.07	1.06±0.01	27.52˚
P8	0.50±0.04	0.59±0.10	15.25±0.06	1.18±0.04	26.57˚
P9	0.48±0.02	0.56±0.06	14.29±0.05	1.17±0.08	26.91˚

Formulation P2 and P7 shown best compressibility properties as well as flow properties. Compressibility index of Formulation P2 was found to be 6.0 %, Hausner's ratio was found to be 1.06 and angle of repose was found to be 22.33˚.Compressibility index of Formulation P7 was found to be 5.56 %, Hausner's ratio was found to be 1.06 and angle of repose was found to be 27.52˚. Both formulations shown excellent compressibility properties and excellent flow properties. From the pre compression parameters, it was concluded that; Formulation number **P2** and **P7** were having good compressibility index, Hausner's ratio and Angle of repose. This concludes that, the blend is having good compressibility and flowing properties.

Post compression parameters of Preliminary Batches-

Table 6: Post compression Parameters of preliminary batches (Thickness, Hardness, % Friability & Weight variation)

Formulation	Thickness (mm)	Hardness (kg/cm^2)	Friability(%)	Weight variation
P1	3.44±0.18	3.5±0.3	0.27±0.01	98.21±0.68
P2	3.42±0.09	3.3±0.2	0.20±0.09	99.47±0.74
P3	3.52±0.17	3.4±0.2	0.21±0.03	100.56±0.78
P4	3.51±0.12	3.9±0.3	0.23±0.10	98.21±1.07
P5	3.53±0.10	3.9±0.4	0.22±0.07	100.16±0.85
P6	3.58±0.08	3.7±0.2	0.28±0.09	99.80±1.85
P7	3.47±0.11	3.3±0.3	0.25±0.04	98.95±0.97
P8	3.54±0.15	3.5±0.4	0.28±0.12	100.27±1.68
P9	3.50±0.09	4.0±0.4	0.30±0.09	99.59±0.95

Table 7: Post compression Parameters of preliminary batches (Disintegration Time Wetting time and Drug content)

Formulation	Disintegration Time(Sec)	Wetting Time(Sec)	Drug Content (%)
P1	35±4	42±2	99.4±0.6
P2	27±3	40±3	99.0±0.5
P3	39±5	34±9	99.6±0.5
P4	30±6	55±5	99.6±0.4
P5	41±4	51±4	99.5±0.7
P6	37±1	54±8	99.2±0.7
P7	40±9	44±8	99.6±0.9
P8	38±4	40±5	99.0±0.6
P9	42±8	47±7	99.4±0.8

Formulation P2 shown best and desired disintegration time and wetting time. The disintegration time of P2 was found to be 27 seconds and wetting time was foundto be 40 seconds.

***In-vitro* Drug release studies of Preliminary batches-**

Table 8: *In-vitro* Drug release studies of Preliminary batches

Time (min)	P1	P2	P3	P4	P5	P6	P7	P8	P9
0	0	0	0	0	0	0	0	0	0
2	19.22	21.56	21.87	8.92	18.58	20.63	10.23	19.88	14.36
4	34.89	36.56	35.44	34.25	30.27	43.56	26.74	35.66	32.19
6	46.87	57.18	59.72	48.66	45.74	59.23	39.22	58.85	56.21
8	59.44	85.37	83.85	58.58	59.92	69.31	48.85	80.67	79.52
10	77.91	99.97	99.43	71.91	70.23	80.33	62.97	93.49	89.79
12	89.41	-	-	80.22	82.45	95.21	79.85	96.61	99.61
14	99.81	-	-	91.85	97.85	99.9	91.59	99.78	-
16	-	-	-	99.11	99.87	-	99.42	-	-

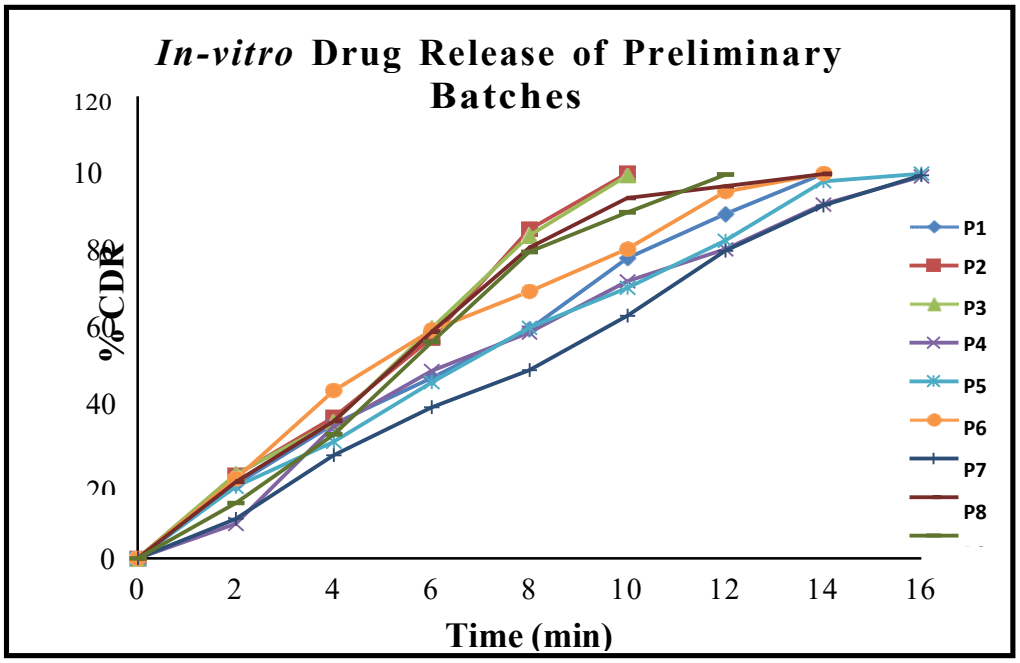

Figure 4: *In-vitro* drug release profile of preliminary batches

Further from post compression parameters, it was concluded that, Formulation number P2 has lowest Wetting time as well as disintegration time which is desirable. Finally, *In-vitro* drug release studies were carried out; the results of *in-vitro* drug release studies states that, Formulation number P2, gave more than 80% is drug release within 8 minutes.

From the observed values of disintegration time, wetting time and Time required to release 80% drug; of different batches, it was observed that **P2** has shown the best and desirable results. So, **Crospovidone** is determined as more suitable Super-disintegrant than others for the preparation of the sublingual tablet of Solifenacin succinate.

Precompression studies of Factorial Batches-

Table 9: Precompression parameters of Factorial batches

Formulation	Bulk Density (gm/mL)	Tapped Density (gm/mL)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (θ)
F1	0.51±0.07	0.58±0.08	12.07±0.02	1.14±0.01	25.68 °
F2	0.55±0.05	0.59±0.02	6.78±0.04	1.07±0.02	22.96 °
F3	0.49±0.03	0.55±0.01	10.91±0.06	1.12±0.01	26.21 °
F4	0.53±0.01	0.59±0.06	10.17±0.01	1.11±0.02	23.87 °
F5	0.48±0.04	0.51±0.04	5.88±0.05	1.06±0.05	23.28 °
F6	0.49±0.07	0.59±0.07	16.95±0.09	1.20±0.04	26.87 °
F7	0.50±0.09	0.57±0.05	12.28±0.05	1.14±0.02	25.68 °
F8	0.45±0.06	0.62±0.06	27.42±0.01	1.38±0.01	26.77 °
F9	0.41±0.04	0.58±0.02	29.31±0.08	1.41±0.04	24.52 °

Formulation F2 and F5 shown best compressibility properties as well as flow properties. Compressibility index of Formulation F2 was found to be 6.78 %, Hausner's ratio was found to be 1.07 and angle of repose was found to be 22.96°.Compressibility index of Formulation F5 was found to be 5.88 %, Hausner's ratio was found to be 1.06 and angle of repose was found to be 23.28°.Both formulations shown excellent compressibility properties and excellent flow properties. From the pre compression parameters, it was concluded that; Formulation number **F2** and **F5** were having good compressibility index, Hausner's ratio and Angle of repose. This concludes that, the blend is having good compressibility and flowing properties.

Post compression parameters of Factorial Batches-

Table 10: Post compression Parameters of preliminary batches (Thickness, Hardness, % Friability & Weight variation)

Formulation	Thickness(mm)	Hardness (kg/cm^2)	Friability (%)	Weight variation
F1	3.48±0.18	3.5±0.3	0.25±0.08	100.81±0.93
F2	3.44±0.19	3.6±0.2	0.25±0.02	100.72±0.39
F3	3.42±0.17	3.2±0.2	0.24±0.07	99.78±0.46
F4	3.50±0.09	3.7±0.5	0.20±0.05	99.12±0.77
F5	3.43±0.08	3.3±0.1	0.21±0.05	100.22±0.57
F6	3.48±0.08	3.6±0.2	0.24±0.04	98.96±1.32

F7	3.47±0.11	3.3±0.3	0.23±0.09	98.94±0.79
F8	3.50±0.14	3.5±0.5	0.21±0.06	100.56±0.61
F9	3.50±0.09	3.9±0.8	0.22±0.03	100.64±1.08

Table 11: Post compression Parameters of Factorial batches (Disintegration time, Wetting Time, % Drug content)

Formulation	Disintegration Time (Sec)	Wetting Time (Sec)	Drug Content (%)
F1	26±6	39±8	99.2±0.9
F2	23±8	35±5	100.0±0.5
F3	25±9	35±6	99.7±0.8
F4	29±8	38±7	99.5±0.8
F5	28±4	40±9	99.6±0.7
F6	27±2	39±8	98.9±0.8
F7	32±9	46±8	99.6±0.9
F8	30±8	44±5	100.0±0.2
F9	27±4	40±7	99.5±0.5

Formulation F2 shown best and desired disintegration time and wetting time. The disintegration time of F2 was found to be 23 seconds and wetting time was foundto be 35 seconds.

Results of checkpoint batch (S1)-

Table 12: Comparison of checkpoint batch and factorial batch

Post compression parameters	Checkpoint batch S1	Factorial batch F2
Weight Variation (mg)	100.81±0.93	100.72±0.39
Thickness (mm)	3.45±0.10	3.44±0.19
Hardness (Kg/cm^2)	3.6±0.3	3.6±0.2
% Friability	0.26±0.08	0.25±0.02
Disintegration time (sec)	23±6	23±8
Wetting time (sec)	36±8	35±5
% Drug content	99.9±0.9	100.0±0.5

All the post compression parameters of checkpoint batch were evaluated and found that all the parameters were matching with the actual factorial batch F2. This proves that the factorial design applied was significant and the data of factorial batches were relevant, up to the mark and satisfactory. The *in-vitro* drug release for checkpoint batch (S1) was compared to that of factorial batch F2 and found that the release pattern of both the tablets were close, equivalent and similar.

Table 13: *In-vitro* drug release comparison of checkpoint batch and factorial batch

Time (min)	S1	F2
0	0	0
2	29.23	26.59
4	55.42	49.63
6	79.59	75.67
8	95.84	88.58
10	99.99	99.99
12	-	-
14	-	-
16	-	-

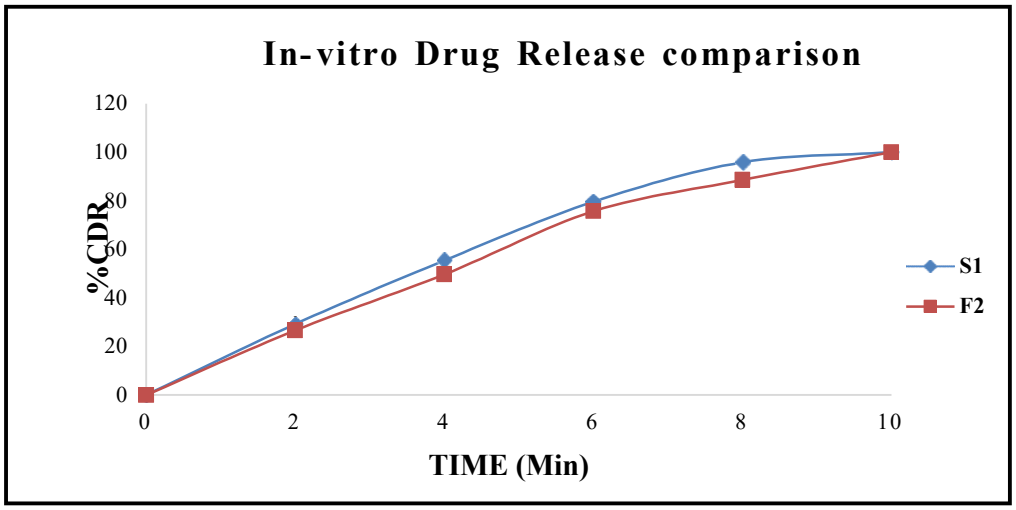

Figure 5: *In-vitro* drug release comparison of checkpoint batch and factorial batch

Comparison of *In-vitro* Drug release profiles of checkpoint point batch (S1) and Factorial batch (F2) concludes that both the formulations are nearly identical and possess same drug release pattern in same time interval.

Comparison with Marketed Formulation-

Optimized formulation **F2** was compared with **Soliten (Sun Pharmaceuticals Ltd)** marketed product and results obtained are tabulated in the table given below.

USP Apparatus: II (Paddle)

Speed: 50 RPM

Medium: Phosphate buffer pH 6.8

Volume: 900 mL

Sampling Time (min): 5, 10, 15, 20 and 30 min.

Table 14: Comparison with Marketed Formulation

	% Drug Release				
Formulation	**5 min**	**10 min**	**15 min**	**20 min**	**30 min**
Soliten	**40.67**	**55.85**	**69.31**	**80.99**	**92.21**
F2	**75.67**	**99.99**	**99.99**	**99.99**	**99.99**

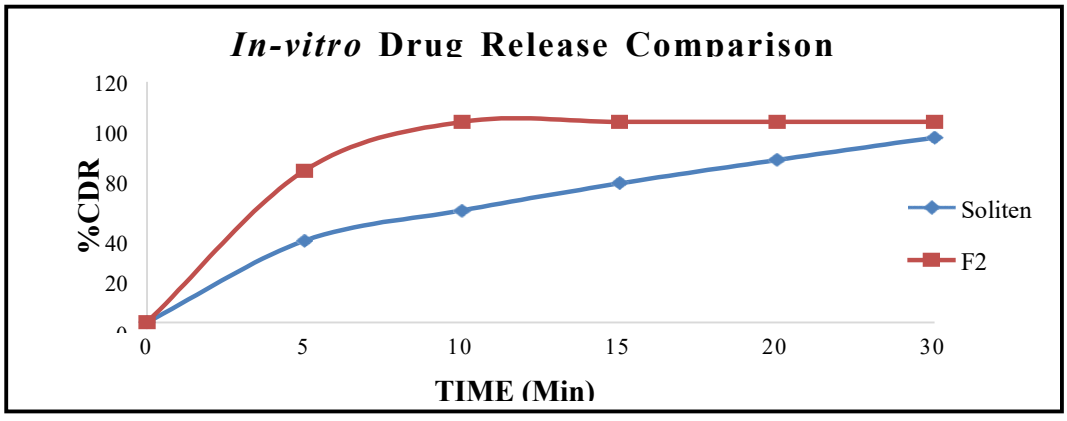

Figure 6: Comparison with Marketed Formulation

Stability Studies-

Stability study of optimized formulation F2 was carried out by keeping the tablets in stability chamber for 1 month at 40^0 C ± 2^0 C and 75% RH± 5%. All the post compression parameters were evaluated. Formulation was found stable and no any critical observationseen during stability.

Table 15: Results of Stability Study

Physical Parameter	Initial	After 1 Month
Physical appearance	White colored, round tablet	White colored, round tablet
Weight variation (mg)	100.32±0.28	100.32±0.28
Thickness (mm)	3.45±0.19	3.45±0.19
Hardness (Kg/cm^2)	3.6±0.2	3.4±0.1
Disintegration time	23±7	24±5
Wetting time	35±4	36±5
% Drug content	100.0±0.4	99.92±0.7

CONCLUSION

It was concluded that the present study was to develop and optimize oral sublingual tabletsof model drug Solifenacin Succinate to give quick onset of action by rapidly disintegrating in a few seconds without the need of water with better patient compliance. In such cases, bioavailability of drug is significantly greater and adverse event is reduced than those observed from conventional tablet dosage form.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation**.**

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