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FORMULATION AND CHARACTERIZATION OF 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 superdisintegrants. 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 H_1-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- *Oral Film, Meclizine, Polymers, Motion sickness, Vertigo, Fast dissolving.*

INTRODUCTION

Oral route is a most preferred route of drug administration for systemic effect due to its ease of administration, non-invasiveness, adaptability, patient compliance and acceptability. 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. The key advantage for fast dissolving oral films is patient compliance and convenience. The main drawback is with drug loading. Drug loading is generally limited to roughly 40 mg. This problem can be solved by increasing the thickness of the film, but that in turn may increase the disintegration and dissolution time. Drug companies are still interested in this technology as it provides fast, accurate dosing that is expected to increase patient compliance, particularly among pediatrics. There is no need for water or measuring and upon dissolution; the dose of drug is swallowed. Thus we can say that Fast-dissolving oral thin film offer fast, accurate dosing in a safe, efficacious format that is convenient and portable, without the need for water or measuring devices.

MATERIAL AND METHOD

DRUG- Meclizine a histamine H1 antagonist used in the treatment of motion sickness, vertigo, and nausea during pregnancy and radiation sickness.

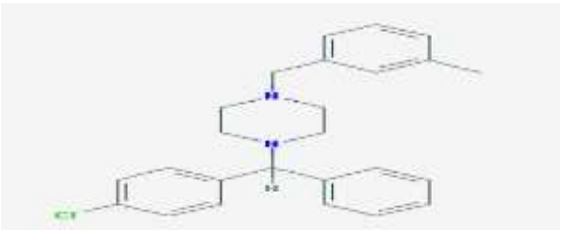

Figure 1: Structure of Meclizine

Excipient- Sodium starch glycolate-

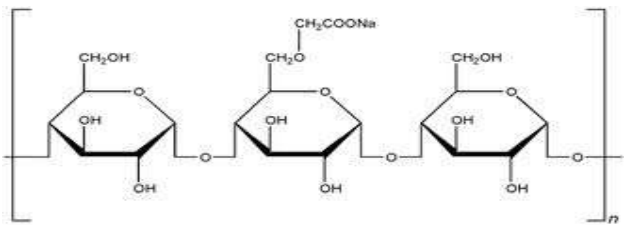

Figure 2: Structure of Sodium starch glycolate

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EXPERIMENTAL WORK

1. Preformulation study

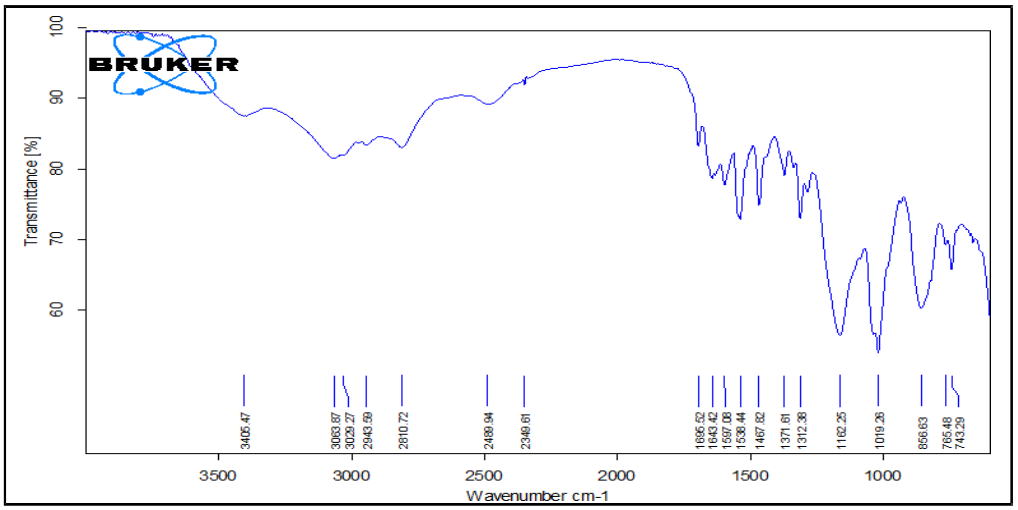

Figure 3: FT-IR Spectrum of Meclizine

2. Identification test using FT-IR Spectroscopy

Infra- red spectrum is an important record which gives sufficient information about the structure of a compound. This technique provides a spectrum containing a large number of absorption band from which a wealth of information can be derived about the structure of an organic compound. The region from 0.8 µ to 2.5 µ is called Near Infra-red and that from 15 µ to 200 µ is called Far infra-red region.

3. 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 solution of 1000 ppm or µg/ml.

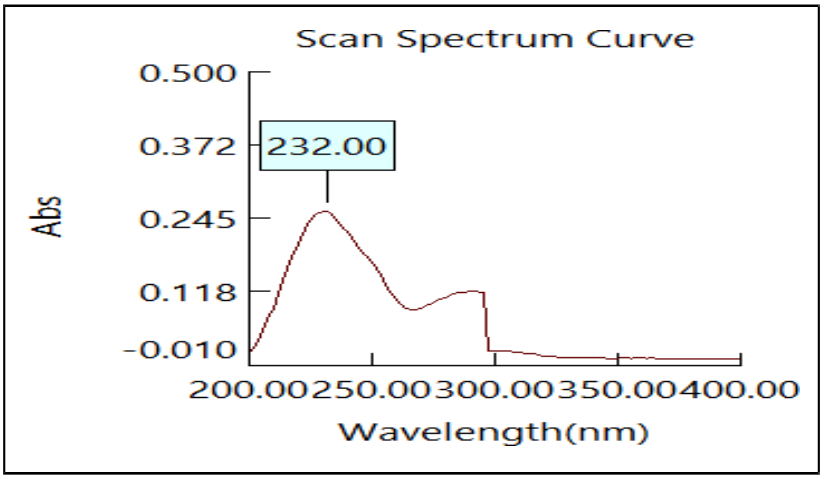

Figure 4: Determination of λ_{max} of Meclizine

4. Preparation of Working Standard Solution

From stock solutions of Meclizine 1 ml was taken and diluted up to 10 ml. from this solution 0.5, 1.0, 1.5, 2.0 and 2.5 ml solutions were transferred to 10ml volumetric flasks and make up the volume up to 10 ml with Methanol, gives standard drug solution of 5,10, 15, 20, 25µg/ml concentration.

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S. No.	Concentration (µg/ml)	Absorbance
1.	5	0.374
2.	10	0.597
3.	15	0.814
4.	20	1.025
5.	25	1.178

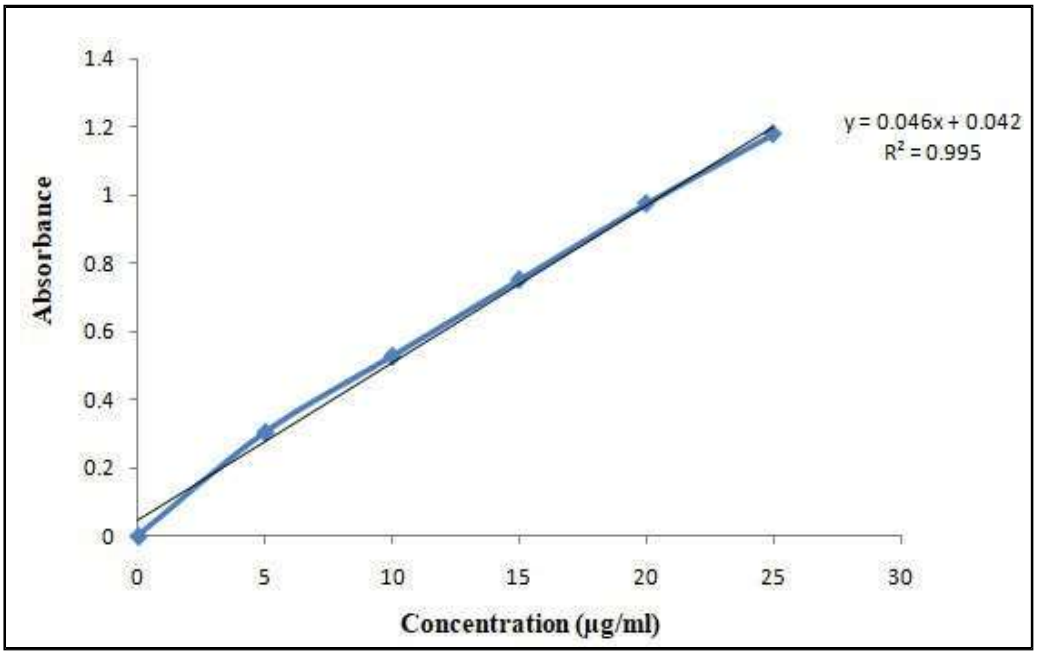

Figure 5: Graph of calibration curve of Meclizine at 232 nm

5. Selection and optimization of film forming agents

Two film forming agents and one co-film forming agent were selected for this research work. The concentration of film forming was important to form a proper thickness for appropriate packaging and handling of oral films. Concentration of film forming agent is optimized on the basis of thickness and appearance of film.

Selection and Optimization of Film Forming Agents

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

HPMC=Hydroxypropyl methylcellulose, PEG 400= Polyethylene glycol 400, SSG= Sodium starch glycolate, CCS =Croscarmellose sodium.

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Evaluation of prepared Dosage form

1.1 Results of Evaluation of prepared Film

Table 1: Results of Evaluation of prepared Film

Formulation code	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)

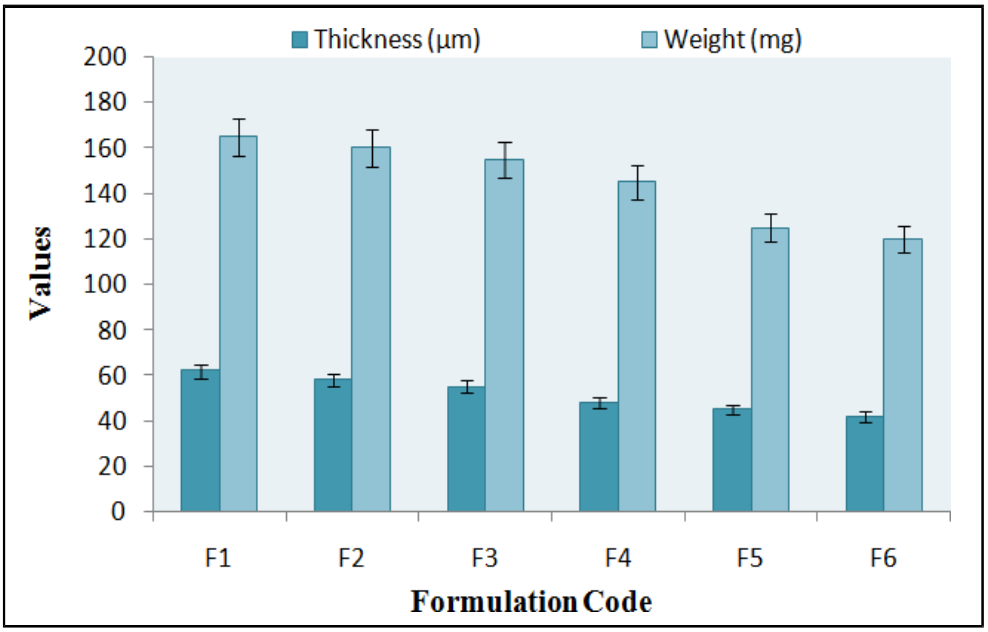

Figure 6: Thickness and weight of formulated films

1.1.1 Result of folding endurance, disintegration time, tensile strength moisture content and assay

Table 2: Result of folding endurance, disintegration time, tensile strength moisture 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)

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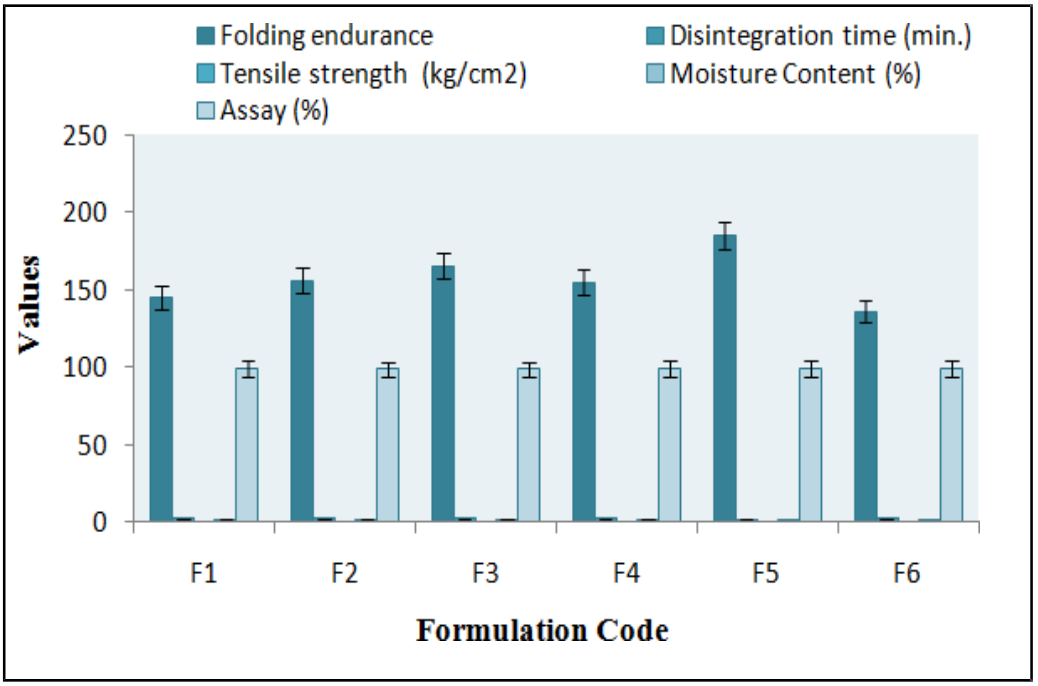

Figure 7. Result of folding endurance, disintegration time, tensile strength moisture content and assay

1.1.2 Results of optimized formulation

Table 3: 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

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

Table 4: 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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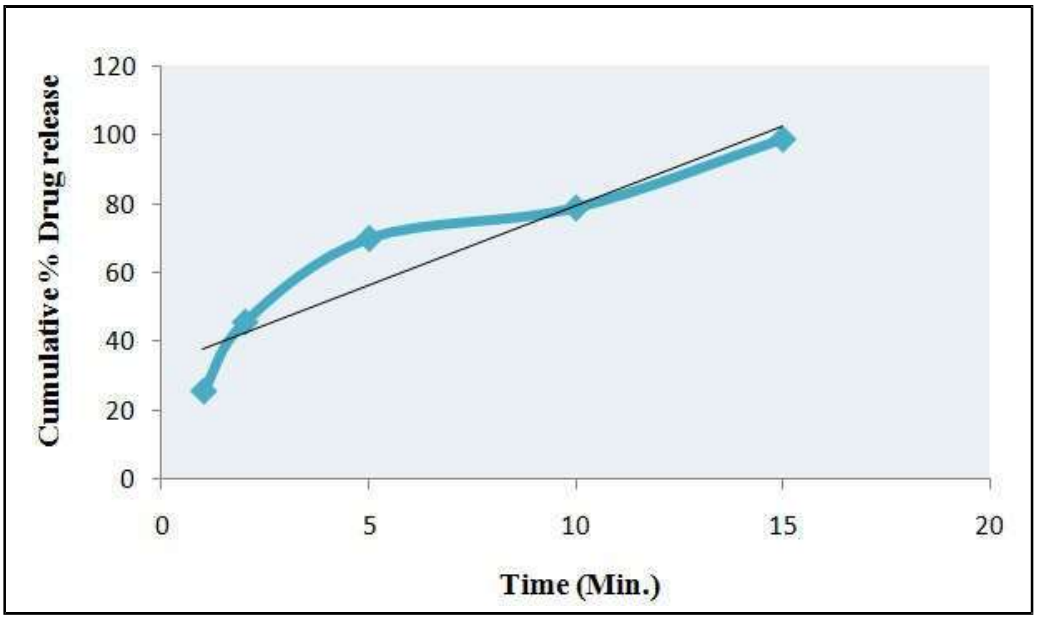

Figure 8: *In-Vitro* release study of optimized formulation F5

1.2 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 5: 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)**

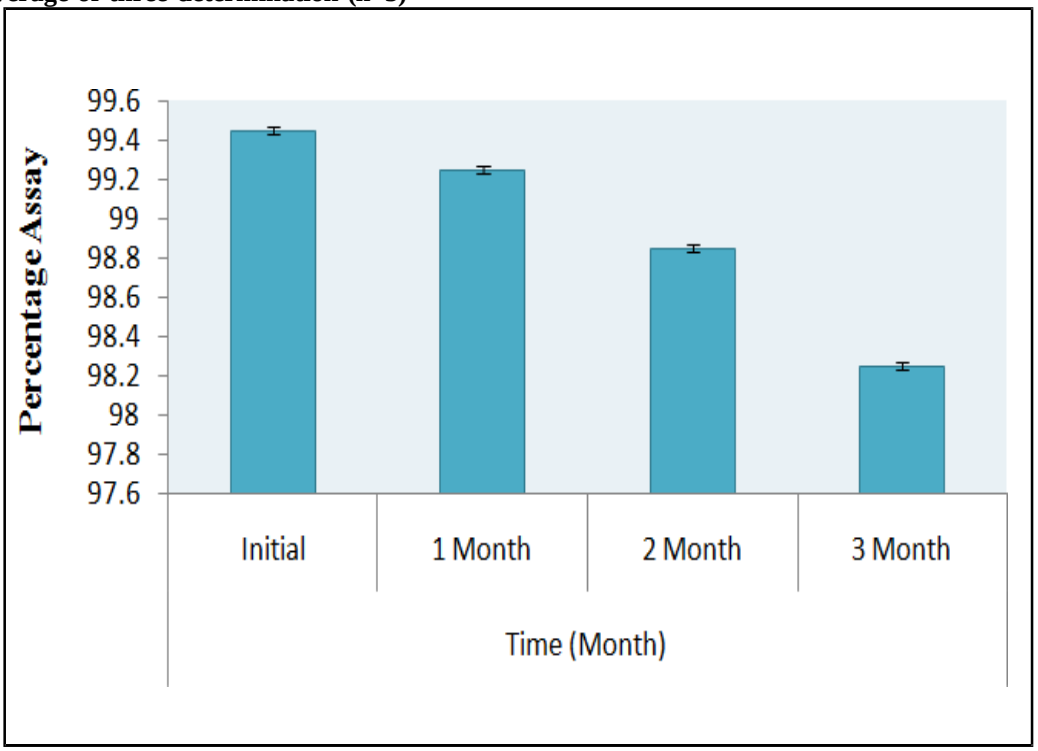

Figure 9: Graph of stability study of Optimized Film (F5)

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SUMMARY AND 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 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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