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Formulation and Evaluation of Sublingual Tablets of Clemastine Fumarate

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ABSTRACT:
The goal of the current work is to formulate sublingual tablets of Clemastine Fumarate by direct compression. Sublingual tablets were made by using a variety of superdisintegrants, including Plantago Ovata Husk (POH) and Sodium Starch Glycolate (SSG). All precompression metrics, including Carr's Index, Hausner's Ratio, and Angle of Repose, are within the range of the powder's standard values, indicating good flow qualities. The fact that the average weight, friability, and hardness all fell within compendial bounds indicated that all formulations had strong mechanical properties. The optimized formulation F9 showed minimum disintegration time of 18.66 ± 1.52 secs, wetting time 14.33 ± 1.15 sec and drug release of 99.69 % in 12 mins among all other batches of tablets. The stability investigation of batch F9 revealed that there was no appreciable change in the product's hardness, wetting time, In vitro disintegration time, drug content and In vitro dissolution profile. According to the results of the study, sublingual tablets of Clemastine Fumarate are a suitable dosage form, indicating that they are likely to be one of the options for Clemastine Fumarate preparations used to treat Allergic Rhinitis.

INTRODUCTION:

Allergic rhinitis (AR) is an atopic disease characterized by symptoms of nasal congestion, clear rhinorrhea, sneezing, postnasal drip, and nasal pruritus. It affects one in six individuals, and it is associated with significant morbidity, loss of productivity, and healthcare costs. Degranulation of host mast cells releases a variety of pre-formed and newly synthesized mediators, including histamine, which is one of the primary mediators of allergic rhinitis.[1-2]

The development of an optimized formulation necessitates systematic investigation and rigorous empirical validation to ensure peak efficacy. Clemastine Fumarate is used twice a day at a dose of 1.34 mg. The dosage may be increased as required, but not to exceed 2.68 mg orally 3 times a day. The oral bioavailability of Clemastine Fumarate is 39%. The volume of distribution was large, V_{ss} = 3.8 L/Kg Clemastine Fumarate is metabolized in the liver chiefly via mono and di-demethylation and glucuronide conjugation.[3-4]

Sublingual administration involves placing the medication under the tongue, where it dissolves and enters the bloodstream directly through the ventral surface of the oral cavity and the floor of the mouth. This delivery route is specifically designed to provide a rapid onset of pharmacological action compared to conventional oral tablets.[5]

By sublingual blood vessels, the drug bypasses hepatic first-pass metabolism, ensuring higher bioavailability. This route is particularly advantageous for patients suffering from dysphagia (common difficulty in swallowing) found across all age groups, but especially prevalent in children, the elderly, and uncooperative patients. Because these

formulations require only a minimal amount of saliva to disintegrate, they offer a safer, more efficient alternative for those on restricted fluid diets or individuals who lack immediate access to water, effectively eliminating the risk of choking associated with traditional swallowing.[6] So objective of the study was to prepare and evaluate clemastine fumarate sublingual tablets.

MATERIALS AND METHOD:

Materials:

Clemastine Fumarate was supplied by Riya Medicals, Maharashtra, India. Avicel PH 102, Sodium lauryl sulfate, Aspartame, Mannitol, Plantago Ovata Husk, Sodium Starch Glycolate (SSG), talc and Magnesium stearate were procured from Chemdyes Corporation, Rajkot, Gujarat, India.

Method: [7-11]

The sublingual Tablets were prepared using the direct compression method. Following passage through sieve #60, geometric dilution was used to combine the exact amount of the active component and all additions evenly. The blend was directly compressed using a Cronimach lab scale rotary compression machine equipped with a die set and an 8 mm flat-faced punch. The mass and compression force of each tablet did not change (Table 1).

Table 1: Formulation of Clemastine Fumarate sublingual tablet

Ingredients (mg)	Formulation code								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Clemastine Fumarate	2.68	2.68	2.68	2.68	2.68	2.68	2.68	2.68	2.68
Avicel pH 102	30	30	30	30	30	30	30	30	30
Plantago Ovata Husk	3	6	9	3	6	9	3	6	9
Sodium Starch Glycolate	3	3	3	6	6	6	9	9	9
D-mannitol	74.12	71.12	68.12	71.12	68.12	65.12	68.12	65.12	62.12
Aspartame	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
SLS	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Talc	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Magnesium stearate	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Total weight	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**

Determination of melting point of Clemastine Fumarate:[12,13]

Melting point of Clemastine Fumarate was measured by capillary apparatus. Minimum amount of drug was placed in a thin-walled capillary tube closed at one end. This capillary was then mounted in a melting point apparatus with thermometer and then their temperature range over which Clemastine Fumarate melts is measured. The readings were taken in triplicate.

Identification by UV Spectroscopy:[14]

Determination of λ_{max} of Clemastine Fumarate in phosphate buffer at pH 6.8:

Appropriate amounts (accurately weighed) of drug (10 mg) were quantitatively measured and then make the stock solution concentration of 100 µg/ml per IP. For determination of λ_{max}, stock solution was scanned between 200-400 nm against phosphate buffer (pH 6.8) as a blank in the UV-Visible spectrophotometer. Working solutions of concentration 5, 10, 15, 20 and 25 ppm were prepared by pipette outing 0.5, 1, 1.5, 2 and 2.5 ml respectively from the stock solution of 100 ppm and diluted up to 10 ml volumetric flask. Absorbance of working solutions was measured in triplicate at λ_{max} at 269 nm against phosphate buffer (pH 6.8) as a blank.

Preparation of Phosphate buffer at pH 6.8: Dissolve 28.80 gm of Disodium Hydrogen Phosphate and 11.45 gm of Potassium Dihydrogen Phosphate in sufficient water to produce 1000 ml.

Determination of drug by FTIR

FTIR was performed for determination of Clemastine Fumarate and was estimated for standard FTIR peaks.

Compatibility study of drug and excipients

FTIR spectroscopy was used for drug and excipients identification and to evaluate their compatibility. FTIR spectroscopy of pure drug and physical mixture of drug and excipients was carried out to check the compatibility of

drug and excipients.

Determination of pre compression parameters [15]
Bulk density, tapered density, Hausner's ratio, Carr's index, and angle of repose were all measured. Good flow qualities were indicated by the powder mixture's minimum Carr's index, Hausner's ratio, and angle of repose.

Determination of post compression parameters
Thickness and diameter
Tablet thickness and diameter were measured by Digi Matic Vernier calipers. Five tablets were randomly collected, and their thickness and diameter were measured by placing between two arms of Vernier calipers.

Hardness
Tablet hardness has been defined as the force required to break a tablet in a diametric compression test. The crushing strength of tablets was measured by using Monsanto type hardness tester.

Weight variation[16]
Twenty tablets were randomly collected, and average weight was determined by using an electronic balance.

% Friability[17,18]
The Roche friabilator was used to assess the tablets' friability. First, ten pills were put into a friabilator and weighed (W Initial). The friabilator was operated at 25 rotations per minute for 4 minutes. After then, the tablets were taken out, cleaned, and weighed once more (W Final). The % friability was calculated by using initial and final weight of tablets.

Wetting time[19,20]
Six circular tissue papers of 10 cm diameter were placed in a petri dish. 10 ml of phosphate buffer (pH 6.8) containing amaranth dye was added to petri dish. A tablet was carefully placed on the surface of tissue paper. Time required for water to reach the upper surface of tablet was noted as a wetting time.

***In vitro* Disintegration test** [21-24]
This test was performed on six tablets using digital tablet disintegration test apparatus. Phosphate buffer (pH 6.8) at 37°±0.5 °C was used as a disintegration media and time in second was recorded for complete disintegration of tablet with no residue remaining in apparatus.

Drug content[24-26]
Ten tablets were powdered and equivalent to 2.68 mg of Clemastine Fumarate was weighed and dissolved in 100 ml of phosphate buffer pH 6.8. The solution was filtered and 0.5 ml from filtrate was diluted to 10 ml and absorbance of this solution was analyzed by UV spectrophotometer at 269 nm.

***In vitro* Drug release study** [27-30]
% drug release of sublingual tablets was determined by USP type II (paddle type) dissolution apparatus. This test performed using 900ml of phosphate buffer (pH 6.8) at 37° ± 0.5 °C at 50 rpm. 5 ml sample solution was withdrawn from dissolution apparatus at regular time interval and the same quantity of sample was replaced with fresh dissolution media. The sample was filtered through 0.45µm membrane filter. Absorbance of these samples was analyzed by using UV spectrophotometer at 269 nm.

Stability study of optimized batch
In the present study, stability study of optimized batch was carried out at 40° ± 2°C / 75 ± 5% RH by wrapping the formulation in aluminum foil to prevent the formulation from exposure to light under the 40° ± 2 °C / 75 ± 5% RH as prescribed by ICH guidelines for accelerated stability study. After completion tablets were evaluated for Hardness, Friability, Drug content, Wetting time, *In vitro* Disintegration time and *In vitro* Drug Release study.

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RESULTS AND DISCUSSION:

PREFORMULATION STUDY:

The objectives of preformulation studies are to develop a portfolio of information about drug substances. So that this information is useful to develop formulation.

Preformulation investigations are designed to identify the physicochemical properties and excipients that may influence the formulation design, method of manufacturing and pharmacokinetic properties of resulting formulation.

Identification of Drug:

Determination of melting point of Clemastine Fumarate:

Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Clemastine Fumarate was found in the range of 175 - 179 °C Reported melting point of Clemastine Fumarate is 178 °C and is thus like the melting point of Clemastine Fumarate (Table 2).

Table 2: Melting point of Clemastine Fumarate

Sr. No.	Reported Melting Point	Observed Melting point
1.	178°C	176 - 178°C
2.		175 - 177 °C
3.		177 - 179 °C

Estimation of drug by UV spectra:

The absorbance of Clemastine Fumarate in a phosphate buffer at pH 6.8 was scanned between 200–400 nm by UV-Visible spectrophotometer. The spectrum of Clemastine Fumarate showed 269 nm at λmax. Calibration curve of Clemastine Fumarate is constructed in phosphate buffer of pH 6.8. From stock solution of Clemastine Fumarate, working solution of concentration range i.e., 5, 10, 15, 20 and 25 ppm were prepared in phosphate buffer of pH 6.8. Absorbance of prepared working solutions were measured at λ_{max} 269 nm against phosphate buffer of pH 6.8 as a blank in UV–Visible Spectrophotometer (Table 3 and Figure1).

Table 3: Absorbance of different concentration of Clemastine Fumarate in phosphate buffer at pH 6.8

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ± S.D.
		I	II	III	
1	5	0.359	0.349	0.354	0.354 ± 0.005
2	10	0.539	0.529	0.534	0.534 ± 0.005
3	15	0.698	0.697	0.695	0.696 ± 0.001
4	20	0.846	0.849	0.854	0.849 ± 0.004
5	25	1.003	1.008	1.009	1.006 ± 0.003

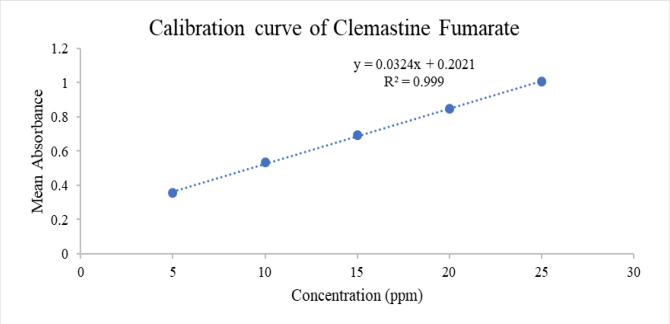

Figure 1: Calibration curve of Clemastine Fumarate in pH buffer 6.8

Identification of Clemastine Fumarate by FTIR Spectra

To identify drug, IR was performed on a pure drug sample. A drug pellet was created by compressing drug with IR grade potassium bromide under 5.5 metric tons of pressure in a KBr press. pellet was placed in IR compartment and scanned with an FTIR spectrophotometer between wave numbers 4000-450 cm-1. When Clemastine Fumarate was mixed with polymers, no changes in IR peaks were observed. These findings suggest that polymers are compatible with Clemastine Fumarate (Figure 2 and 3).

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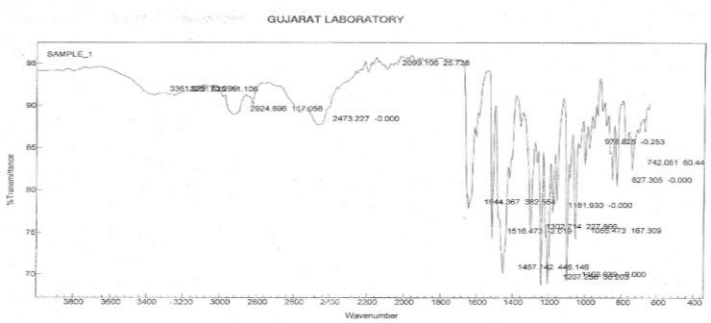

Figure 2: Ftir Spectra of Pure Clemastine Fumarate

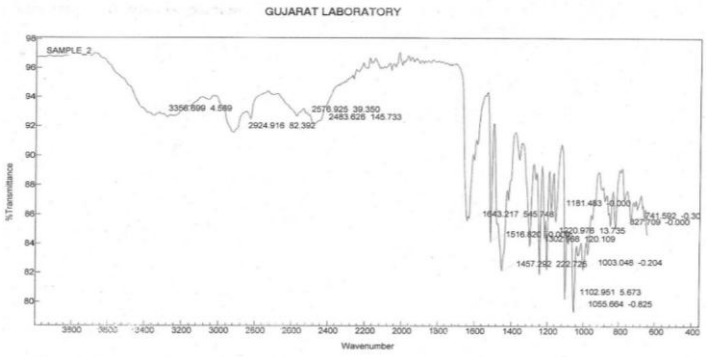

Figure 3: FTIR Spectra of Pure Clemastine Fumarate with excipients

PRECOMPRESSION PARAMETERS:

All formulation blends were evaluated for bulk density and tapped density. Bulk density was found to be 0.41± 0.031 gm/ml to 0.46 ± 0.038 gm/ml and tapped density was found to be 0.62± 0.015 gm/ml to 0.67 ± 0.011 gm/ml. Percentage Compressibility Index was determined by using bulk density and tapped density. Carr's index of all formulation blend lies within the range of 27.69± 0.02% to 34.42± 0.08%. Hausner's ratio of all formulation was evaluated from bulk and tapped density and it was found in the range of 1.40± 0.05 to 1.57± 0.05. Angle of repose of all formulation was in the range of 21.30 °θ ± 0. 28 to 40.69 °θ ± 0.35. (Table 4).

Table 4: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose

Batch code	Bulk density (gm/ml) (mean ± S.D.)	Tapped density (gm/ml) (mean ± S.D.)	Carr's index (%) (mean ± S.D.)	Hausner's Ratio (mean ± S.D.)	Angle of repose (°θ) (mean ± S.D.)
F1	0.44± 0.035	0.62± 0.015	30.76± 0.05	1.40± 0.08	23.74± 0.22
F2	0.41± 0.031	0.64± 0.018	29.82± 0.02	1.56± 0.05	40.69± 0.35
F3	0.46± 0.038	0.65± 0.022	34.42± 0.08	1.44± 0.03	27.27± 0.29
F4	0.44± 0.041	0.62± 0.016	28.33± 0.05	1.40± 0.05	23.36± 0.33
F5	0.42± 0.036	0.66± 0.014	31.74± 0.07	1.57± 0.05	39.68± 0.12
F6	0.45± 0.035	0.63± 0.021	34.42± 0.02	1.40± 0.07	22.78± 0.22
F7	0.43± 0.037	0.67± 0.011	32.37± 0.07	1.55± 0.08	21.30± 0.28
F8	0.45± 0.039	0.64± 0.019	27.69± 0.05	1.42± 0.06	24.22± 0. 36
F9	0.43± 0.041	0.62± 0.024	31.81± 0.05	1.44± 0.05	23.74± 0. 30

*** All values are expressed as mean ± SD; (n=3)**

Post-Compression Parameters:

Thickness of the formulated batches was found to be in the range of 2.95 ± 0.044 mm to 3.13 ± 0.061 mm. Diameter of the formulated batches was in the range of 8.02 ± 0.075 mm to 8.17 ± 0.115 mm. Weight variation of F1 to F9 was found to be from 119.5 ± 1.47 mg to 121.5 ± 1.41 mg. Thus, all the formulated batches prepared comply with the Weight variation limits of the pharmacopeia. It is well known that tablets with more hardness shows longer disintegration time. Mechanical integrity is of paramount importance in successful formulation of sublingual tablet; hence hardness of tablets was determined. Hardness of sublingual tablet prepared by direct compression method was

found in the range of 2.6 ± 0.12 kg/cm^2 to 3.5 ± 0.15 kg/cm^2. Friability of the tablets was found in the range of 0.41 to 0.74 %. According to IP, Limits of Friability is less than 1%. Observed values of friability indicated that tablets were having good mechanical stability (Table 5).

Table 5: Thickness, Diameter, Weight variation, Hardness and Friability

Batch code	Thickness (mm ± S.D.)	Diameter (mm ± S.D.)	Weight variation (mg ± S.D.)	Hardness (kg/cm^2± S.D.)	Friability (%)
F1	3.07 ± 0.058	8.04 ± 0.115	120.2 ± 1.58	3.1 ± 0.12	0.41
F2	2.96 ± 0.021	8.02 ± 0.075	119.9 ± 1.33	2.9 ± 0.13	0.74
F3	3.13 ± 0.058	8.12 ± 0.058	121.5 ± 1.41	3.1 ± 0.12	0.50
F4	2.96 ± 0.118	8.07 ± 0.058	120.5 ± 1.32	2.9 ± 0.14	0.57
F5	3.07 ± 0.115	8.13 ± 0.058	119.5 ± 1.47	3.1 ± 0.12	0.33
F6	3.08 ± 0.035	8.06 ± 0.058	120.2 ± 1.37	2.8 ± 0.15	0.41
F7	2.95 ± 0.044	8.17 ± 0.115	121.5 ± 1.39	2.6 ± 0.12	0.74
F8	3.13 ± 0.061	8.03 ± 0.058	120.3 ± 1.58	3.5 ± 0.15	0.50
F9	3.09 ± 0.012	8.04 ± 0.058	120.2 ± 1.48	2.8 ± 0.15	0.50

*** All values are expressed as mean ± SD; (n=6)**

Wetting time of the batches formulated was found to be in the range of 14.33 ± 1.15 sec. to 44.66 ± 0.58 sec. The batch F9 Having 9 mg POH and 9 mg SSG was found to be having least (14.33 ± 1.15 sec) wetting time as compared to other batches. *In vitro* Disintegration time of the batches formulated was found to be in the range of 18.66 ± 1.52 sec to 47.33 ± 0.57 sec. The batch F9 Having 9 mg Plantago Ovata Husk and 9 mg SSG was found to be having least (18.66 ± 1.52 sec) *In vitro* Disintegration time as compared to other batches. Drug content of the tablets prepared by direct compression method was found to be 96.69 to 99.68 %. These results of drug content indicated that sublingual tablets had uniform distribution and proper dose of active ingredients (Table 6).

Table 6: Wetting time, In-Vitro disintegration time and Drug Content

Batch code	Wetting time (sec. ± S.D.)	*In vitro* disintegration time (sec. ± S.D.)	Drug content (%)
F1	44.66 ± 0.58	47.33 ± 0.57	97.97
F2	30.67 ± 1.53	35.66 ± 1.52	96.69
F3	17.33 ± 1.53	24.92 ± 1.73	98.74
F4	37.98 ± 0.58	42.33 ± 0.57	99.68
F5	28.33 ± 0.58	33.66 ± 0.57	99.17
F6	16.33 ± 1.15	22.33 ± 2.51	98.19
F7	25.67 ± 1.53	31.55 ± 1.52	99.36
F8	22.04 ± 1.73	26.33 ± 1.52	98.73
F9	14.33 ± 1.15	18.66 ± 1.52	99.28

*** All values are expressed as mean ± SD; (n=6)**

In vitro Drug Release study is performed by using dissolution test apparatus type II (paddle) in 500 ml of the phosphate buffer at pH 6.8 as a dissolution medium at 37° ± 0.5 °C at 50 rpm. As the concentration of super disintegrant increases, there is increase in the drug release from the tablet. More than 50% of drug released in 3 mins. Formulations F1 to F3 show drug release 97.06±0.21 %, 99.11 ±0.28 %, and 99.27±0.24 % at the end of 18, 18 and 15 mins, respectively. Formulation F4 to F6 shows drug release 98.79±0.37 %, 96.64 ±0.26 % and 98.55 ±0.46% at the end of 18, 15 and 12 min, respectively. Formulation F7 to F9 shows drug release 97.21 ±0.44 %, 98.71±0.26 % and 99.69 ±0.25 % at the end of 15, 15 and 12 mins, respectively. Drug release profile indicates that Batch F9 containing 9 mg Plantaga ovata husk and 9 mg Sodium starch glycolate showed maximum drug release in just 12 min (Figure 4,5 and 6).

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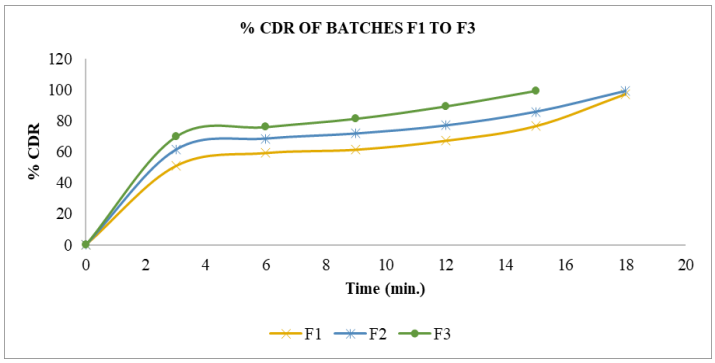

Figure 4: *In vitro* drug release of Batches F1 to F3

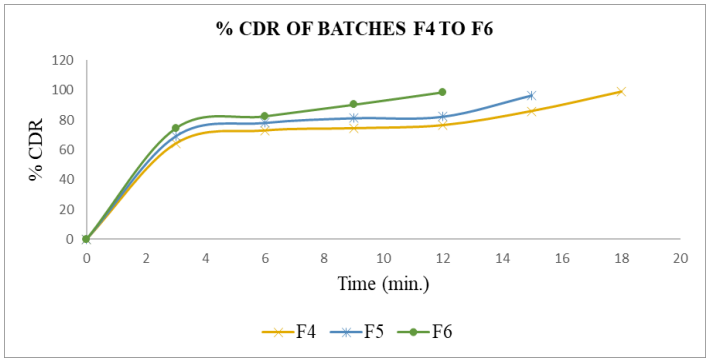

Figure 5: *In vitro* drug release of Batches F4 to F6

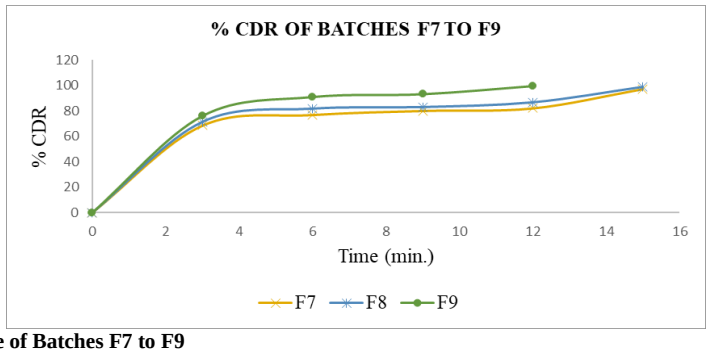

Figure 6: *In vitro* drug release of Batches F7 to F9

RESULT OF STABILITY STUDY:

Based on all above parameters it was concluded that the batch F9 was an optimized batch, as it had good surface appearance, Mechanical strength and Drug Content. A stability study carried out at 40° ± 2 °C and 75 ± 5% RH. After period of stability study Hardness, Wetting time, *In vitro* Disintegration time and *In vitro* Drug release study was carried out. Results of stability study shows that there is no significant difference in the all performed parameters. So, it was concluded that selected formulation is stable for longer period of time. Stability data showed that all the parameters were in acceptable limits as there was minor change in the results. Thus, the prepared batch F9 was stable over period of stability study. (Table 7 and 8).

Comparison study between the result of optimized batch and after period of stability of optimized batch is graphically illustrated in Figure 7.

Table 7: Result of the Stability study

Sr. No.	Evaluation parameter	Results	
		Optimized batch F9	after 1 month at 40° ± 2 °C and 75 ± 5 % RH
1	Hardness	2.80 ± 0.15	2.78 ± 0.12

2	Wetting Time	14.33 ± 1.15	13.22 ± 1.53
3	*In vitro* Disintegration Time	18.66 ± 1.52	17.12 ± 1.52
4	Drug Content	99.28	98.91

Table 8: *In vitro* Drug Release study of Stability batch

Time (Min.)	% CDR of Optimized Batch F9 (%)	% CDR of batch F9 After Time Period of 1 Month (%)
0	0	0
3	76.09	73.91
6	91.09	87.64
9	93.29	90.44
12	99.69	97.18

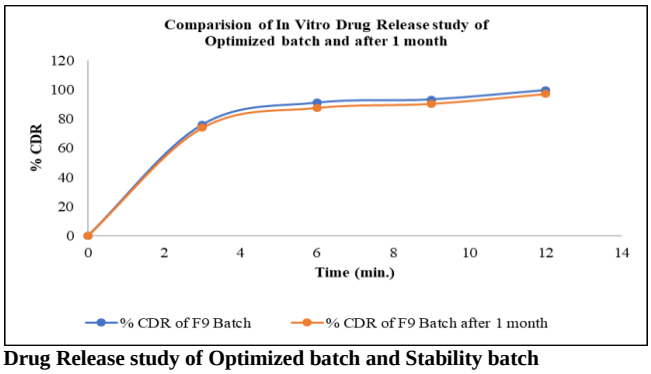

Figure 7: Comparison of *In vitro* Drug Release study of Optimized batch and Stability batch

CONCLUSION:

The concept of sublingual tablet containing Clemastine Fumarate offers a suitable and practical approach in serving the desired objective to treat Allergic Rhinitis. The excipients used in the formulation were inexpensive and are easily available. Most of the excipients used in formulation are water-soluble and hence have better patient acceptability. The result of FTIR showed that there was no interaction between drug and excipients used. Sublingual tablets of Clemastine Fumarate were prepared by Direct compression method using different Super disintegrants. All precompression parameters like Carr's Index, Hausner's Ratio and Angle of Repose meets the standard values of powder indicating good flow properties. The average weight, friability and hardness were within compendial limits which showed that all formulations possessed good mechanical strength. Drug content uniformity was within acceptable limits, which indicates a homogeneous distribution of drug in tablets. For the preparation of Sublingual tablets various Super disintegrants were used Plantago Ovata Husk and SSG. The formulation F9 was optimized which showed minimum disintegration time of 18.66 ± 1.52 secs, wetting time 14.33 ± 1.15 sec and drug release of 99.69 ± 0.25 % in 12 mins among all other 9 batches of tablets. The result of stability study of batch F9 showed that there was no significant change in all parameters for a period of one month when stored at 40° ± 2 °C and 75 ± 5% RH. From the study it was concluded that Sublingual tablets of Clemastine Fumarate can be successfully prepared using Direct compression method, which can provide rapid drug release within a short period time. Thus, it will be an important factor in improving patient compliance which is prerequisite to treat allergic rhinitis for all age groups.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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