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FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM OF MECLIZINE

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ABSTRACT
Formulation of fast dissolving buccal film involves material such as strip- forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents, permeation enhancers, and super disintegrants. All the excipients used in the formulation of fast dissolving film should be approved for use in oral pharmaceutical dosage forms as per regulatory perspectives. Meclizine, a piperazine-derivative H1-receptor antagonist similar to buclizine, cyclizine, and hydroxyzine, is used as an antivertigo/antiemetic agent. Meclizine is used in the management of nausea, vomiting, and dizziness associated with motion sickness and vertigo in diseases affecting the vestibular apparatus.

KEYWORDS: *Buccal Film, Meclizine, H1-receptor, super disintegrants, excipients, hydroxyzine.*

INTRODUCTION

Oral fast disintegrating dosage form mainly consist of oral disintegrating tablets which disintegrate rapidly, usually within a matter of seconds, when placed upon the tongue but leave residues in mouth which causes feeling of grittiness in mouth. Even with fast dissolving tablets there is a fear of choking due to its tablettype appearance. One study showed that 26% of 1576 patients experienced difficulty in swallowing tablets. The most common complaint was tablet size, followed bysurface form and taste. To overcome problems of mouth dissolving tablets, a new drug delivery system for the oral delivery of the drugs, was developed which is known as Fast dissolving films/mouth dissolving films/oral dispersible film/oral dissolving film/oral disintegrating film.

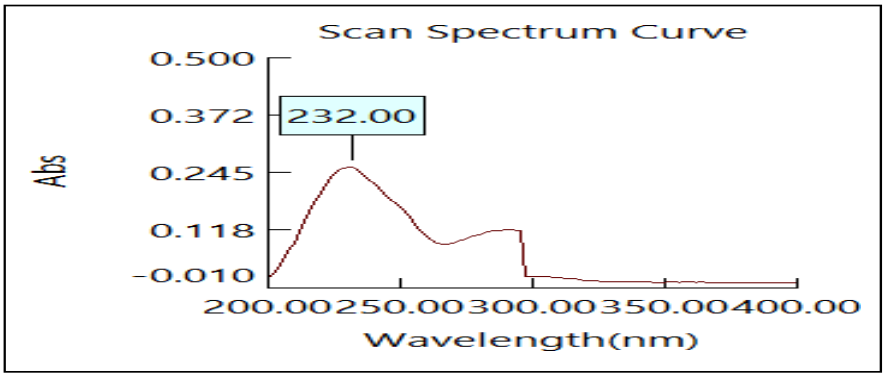
Fast dissolving oral films ($FDOF_s$) is a type of oral drug delivery system for the oral delivery of the drug which was developed based on the technology of the transdermal patches. This delivery system consists of a thin filmof the size of a postage stamp, which is placed on the patient's tongue or mucosal tissue, where it instantly hydrates by absorbing saliva; the film then rapidly disintegrates and dissolves to release the drug for oral mucosal absorption. This fast dissolving action is primarily due to the large surface area of the film, which wets quickly when exposed to the moist oral environment. Fast dissolving oral films were initially introduced in the market as breath fresheners and personal care products such as dental care strips and soap strips. However, these dosage forms were introduced in the United States and European pharmaceuticalmarkets for therapeutic benefits.

MATERIAL AND METHOD

Material- Meclizine drug was purchased from Srikem Laboratories and other chemicals were purchased from CDH and Himedia laboratory.

Method- Determination of λ_{max} of Meclizine

The λ_{max} of Meclizine was determined by running the spectrum of drug solution in double beam ultraviolet spectrophotometer (Bhide and Nachinolkar, 2018). Accurately weighed 10 mg of drug was dissolved in 10 ml of Methanol in 10 ml ofvolumetric flask. The resulted solution 1000µg/ml and from this solution 0.1 ml pipette out and transfer into 10 ml volumetric flask and volume make up with Methanol prepare suitable dilution to make it to a concentration of 10µg/ml for Meclizine. The spectrum of this solution was run in 200-400 nm range in U.V. spectrophotometer (Labindia-3000+). The spectrum peak point graphs of absorbanceof Meclizine versus wave length were shown in figure.



Determination of λ_{max} of Meclizine

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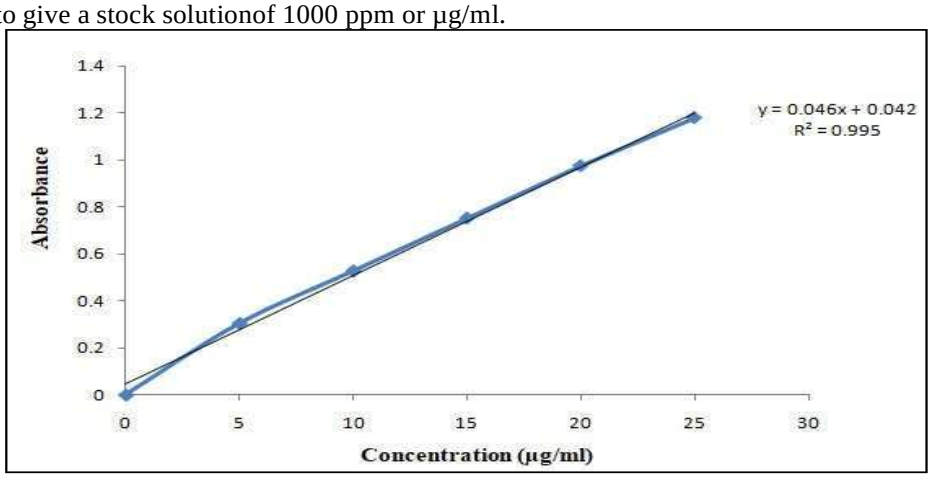
Calibration curve of Meclizine Preparation of Standard Stock Solution

10mg of drugs was weighed accurately and transferred to 10 ml volumetric flask, and the volume was adjusted to the mark with the Methanol to give a stock solutionof 1000 ppm or µg/ml.



Graph of calibration curve of Meclizine at 232 nm

Formulation of oral film of Meclizine-

Name of ingredients(mg for 12 strips)	F1	F2	F3	F4	F5	F6
API Equivalent to 25mg (100 mg of physical mixture)	1200	1200	1200	1200	1200	1200
HPMC	400	600	800	400	600	800
Glycerin	-	-	-	-	-	-
PEG-400	100	100	100	100	100	100
SSG (mg)	100	150	200	-	-	-
CCS (mg)	-	-	-	100	150	200
Aspartame (mg)	25	25	25	25	25	25
Citric acid (mg)	50	50	50	50	50	50
DM water qs to (ml)	30	30	30	30	30	30

Meclizine containing fast dissolving films was fabricated by the solvent casting method (Mahesh *et al.*, 2010). The optimized amount of HPMC was dissolved in 5ml of water and stirrered continuously for 1 hour, optimized amount of plasticizerand drug were dissolved in 95% ethanol and then added to the polymeric solution, the optimized amount of drug was dissolved in 2ml of water and kept in sonicator forproper dispersion. Polymeric solution was stirred for 30 min using magnetic stirrer and was kept in undisturbed condition till the entrapped air bubbles were removed. The aqueous solution was casted in a glass moulds having 2.5 x 2.5 cm^2 10 films area and was dried at controlled room temperature (25°-30°C, 45 %RH) as well as at increased temperature (microwave oven). The film took approximately 48 hr to dryat controlled room temperature. The dried film was carefully removed from the glassplates and was cut into size required for testing. The films were stored in air tight plastic bags till further use.

RESULTS AND DISCUSSION

1.Results of Preformulation study

A) Physical evaluation

Table 1: Physical evaluation of drug

S. No.	Sensory characters	Results of Physical evaluation
		Meclizine
1.	Colour	Slightly yellowish, crystalline powder
2.	Odor	Slight odor
3.	Taste	Tasteless

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B) Results of Solubility

Table 2: Solubility of Meclizine

Solvent used	Results of Solubility
Distilled Water	Sparingly soluble
0.1 N Hydrochloric acid	Soluble
Ethanol	Soluble
Methanol	Soluble
Chloroform	Soluble
0.1 N NaOH	Sparingly soluble
Phosphate buffer pH 6.8	Sparingly soluble

C) Results of Melting point

Table 3: Melting point of Meclizine

S. No.	Melting Point of Meclizine
1.	220-223□

D) Identification test using FTIR Spectroscopy

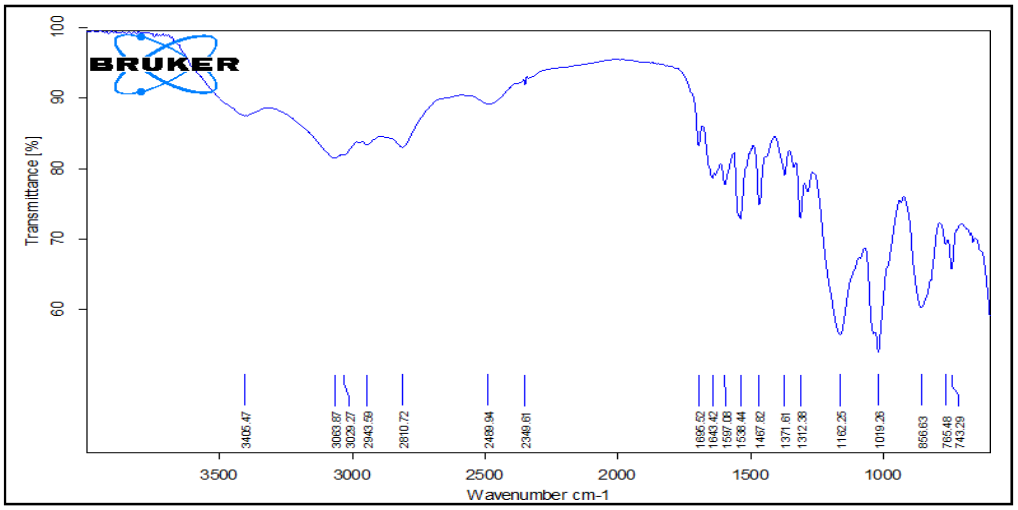

Figure 1: FT-IR Spectrum of Meclizine

E) Results of Loss on drying:

Table 4: Loss on drying of Meclizine

S. No.	Initial weight	Final weight after 15 minutes	% loss of drying	Avg. % loss of drying
1.	5gm	4.87	2.6	2.86±1.48
2.	5gm	4.94	1.2	
3.	5gm	4.76	4.8	

(N=3, mean±SD)

2.Evaluation of solid dispersions

Table 5: Percentage cumulative drug release of physical mixture

S. No.	Time interval (min.)	Percentage cumulative drug release of physical mixture*			
1	**0**	**1:1**	**1:2**	**1:3**	**Pure Drug**
2	30	25.56	29.98	35.65	9.45
3	60	36.65	38.85	42.23	11.23
4	120	45.58	52.23	59.98	14.45
5	240	55.54	63.45	69.94	16.65
6	360	62.23	71.15	73.36	18.89
7	480	65.25	73.32	76.45	20.41

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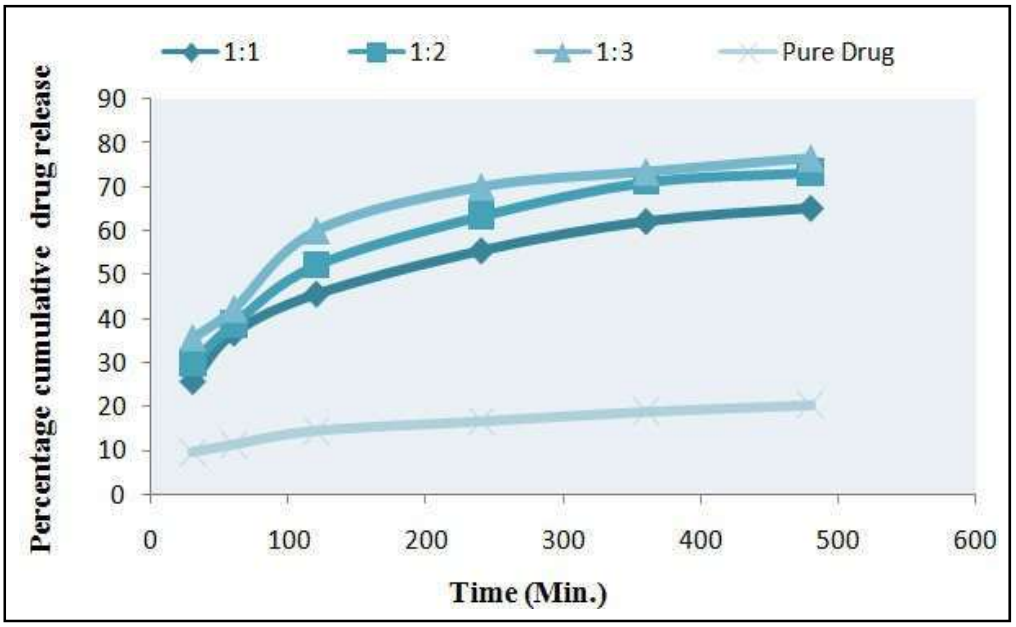

Figure 2: Percentage cumulative drug release of physical mixture and puredrug

2.1 Percentage drug content

Table 6: Results of drug content

Label claim	Amount found*	Label claim (%)	S.D.	% RSD
25mg	24.95	99.80	0.045	0.038

***Average of three determination (n=3)

2.1.1 Differential scanning calorimetry (DSC)

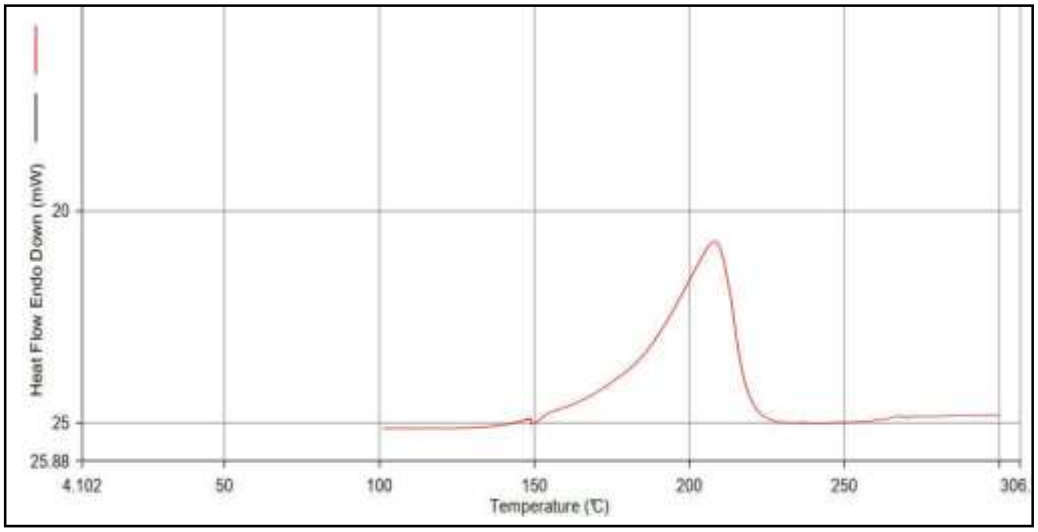

Figure 3: DSC analysis of pure Meclizine

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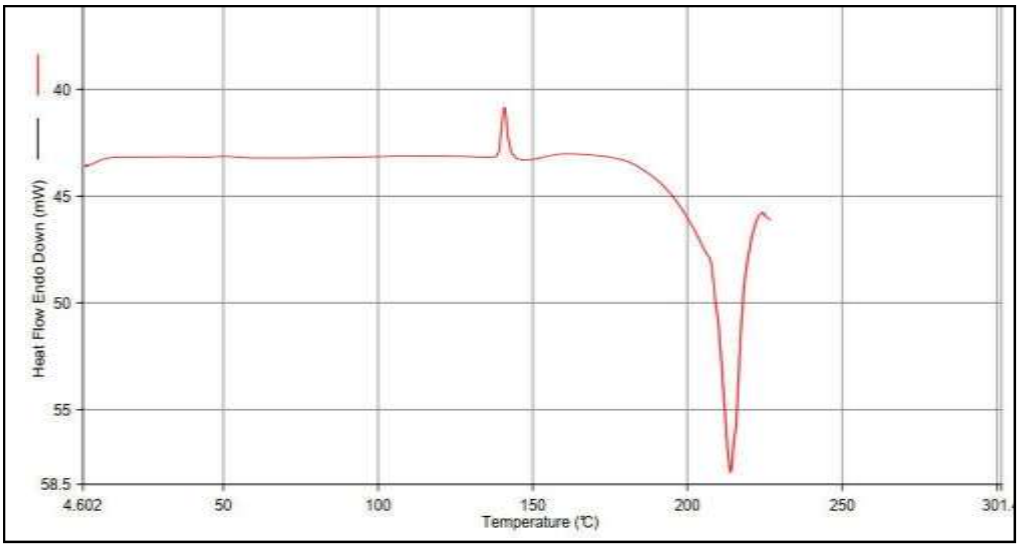

Figure 4: DSC analysis of optimized batch (MCZ +PEG 4000)

As the solid dispersion exhibited no endothermic peak corresponding to the meltingpoint of MCZ that the drug is dispersed amorphously in PEG matrix.

3.Results of Evaluation of prepared Film

Table 7: Results of Evaluation of prepared Film

Formulationcode	General Appearance	Thickness (µm)*	Weight (mg)*
F1	Translucent	62±5	165±3
F2	Translucent	58±6	160±4
F3	Translucent	55±5	155±5
F4	Translucent	48±4	145±6
F5	Translucent	45±5	125±7
F6	Translucent	42±4	120±3

***** (N=3, mean±SD)

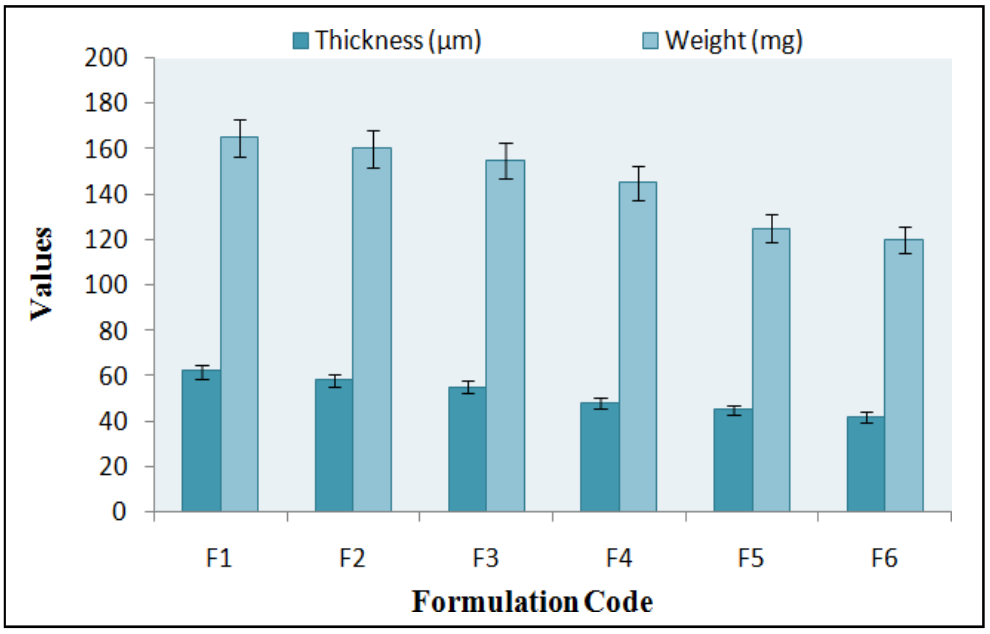

Figure 5: Thickness and weight of formulated films

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3.1Result of folding endurance, disintegration time, tensile strength moisturecontent and assay

Table 8: Result of folding endurance, disintegration time, tensile strengthmoisture content and assay

Formulation code	Folding endurance	Disintegration time (min.) *	Tensile strength (kg/cm^2) *	Moisture Content (%)*	Assay (%)*
F1	145±3	2.36±0.25	0.65±0.05	1.45±0.32	98.85±0.36
F2	156±4	2.25±0.36	0.47±0.03	1.52±0.25	98.56±0.25
F3	165±3	2.45±0.32	0.58±0.02	1.58±0.65	98.78±0.14
F4	155±2	2.11±0.25	0.63±0.04	1.47±0.14	98.85±0.36
F5	185±4	1.45±0.14	0.74±0.06	1.25±0.25	99.11±0.25
F6	136±5	2.36±0.25	0.62±0.05	1.36±0.36	98.96±0.32

***** (N=3, mean±SD)

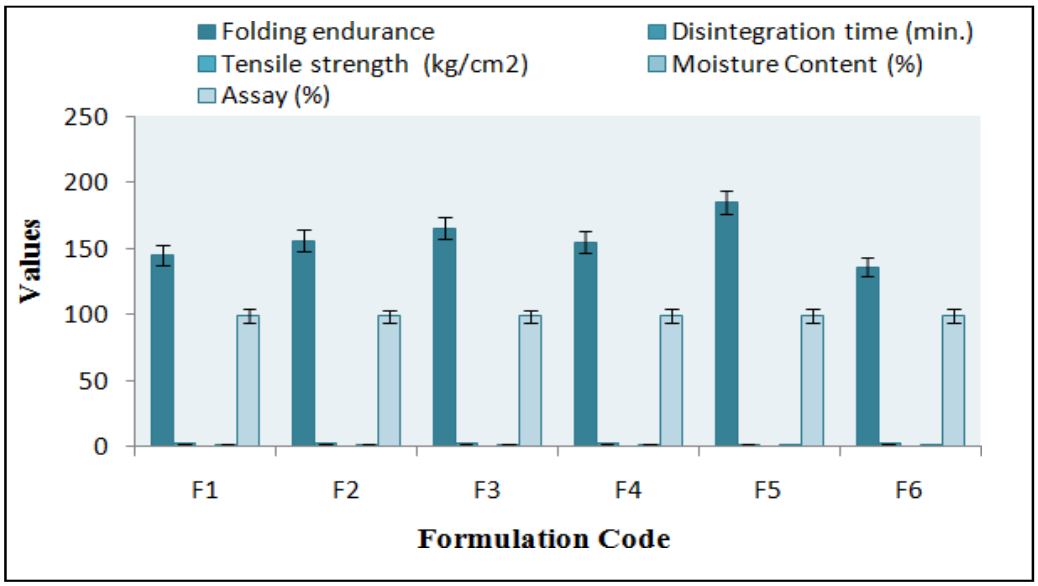

Figure 6: Result of folding endurance, disintegration time, tensile strengthmoisture content and assay

3.1.2 Results of optimized formulation

Table 9: Results of Optimized formulation F5

Name of Ingredients	Composition (mg) Per Strip
API	1200
HPMC K15	600
PEG-400	-
SSG	100
CCS	-
Aspartame	150
Citric acid	25
DM water qs to (ml)	30

3.1.3 Results of *in-vitro* release study of optimized formulation F5

Table 10: Results of *in-vitro* release study of optimized formulation F5

S. No.	Time (Min.)	Cumulative % Drug release*
1.	1	25.58±0.45
2.	2	45.65±0.25
3.	5	69.98±0.36
4.	10	78.85±0.25
5.	15	98.85±0.23

*(N=3, mean±SD)

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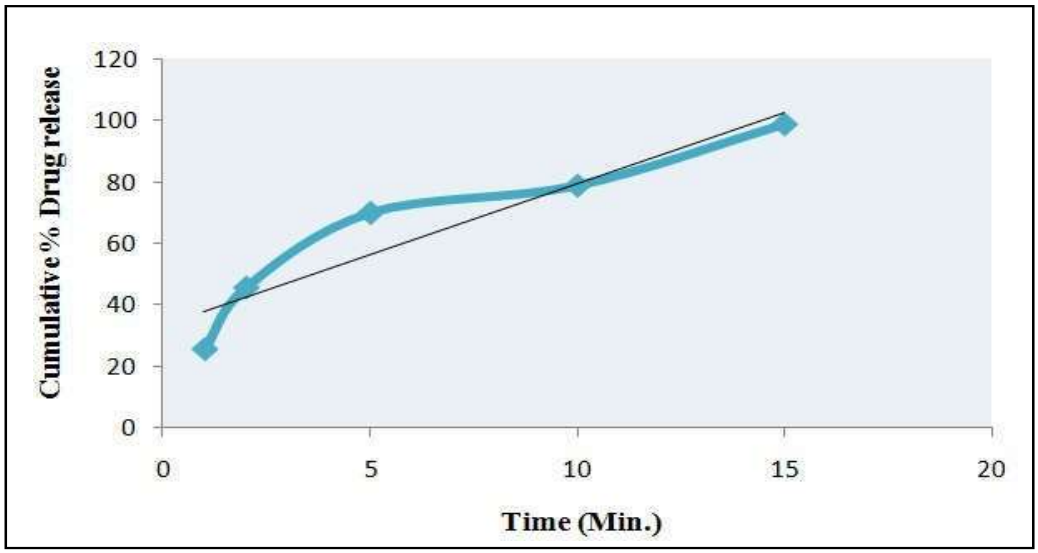

Figure 7: *In-Vitro* release study of optimized formulation F5

4.Results of stability studies

Minor difference was found between evaluated parameters before and after ageing/storage and all was in acceptable limits. Therefore formulation remains stable for sufficient time.

Table 11: Characterization of stability study of Optimized Film (F5)

Characteristic	Time (Month)			
	Initial	1 Month	2 Month	3 Month
% Assay*	99.45	99.25	98.85	98.25

*Average of three determination (n=3)

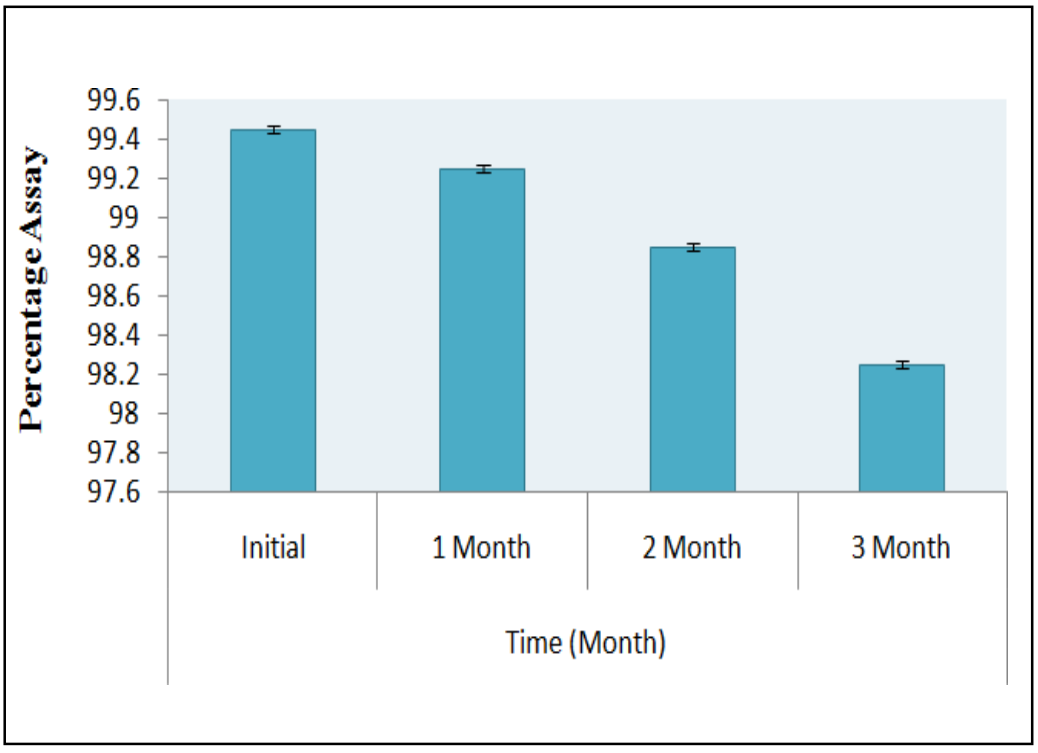

Figure 8: Graph of stability study of Optimized Film (F5)

CONCLUSION

From the latest research it can be inferred that fast-dissolving oral films of drug release are preferable. The films prepared by HPMC, and SSG had shown strong mechanical power, release of narcotics, period for disintegration and

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analysis of dissolution. F5 formulation is considered the better with less disintegrating time and release in 15 min according to the results obtained. Percent drug release and disintegration time was taken as responses for study which were found within the accepted ranges. Meclizine administered in the form of fast dissolving films will be potential novel drug dosage form for pediatric, geriatric and also for general population by providing faster release and better patient compliance.

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