INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Research Article

Formulation And Evaluation of Mucoadhesive Buccal Patch by Natural Polymer Drug Containing Domperidone

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ARTICLE INFO

Received: 23 July 2024
Accepted: 22 July 2024
Published: 29 July 2024

Keywords:
Chitosan, Poly-vinyl alcohol, Mucoadhesive, Buccal patch, Domperidone.

DOI:
10.5281/zenodo.13122963

ABSTRACT

The Present study is providing Domperidone is a D1, D2 antagonist; it is used in treatment of vomiting caused by motion sickness. As conventional doses release the Domperidone in just few minutes & therefore the therapeutic concentrations are maintained for a short period of time generating a need for administration of another dose. This was achieved by consisting with natural polymer system. These mucoadhesive buccal patches mainly prepared for release of drug for longer time of period i.e., 10hrs & utilizing the drug to full extent avoiding unnecessary frequency of dosing. For the formulation of Mucoadhesive buccal patches HPMC15cps Chitosan & PVPK30 were used as matrix forming agents. Other excipients used are Propylene glycol as a plasticizer. IR spectroscopy confirmed the absence of any drug/polymer's interactions. The mucoadhesive buccal patches were prepared by solvent casting method using magnetic stirrer. The prepared mucoadhesive buccal patches were evaluated for thickness, folding endurance, weight variation, water uptake, bioadhesive strength, drug content uniformity, surface pH, Mechanical strength, Scanning electron microscopy (SEM), In-vitro release study, Ex-vivo drug release study and Stability study. Formulation F3 showed good Bioadhesive strength and a controlled drug release and shown good result for all other parameters when compared with all other formulations. Hence formulation F3 is the optimized formulation. Stability studies were carried out for F3 formulation they had showed good stability when stored at accelerated stability state as per the ICH guideline. It was observed that Formulations F3 retained the drug release up to 24hrs. Thus, conclusion can be made that stable dosage form can be developed for Domperidone for controlled release by buccal patches.

INTRODUCTION

Emesis is a natural impulse unnatural by nucleus in the brainstem acknowledged as the queasiness centre. During retching, the lesser oesophageal sphincter relaxes abdominal skeletal strength contract, and forceful peristaltic contraction of the

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

strong outdoor work in the opposite track of normal, dynamic tummy along with small intestine stuffing upward hooked on the oesophagus. While these contractions are brutal enough, the stuffing of the GI tract canister passes from first to last the greater oesophageal sphincter, cause emesis [1].

The discharge of the contents of the stomach through the mouth canal is known as emesis. Emesis is preceded by nausea, which is a sick feeling. Vomiting is an adaptive behaviour that can help you get rid of hazardous stuff you've eaten. Nausea and vomiting, on the other hand, can occur [2].

Transmucosal Drug Delivery System

Transmucosal liberation of beneficial agents is a well-liked & expedient method because mucous membranes are comparatively holey; transmucosal government of medicinal drugs is a common and convenient approach [3]. This allows for quick uptake of a medicine addicted to the total transmission while bypassing hepatic major go by processing. Controlled release focused and localised drug delivery, avoidance of drug degradation, longer action, bypassing first pass metabolism, and a reduction in balanced state plasma intensity variation are all benefits of transmucosal medicine government [4].

Various types of Delivery Systems are used in the transmucosal route:

- Buccal medicine release method
- GIT medicine relief organization
- Nasal medicine liberation classification
- Ocular medicine liberation method
- Rectal medicine release System.
- Vaginal medicine liberation system [5].

MATERIALS AND METHOD

Materials

The following materials & instruments were used for the preparation of Dimenhydrinate buccal patches [6].

Table No. 1: List of Chemicals Used

S.No.	Name	Grade	Supplier
1.	Domperidone	Pharmaceutical	Aurobindo pharmaceuticals.
2.	HPMC-E15	USP-EP	Elkem laboratory
3.	Chitosan	Lab	SD Fine Chemical Limited. Mumbai
4.	CH_3COOH	Lab	SD Fine Chemical Limited. Mumbai
5.	Poly vinyl pyrrolidine	Lab	SD Fine Chemical Limited. Mumbai
6.	Propylene Glycol	Lab	SD Fine Chemical Limited. Mumbai
7.	Dist. H2O	Lab	SD Fine Chemical Limited. Mumbai

Methods

Identification of Drug

Physical appearance [7]

Organoleptic properties	Specification/limits	Observation
State	Powder	Powder
Colour	White to slightly beige	White
Taste	Sour/bitter	Bitter
Odour	Odourless	Odourless

Melting point

Melting aspect is a critical physical asset of natural compounds, which has located extensive use in chemical identity, as a criterion of purity and for the calculation of various critical physicochemical homes which include vapour pressure and aqueous solubility [8].

Capillary melt technique

Melting factor of Domperidone modified into determined with the aid of the usage of capillary

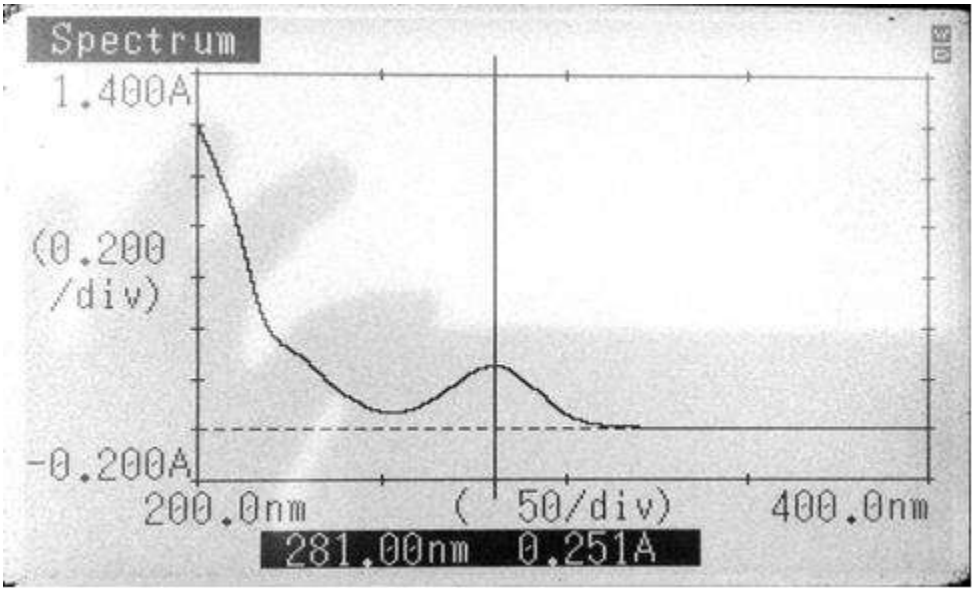
soften technique the usage of melting element system (msw-403, macro clinical works, New Delhi).

Table No. 2: Melting series of Domperidone

S. No.	Melting range(^{0}C)	Mean (^{0}C)	Mean
1.	234 to 236ºC	235	
2.	234-238ºC	236	237±2.3ºC
3.	238-242ºC	240	

λmax by Ultraviolet Spectroscopy

UV absorption spectrum of Domperidone at 0.1N Hcl exhibits a most λmax at 228nm. Absorption obtained for numerous concentrations of Domperidone at 0.1N HCL given in table 6.2. The plot of absorbance as opposed to Domperidone awareness became discovered to be linear over the awareness variety of 216µg/ml. This drug follows the beer-lambert regulation in the 216µg/ml range. The most absorption of domperidone became discovered just before being 281nm [9].



Graph No. 1: U. V. range of Domperidone

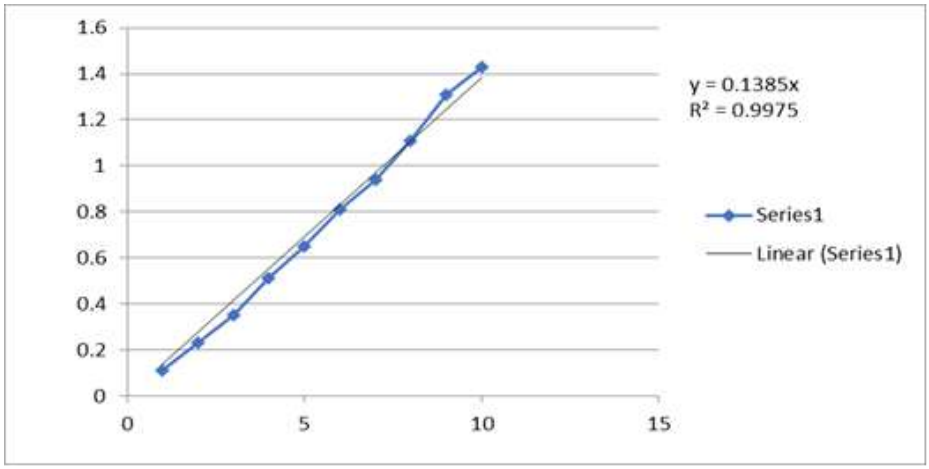
Preparation of Standard Curve of Domperidone

Dissolve 100mg of this medicine in 100ml of methanol & accurately weigh to attain an answer with a concentration of 1000µg/ml, that is known as inventory answer take 1 ml of the chemical answer from the inventory solution 1 in a 100ml volumetric flask, dilute it with distilled water to make one hundred ml, and get in touch with it inventory solution ii. Drug answers were organized from stock answers 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10µg/ml and scanned at 280nm the usage of methanol as control using UV Visible spectrophotometer [10].

Table No.3: Absorbance of Different Concentration of Drug Solution

CONCENTRATION (µg/ml)	ABSORBANCE (nm)
1.	0.11
2.	0.23
3.	0.35
4.	0.51

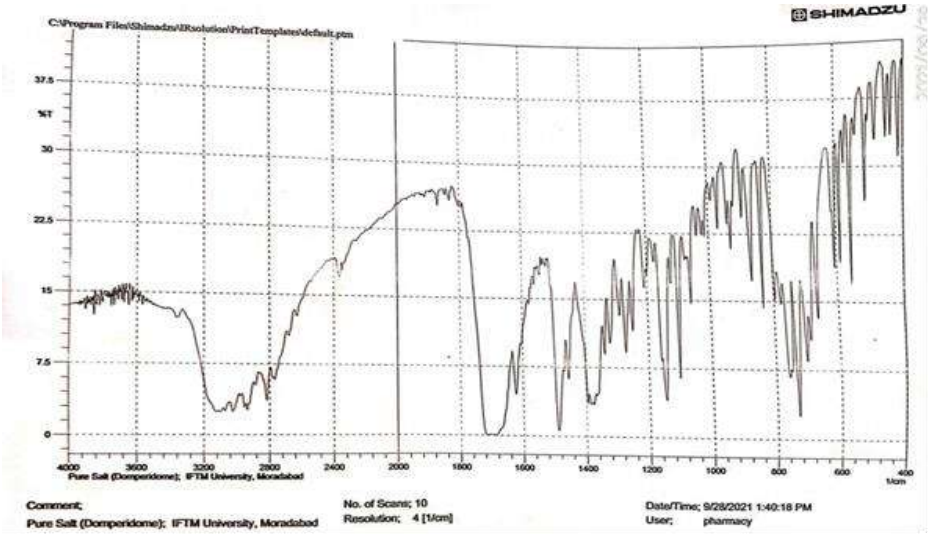
5.	0.65
6.	0.81
7.	0.94
8.	1.11
9.	1.31
10.	1.43



Graph No. 2: Regressed Curve of Domperidone

I. R. Spectroscopy

An I. R. The spectrophotometer area for recording a spectrum with I. R. Includes an optical machine able to presenting monochromatic light in an area of 4000-400cm. 444 (about 2.5-16μm) and a way for measuring the intensity ratio of transmitted and incident mild. Fourier transform I. R. Spectrophotometers replace traditional dispersion units. System 1 mg of drug pattern (Domperidone) and one hundred mg of potassium bromide were placed in a mortar & ground to a powder. A little amount of pulverized model changed keen on positioned into a granulator and compressed to a weight of 10kg/cm 2. The organized sediment was saved in a model holder & scanned as of 4000 cm1 to 400 cm1. I. R. spectra of drug test were obtained usage of FTIR 8400s, Shimadzu [11].



Graph No. 3: IR of Domperidone

Table No.4: Important peaks of Infrared spectrum

S. No.	Functional Group	IR Range	evaluation of Peak (cm-1)
1	CH stretch in CH3 group	1020-1220	1041.60
2	CH stretch in aromatic ring	3100-3000	3030.27
3	NH stretch in Hetero aromatic ring	3500-3220	3329.25
4	CCl stretch of mono chlorinated. aromatic complex	750-700	702.11
5	CH stretch in Methoxy cluster	2815-2850	2818.09
6	CH yielding trembling in CH2. cluster of RCH2N=	1475-1445	1462.09

Solubility Analysis

Solubility evaluation became executed to pick the appropriate solvent system for dissolving the drug & to check its solubility inside dissolution medium just before being used. The solubility of domperidone within 6.8 phosphate buffer is 32.52µg/ml. The effects indicate an extra solubility of the stable dispersion as compared to the natural drug in the phosphate buffer 6, 8 solutions, which may be due to the complex formation between the medicine, PEG600 & pvpc25. The Formulations prepared through means of solvent evaporation from F1-F5 display: greater solubility evaluate to the organized solid dispersion. Different way. A1:4:1 ratio of drug: PEG 6000: PVPC25 shows extra solubility in those formulations containing A4. The solubility of method A4 is 92.91/ml [12].

Table No. 5: Descriptive expressions of solubility

Expressive Terms	Part of Solvent necessary for 1 part of Solute as per IP
Extremely Soluble	<1
Generously Soluble	1-10
Soluble	10-30
In Moderation Soluble	32-100
A Little Soluble	100-1000
Very Little Soluble	1000-10000
Almost Insoluble	10000<

Table No.6: Solubility Profile of Domperidone in Different Solvents

S. No.	Solvents	Solubility of Domperidone (gm/ml)	Solubility category as per I.P.
1	Distilled Water	0.0108	in moderation soluble
2	0.1 N HCl	0.0202	in moderation soluble
3	0.001 N HCl	0.0122	Sparingly soluble
4	pH 6.8 Acetate buffer	0.1068	Soluble
5	Acetic acid	0.2806	Freely soluble

Partition Coefficient

In drug discovery and development, lipophilicity is usually expressed by the partition between aqueous and organic phase [13].

The partition co-efficient Kpc of a medicine is given through.

$$logp = log \frac{\text{concentration in octanol}}{\text{concentration in water}}$$

separation co-efficient of medicine was considered by the formula specified beyond along with was found to be **3.84**.

Here,

$[Drug]_{octanol}$ = conc. of drug into n-octanol

$[Drug]_{water}$ = conc. of preparation into H2O

A sample of the drug is shaken with a mixture of n-octanol and water and its concentration in each layer is determined [13].

Slaughter going on aeration & humidity contented.

The LOD is intended to degree quantity of H2O & volatiles within a pattern whilst the example is dried underneath particular situations [105^0c, 3hours]. The LOD is decided through heating the sample in an oven below its melting factor and includes water and solvent content. LOD is approx. An analytical approach that gets rid of water in addition to all other risky impurities from a sample [14].

$$\% \text{ LOD} = \frac{\text{Weight of sample before dry} - \text{weight of sample after dry}}{\text{Weight of sample before dry}} \times 100$$

Table No. 7: % LOD of Domperidone

Sample weight (gm)	Final weight(gm)	% Loss on drying
1.0	0.9985	0.15
1.0	0.9979	0.21
1.0	0.9988	0.12
	Average (% Loss on drying)	**0.163**

MOISTURE CONTENT

Moisture content is the amount of H2O current in the trial [15].

Moisture content of drug can be determined by-

%MC= (w-d/w) ×100

w= wet wt.

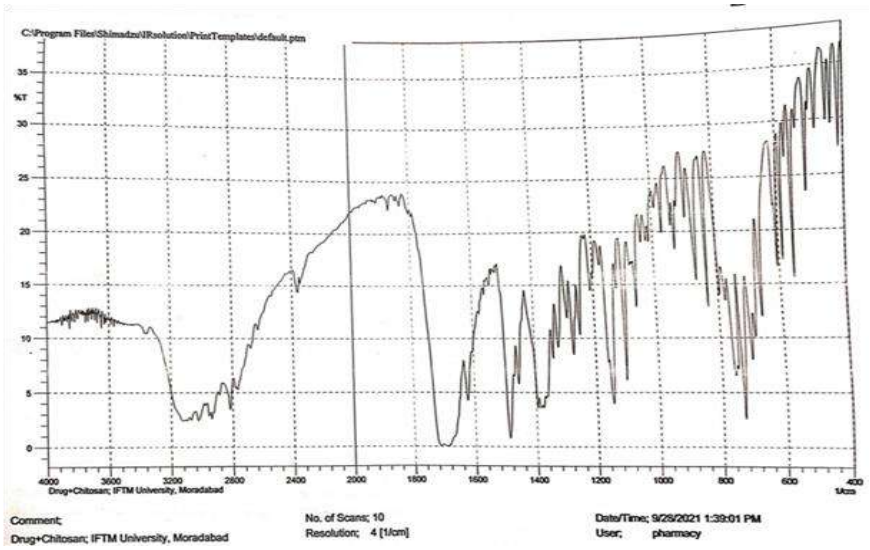
d= wt. later than dried out

Moisture contents or water contents are usually given in percent of the sample mass. The moisture content of domperidone was found to be **1.2%**

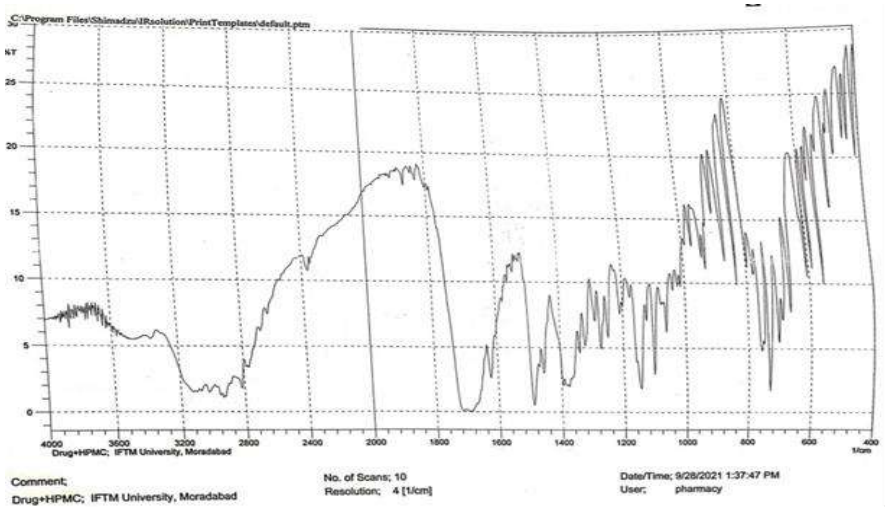
Drug excipient interaction

Suitable formula design and method calls for deliberation of physical, chemical & organic properties of all medicine materials as well as excipients second-hand in manufacture of product. Every polymer old in components changed into mixed with the drug in an amount realistic with appreciates to the final components [16]. Every polymer became thoroughly blended by way of the drug to growth medicine polymer molecular touch, dashing up reaction if potential. Compatibility studies of excipients are an essential a part of product research to decide drug-excipient interactions. Measurements after a period of storage using the appropriate logical method showed no interplay among medicine and excipient [17].

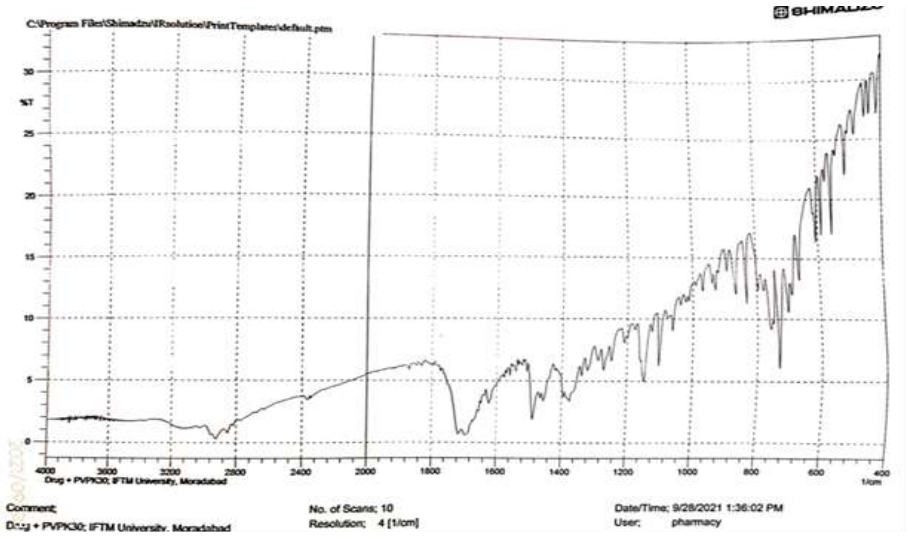
I. R. spectrum of Polymer and Drug



Graph No. 4: I. R. spectrum of Domperidone and Chitosan



Graph No. 5: I. R. Spectrum of Domperidone & Hypromellose



Graph No. 6: I. R. spectrum of Domperidone & PVPK30

Formulation Development

Preparation of backing membrane- Firstly prepared backing membrane. Take 4% PVA solution in distilled water, then it was poured in Petridis over aluminium foil, it was kept in the oven at 42^0c dried backing membrane was prepared [18].

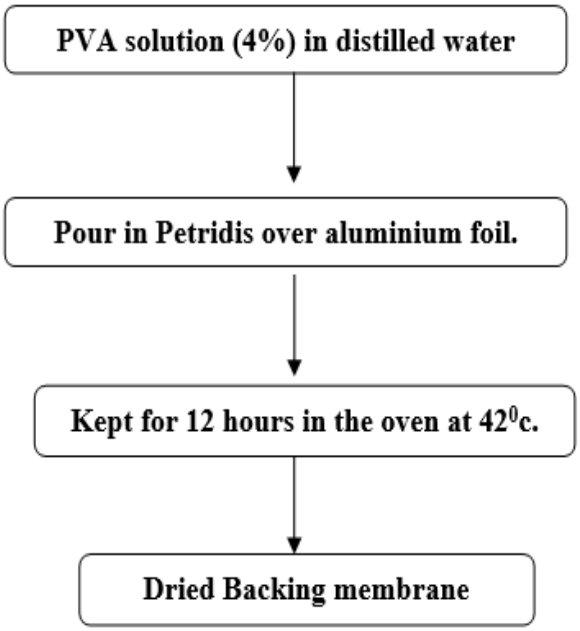


Fig.- Method for preparation of backing membrane.

Optimization of drug and polymer ratio

A selection of polymers is to be had to create the buccal patch. The choice of polymer is one of the most crucial and important parameters for a hit system improvement. The polymer used to make the buccal patch [19].

Preparation of buccal patches

Table No. 8: Symphony Of Domperidone In Buccal Patches

Patches contain Domperidone, HPMC, Chitosan, PVPK30 and PG in one-of-a-kind ratios have been manufactured by way of casting from solvents. Medicine is dissolved in five ml of methanol, as well as the polymer changed into dissolved in a take apart container of 20 ml of distilled water Whilst Stirring Constantly For 4hours [20].

Evaluation of Buccal Patches

Thickness uniformity

Formulations	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9	F-10
Drug	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg	10.00 mg
Chitosan in 1% acetic acid	1	1	1	2	3	1	1	1	2	3
HPMC 15cps	1	2	3	1	2	*	*	*	*	*
PVPK30	*	*	*	*	*	1	2	3	1	2
PG	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
DW	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml	qs 10.00 ml

Total quantity of polymers = 500mg

breadth of patches was calculated at 5 dissimilar indiscriminately particular a skin condition via twist gauge. The mean along with standard were considered [21].

Weight uniformity

Each movie (1x1 cm2) becomes weighed on a digital scale at different places on the movie and the common weight was considered [22].

Folding endurance:

the fold electricity of the buccal patch become decided through taking a 20 mm diameter patch and folding it again and again until it was torn within the equal place. The quantity of times a patch will be folded inside the equal role without breaking it determined the fold durability price. The check became run 3 times and the imply and fashionable had been calculated [23].

Swelling study

The weight of the buccal patch was measured by digital electronic weighing balance. Patches are positioned on the shell of an agar serving dish in addition to approved to engorge by keeping it an incubator at 37 ºC and the diameter is measured at predetermined time intervals for 90 minutes. inflammation index was considered on or after following equation-

{**Swelling index = (W2- W1 / W1) ×100**}

Were,

SI (%) is percent swelling.

W2 is the swollen patch wt.

W1 is the first wt. of the patch [24].

Surface pH

To determine the surface ph, 3 films of every formulation were allowed to swell on the surface of an agar plate for two hours. The surface ph changed into measured by using placing a ph paper at the floor of the swollen component. The common of three readings was recorded [25].

Table No. 9: Evaluation of trial batches

Formulation	Thickness (mm) ± SD (n=3)	Weight Uniformity (mgs ± SD)	Folding endurance ±SD (n=3)	Swelling index	Surface Ph
F-1	0.23± 0.005	37.86±0.15	305± 4.04	148.6±2.045	06.68 ± 0.13
F-2	0.22± 0.014	40.79±0.18	305± 4.72	169.7±2.122	06.56 ± 0.11
F-3	0.24± 0.002	44.20±0.32	313± 2.51	214.7±1.348	06.46 ± 0.05
F-4	0.26± 0.0023	47.30±0.40	318± 2.51	152.4±2.213	06.48 ± 0.16
F-5	0.25± 0.001	50.40±0.42	302± 1.00	121.9±2.124	06.30 ± 0.20
F-6	0.23± 0.003	53.40±0.35	312± 2.51	147.4±2.321	06.32 ± 0.08
F-7	0.24± 0.023	56.48±0.36	318± 2.52	210.9±2.112	06.44 ± 0.13
F-8	0.26± 0.01	59.75±0.20	310± 5.50	271.6±2.123	06.74 ± 0.15
F-9	0.26± 0.034	58.75±0.20	309± 5.51	204.6±2.387	06.46 ± 0.09
F-10	0.25± 0.023	57.75±0.20	304± 4.50	253.7±2.154	06.00 ± 0.63

Mucoadhesive Strength

Mucoadhesion, a pair of chrome harden cylinders among a diameter of 11 ± zero. 2mm were used within place of clamp. A round (diameter 1cm) polymer patch sample become organized and preload turned into applied for 5min, 2min, and 15min. The maximum pulling force (fmax) is constant in newtons [26].

Table No. 10: Mucoadhesive strength of trial batches

S. No.	Formulation	Performance parameters (Bio-adhesive)		
		Bioadhesive power (gm) ± SD (n=3)	power of Adhesion (N) ± SD (n=3)	Bond potency ± SD (n=3) (kg/mm2)
1	**F-1**	144.300 ± 02.64	01.400 ± 0.03	453.020 ± 05.34

2	**F-2**	149.340 ± 02.13	01.440 ± 0.02	432.120 ± 03.65
3	**F-3**	187.670 ± 00.78	01.820 ± 0.05	586.090 ± 05.23
4	**F-4**	176.280 ± 00.98	01.620 ± 0.01	543.630 ± 01.86
5	**F-5**	167.330 ± 01.34	01.750 ± 0.01	513.780 ± 04.33
6	**F-6**	132.640 ± 03.67	01.620 ± 0.06	421.120 ± 06.98
7	**F-7**	134.230 ± 02.87	01.420 ± 0.04	435.470 ± 05.32
8	**F-8**	167.350 ± 01.74	01.470 ± 0.03	564.650 ± 06.90
9	**F-9**	168.230 ± 01.53	01.760 ± 0.01	523.340 ± 03.23
10	**F-10**	159.460 ± 01.13	01.120 ± 0.01	498.210 ± 04.98

Medicinal drug content material

Medication content material uniformity became calculated through taking 3 film devices of every expression had been occupied in separate 100ml of volumetric steins, a hundred ml of ph6. Eight phosphate buffers were introduced and constantly stirred for 24hours. Effects had been filter, adulterated suitably & anatomized at 281nm in an ultraviolet spectrophotometer. regular medication filling of 3 flicks turned into taken as final reading [27].

In-vitro medicine release looks at.

The in-vitro termination was studied during phosphate buffer ph -6.8. The in-vitro dissolution study was accomplished inside triplet & outcomes exposed in table which suggest of mirror standards. In-vitro launched facts attained designed for patches F1-F10 are tabulated here table no. Alone from 10:00-19:00 results from in vitro dissolution studies acquired from those formulations were blended into 4 records processing models [28-34]:

1. The probability of drug release increases over the years. (Zero order).
2. The logarithm of the buildup possibility of the ultimate drug as a feature of time. (The first order).
3. Will increase the probability of drug release with admire to the rectangular root of time. (Higuchi synopsis) four. Log threat vs. Log time of drug release. (Peppa graph) the graph suggests the time versus opportunity for drug release for diverse buccal plaques. Increase opportunity pills released to flora are 99.78 (08hours), 99.58 (7hour), 99.49 (10hours), 100.17 (09hour), 100.18 (9hour), 97.15 (08hour), 98.54 (08hours), 100.75 (10hours), 99.67 (09hours), and 100.6 (9hour) independently intended for F1 to F10. Plots of random drug launch versus time for all formulations are proven in graphs 6-24 and the relative boom in release is shown in graph quantity 2.26.

Table No.11: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F1.

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.016	11.59	1.064
3	01	0.000	1.000	0.027	19.67	1.294
4	02	0.301	1.414	0.047	34.36	1.536
5	03	0.477	1.732	0.061	44.85	1.651
6	04	0.602	2.000	0.085	62.68	1.797
7	05	0.698	2.236	0.101	74.89	1.874
8	06	0.778	2.449	0.112	83.59	1.922
9	07	0.845	2.645	0.123	92.37	1.965
10	08	0.903	2.828	0.132	99.78	1.999

Table No. 12: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F2

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.023	16.4	1.214
3	01	0.000	1.000	0.045	32.25	1.508
4	02	0.301	1.414	0.065	46.83	1.670
5	03	0.477	1.732	0.087	62.98	1.799
6	04	0.602	2.000	0.105	76.44	1.883
7	05	0.698	2.236	0.112	82.18	1.914
8	06	0.778	2.449	0.128	94.39	1.974
9	07	0.845	2.645	0.134	99.58	1.998

Table No.13: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F3

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.013	9.47	0.976
3	01	0.000	1.000	0.023	16.85	1.226
4	02	0.301	1.414	0.043	31.58	1.499
5	03	0.477	1.732	0.062	45.74	1.660
6	04	0.602	2.000	0.073	54.20	1.734
7	05	0.698	2.236	0.087	64.93	1.812
8	06	0.778	2.449	0.099	74.31	1.871
9	07	0.845	2.645	0.113	85.23	1.930
10	08	0.903	2.828	0.119	90.42	1.956
11	09	0.954	3.000	0.125	95.66	1.980
12	10	0001	3.162	0.129	99.49	1.998

Table No.14: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F4

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.015	10.66	1.028
3	01	0.000	1.000	0.032	22.86	1.359
4	02	0.301	1.414	0.043	30.91	1.490
5	03	0.477	1.732	0.064	46.15	1.664
6	04	0.602	2.000	0.072	52.30	1.718
7	05	0.698	2.236	0.091	66.33	1.821
8	06	0.778	2.449	0.112	81.91	1.913
9	07	0.845	2.645	0.123	90.53	1.956
10	08	0.903	2.828	0.132	97.8	1.990
11	09	0.9542	0003	0.135	100.17	2.000

Table No. 15: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F5

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.011	7.92	0.899
3	01	0.000	1.000	0.021	15.21	1.182
4	02	0.301	1.414	0.029	21.13	1.324
5	03	0.477	1.732	0.049	35.75	1.553
6	04	0.602	2.000	0.075	54.84	1.739
7	05	0.698	2.236	0.087	64.03	1.806
8	06	0.778	2.449	0.096	71.14	1.852
9	07	0.845	2.645	0.110	81.93	1.913
10	08	0.903	2.828	0.123	92.09	1.964
11	09	0.954	3.000	0.133	100.18	2.000

Table No. 16: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F6

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.016	11.71	1.068
3	01	0.000	1.000	0.023	16.96	1.229
4	02	0.301	1.414	0.043	31.78	1.502
5	03	0.477	1.732	0.056	41.61	1.619
6	04	0.602	2.000	0.089	66.19	1.820
7	05	0.698	2.236	0.102	76.37	1.882
8	06	0.778	2.449	0.115	86.64	1.937
9	07	0.845	2.645	0.121	92.87	1.963
10	08	0.903	2.828	0.127	99.15	1.987

Table No.17: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F7

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.015	11.01	1.042
3	01	0.000	1.000	0.024	17.73	1.248
4	02	0.301	1.414	0.034	25.25	1.402
5	03	0.477	1.732	0.053	39.46	1.596
6	04	0.602	2.000	0.074	55.27	1.742
7	05	0.698	2.236	0.089	66.83	1.824
8	06	0.778	2.449	0.108	81.44	1.910
9	07	0.845	2.645	0.121	91.78	1.962
10	08	0.903	2.828	0.129	98.54	1.993

Table No.18: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F8

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.012	8.62	0.935
3	01	0.000	1.000	0.016	11.58	1.063
4	02	0.301	1.414	0.022	16.01	1.204
5	03	0.477	1.732	0.032	23.36	1.368
6	04	0.602	2.000	0.043	31.49	1.498
7	05	0.698	2.236	0.065	47.62	1.677
8	06	0.778	2.449	0.087	63.90	1.805
9	07	0.845	2.645	0.101	74.59	1.872
10	08	0.903	2.828	0.111	82.50	1.916
11	09	0.954	3.000	0.128	95.52	1.980
12	10	1	3.162	0.136	100.75	2.003

Table No.19 In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F9

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.019	13.76	1.138
3	01	0.000	1.000	0.026	18.97	1.278
4	02	0.301	1.414	0.034	24.96	1.397
5	03	0.477	1.732	0.056	41.14	1.614
6	04	0.602	2.000	0.078	57.49	1.759
7	05	0.698	2.236	0.089	66.03	1.819
8	06	0.778	2.449	0.110	81.89	1.913
9	07	0.845	2.645	0.118	88.48	1.946
10	08	0.903	2.828	0.126	95.13	1.978
11	09	0.954	3.000	0.131	99.67	1.998

Table No.20: In-vitro medicine discharge look at muco-adhesive buccal patch of Domperidone F10

S. No.	Time (Instance) in hrs	Time (Log)	SQ. RT of time	Absorbance (281 nm)	CUM% release	Log CUM% release
1	00	0.000	0.000	0.000	0.000	0.000
2	0.5	-0.301	0.707	0.017	12.87	1.109
3	01	0.000	1.000	0.028	20.14	1.304
4	02	0.301	1.414	0.038	27.49	1.439
5	03	0.477	1.732	0.054	39.21	1.593
6	04	0.602	2.000	0.076	55.32	1.742
7	05	0.698	2.236	0.097	70.88	1.850
8	06	0.778	2.449	0.112	82.30	1.915
9	07	0.845	2.645	0.119	88.10	1.945
10	08	0.903	2.828	0.129	96.11	1.982
11	09	0.954	3	0.134	100.60	2.002

Table No. 21: Collective % medicine discharge of formulation F1 - F10.

S. No.	Time Hrs	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9	F-10
1	00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
2	0.5	11.59	16.4	9.47	10.66	7.92	11.71	11.01	8.62	13.76	12.87
3	01	19.67	32.25	16.85	22.86	15.21	16.96	17.73	11.58	18.97	20.14
4	02	34.36	46.83	31.58	30.91	21.13	31.78	25.25	16.01	24.96	27.49
5	03	44.85	62.98	45.74	46.15	35.75	41.61	39.46	23.36	41.14	39.21
6	04	62.68	76.44	54.20	52.30	54.84	66.19	55.27	31.49	57.49	55.32
7	05	74.89	82.18	64.93	66.33	64.03	76.37	66.83	47.62	66.03	70.88
8	06	83.59	94.39	74.31	81.91	71.14	86.64	81.44	63.90	81.89	82.30
9	07	92.37	99.58	85.23	90.53	81.93	92.87	91.78	74.59	88.48	88.10
10	08	99.78	99.64	90.42	97.8	92.09	99.15	98.54	82.50	95.13	96.11

Stability studies

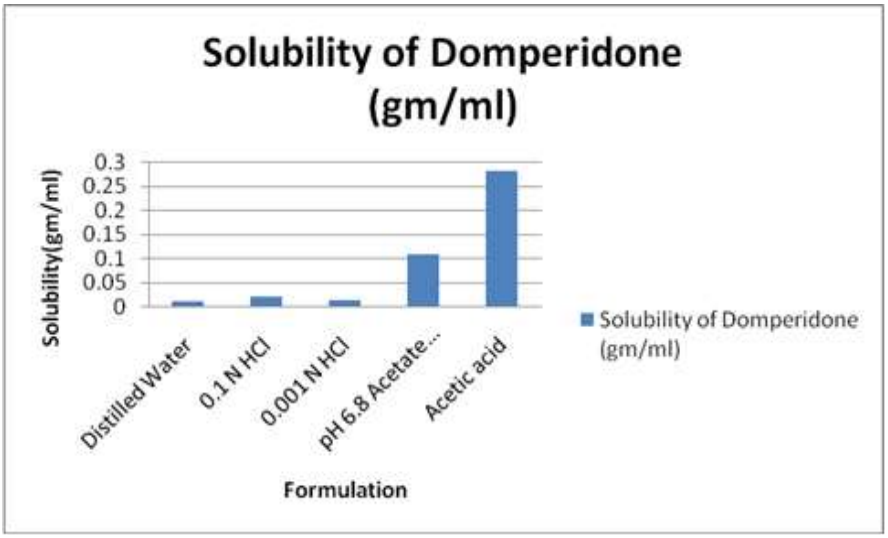
The stableness of a medicine may exist described because time as of the date of manufacture as well as packaging of drug to the instant whilst its chemical or herbal impact isn't lower than the specified area of the indicated power and there's no exchange in its bodily properties [35]. Conspicuously or conversely. The balance observes changed into executed according with ICH Q1C guidelines to evaluate drug balance and expression. The maximum first-rate expression is sealed in an aluminium box and stored at room temperature in a moist chamber at 40±0.5 for 1month [36].

RESULTS

Detection of uncontaminated medicine

Solubility Study:

Approximate solubilities of substance are indicating via the expressive requisites in the associated.



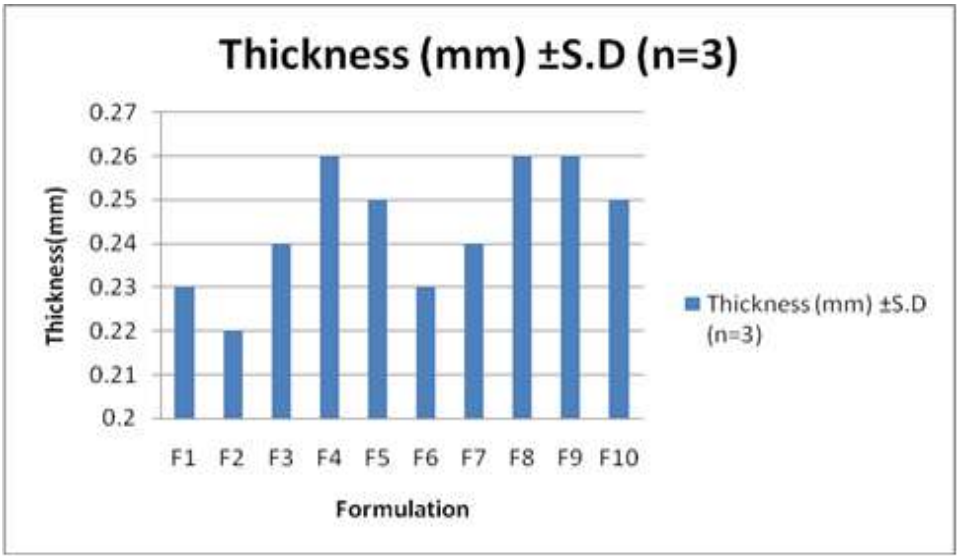
Graph No. 7: Solubility of Domperidone

EVALUATION PARAMETERS

Thickness of the Patches

The thinness of the patches was assessing at 6 dissimilar point of the patch via thinness gauze (Mitutoyo, Japan). For every formulation, 3 erratically certain patches were use.

The thickness of organized buccal patch of every formulation is unwavering surrounded by assortment of 0.23 to 0.26mm.

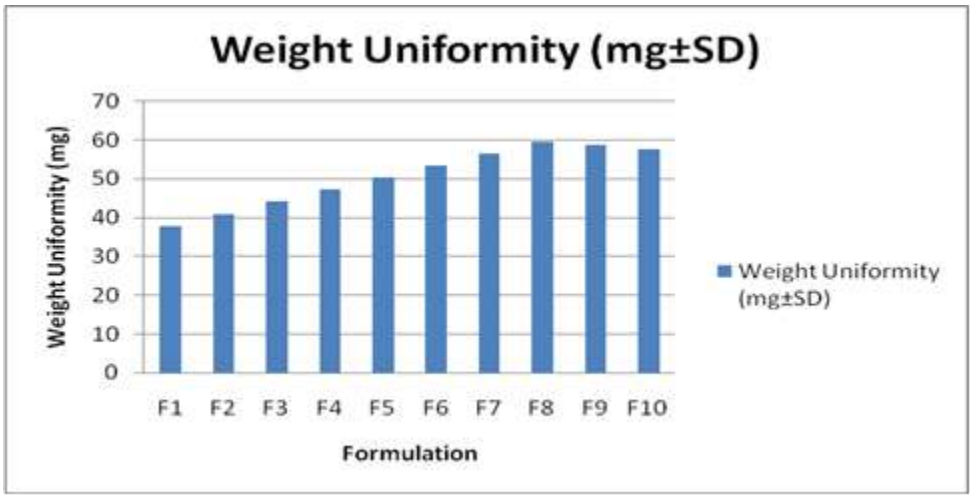


Graph No. 8: Bar diagram of formulation showing thickness of patch of trial batches.

The prepared formulations were found to have thickness in between 0.23- 0.26mm. The signify thickness of the buccal patch prepared increases by means of increase in the amount of polymer percentage. When the concentration of chitosan and HPMC are increased then increasing the thickness of patches. The optimized batch F3 was found to have thickness of 0.24 and was within limits.

Weight Uniformity:

The wt. of formulate buccal patches ranges in between 37.86±0.15mg to 59.75±0.20 mg.

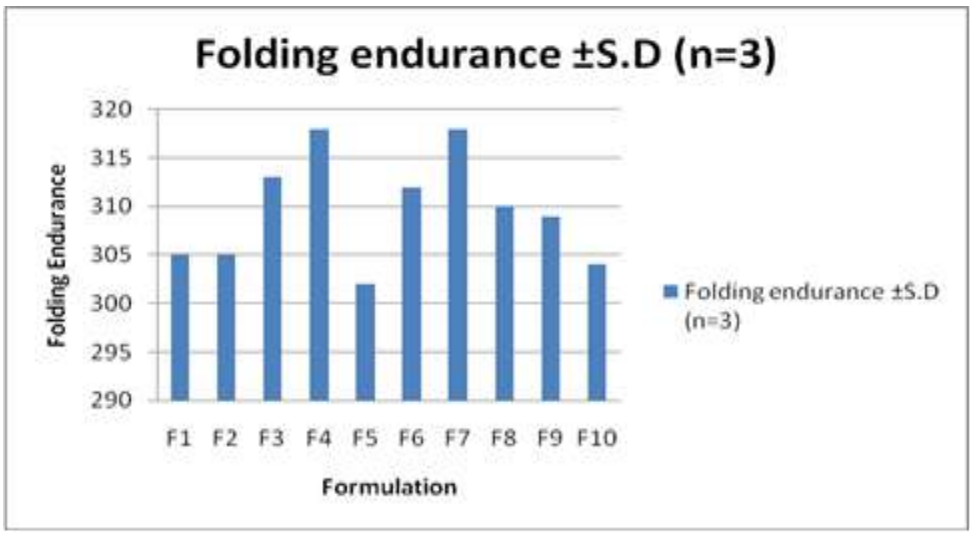


Graph No. 9: Bar diagram of formulation showing weight uniformity of trial batches.

The prepared formulations were found to have weight in between 37.86±0.15 mg to 59.75±0.20 mg. The optimized batch F3 was found to have weight of 44.20 and was within limits. As the proportion of the polymers is increasing, correspondingly the wt. of the films is increasing.

Folding endurance:

Number of instances film knows how to be folded within same role with no tearing determined the fold sturdiness cost. The imply and standard deviation of the 3 observations have been calculated.

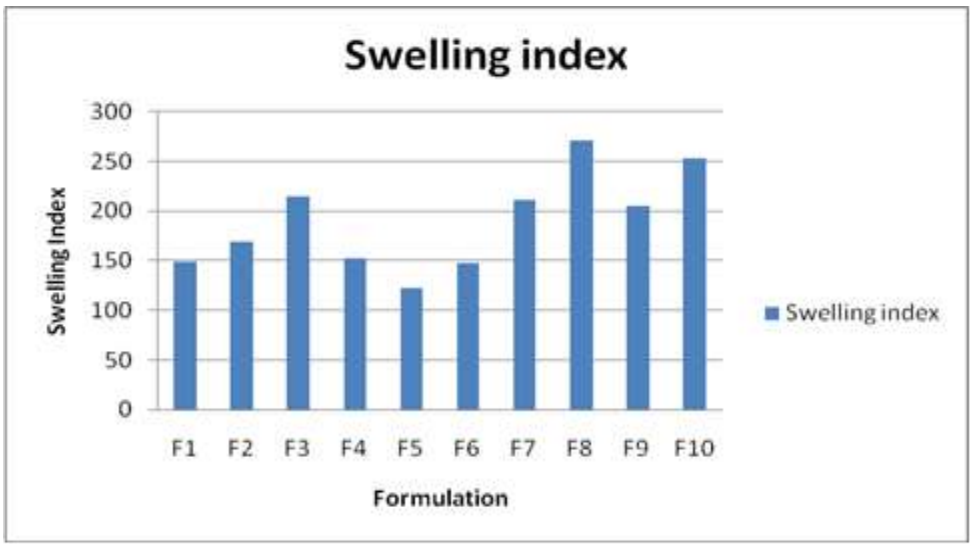


Graph No. 10: Bar diagram of formulation showing Folding endurance of trial batches.

Folding stamina of every formulation was unwavering within the range of 302 - 318. It exposed that high-quality elasticity of patch. The optimized batch F3 was found to have folding endurance of 313 and was within limits.

Swelling Index

The percentage swelling index taken at predetermined the calculated percentage swelling.

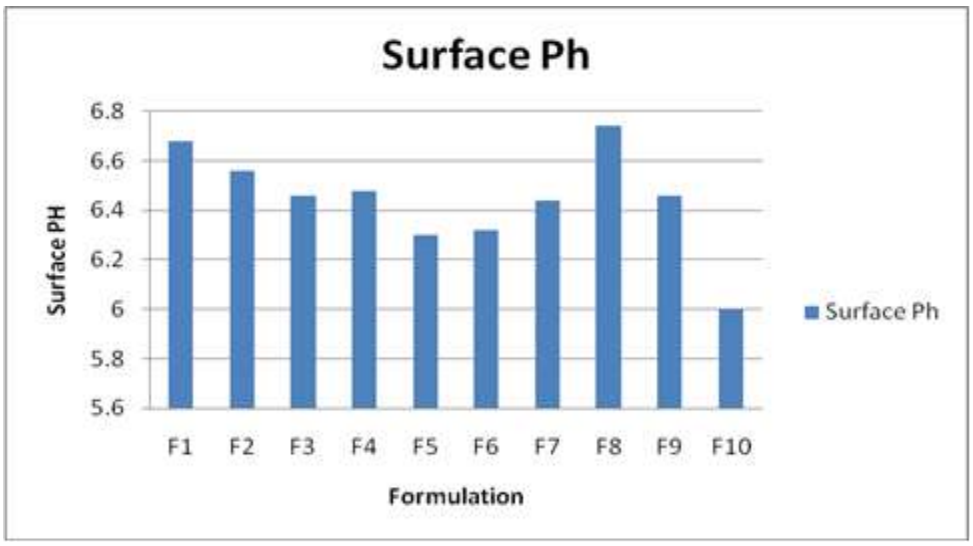


Graph No. 11: Bar diagram of formulation showing Swelling index of trial batches.

The prepared formulations were found to have swelling index in between 112.9% to 271.6%. The optimized batch F3was found to have swelling index of 214% and was within limits. Patch containing chitosan and Hydroxy Propyl methyl Cellulose showed considerable swelling of the patch.

Surface P^H:

The shell pH was precise by way of pH paper positioned on top of shell of inflated patch. Mean of 2 explanations were considered.



Graph No. 12: Bar diagram of formulation showing Surface pH of trial batches.

The shell pH of formulated batches was originated to be in the range of 6.68±0.13 to 6.74±0.15. The optimized batch F3 was found to have Surface pH of 6.46 and was within limits.

Performance alternatives:

Uniformity of energetic element content material:

Table 9.2 suggests the drug content uniformity outcomes of every component. Three replicates of every look at were accomplished. The average drug content became discovered to variety from 3.68 to 3.8 for the prepared (10mm diameter patches every) buccal patch components

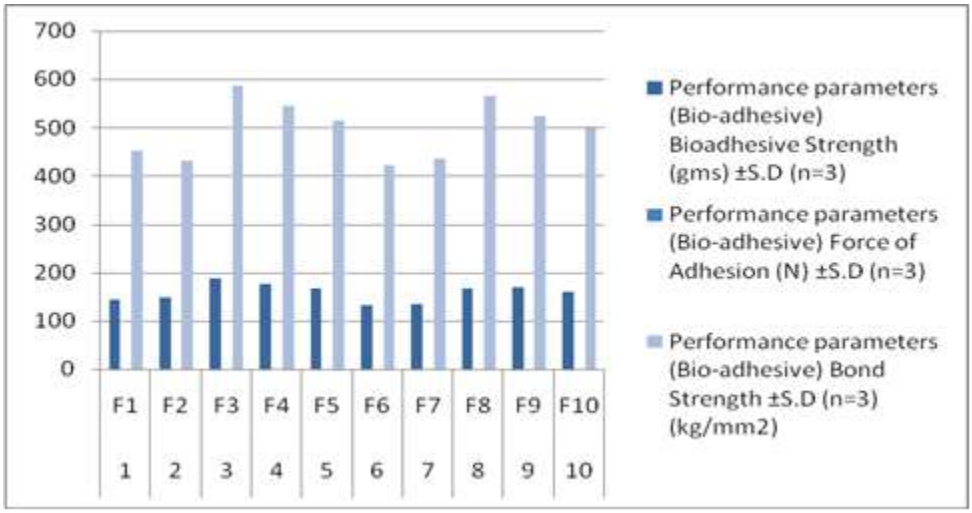
Bioadhesion electricity size:

An effective buccal mucosal tool ought to maintain near contact among the mucus layer overlying epithelial tissue. This limitation may be awfully important for a hit use of this formulation. Therefore, an in-vitro assessment of the buccal vicinity changed into carried out using the porcine gastric mucosa. It's far an oblique degree of bioadhesive electricity in grams. Table no. 09.1 shows the bio-adhesiveness of each buccal patch components. Mean Bioadhesion energy values were found to be 144.3, 149.34, 187.67, 176.28, 167.33, 132.64, 134.23, 167.35, 168.23 & 159.46 for F1, in that order. The bond (n) is 1.40, 1.44, 1.82, 1.62, 1.75, 1.62, 1.42, 1.47, 1.76, & 1.12(n) for F1- F10, correspondingly. Bonding agent energy (nm2) for F1-F1, 453.08, 432.12, 586.09, 543.63, 513.78, 421.12, 435.47, 564.65, 523.34 and 498.21(nm10) Power taking place adhesion (n) 1.40, 1.44, 1.82, 1.62, 1.75, 1.62, 1.42, 1.47, 1.76 & 1.12(n) for F1 - F10 correspondingly. Bond power (nm-2) 453.08, 432.12, 586.09, 543.63, 513.78, 421.12, 435.47, 564.65, 523.34 & 498.21 (nm-2) for F1 - F10 in that order.

Table No.22: assessment of overall performance parameter of various domperidone muco-adhesive buccal patch, respectively.

S. No.	Formulation	Performance parameters (Bio-adhesive)		
		Bio-adhesive force (gm) ± SD (n=3)	strength of Adhesion (n) ± S.D (n=3)	Bond vigour ± SD (n=3) (kg/mm2)
1	**F-1**	144.30 ± 02.64	01.40 ± 00.03	453.02 ± 05.34
2	**F-2**	149.34 ± 02.13	01.44 ± 00.02	432.12 ± 03.65
3	**F-3**	187.67 ± 00.78	01.82 ± 00.05	586.09 ± 05.23
4	**F-4**	176.28 ± 00.98	01.62 ± 00.01	543.63 ± 01.86

5	**F-5**	167.33 ± 01.34	01.75 ± 00.01	513.78 ± 04.33
6	**F-6**	132.64 ± 03.67	01.62 ± 00.06	421.12 ± 06.98
7	**F-7**	134.23 ± 02.87	01.42 ± 00.04	435.47 ± 05.32
8	**F-8**	167.35 ± 01.74	01.47 ± 00.03	564.65 ± 06.90
9	**F-9**	168.23 ± 01.53	01.76 ± 00.01	523.34 ± 03.23
10	**F-10**	159.46 ± 01.13	01.12 ± 00.01	498.21 ± 04.98



Graph No. 13: Bar diagram of formulation showing Bioadhesive strength of trial batches.

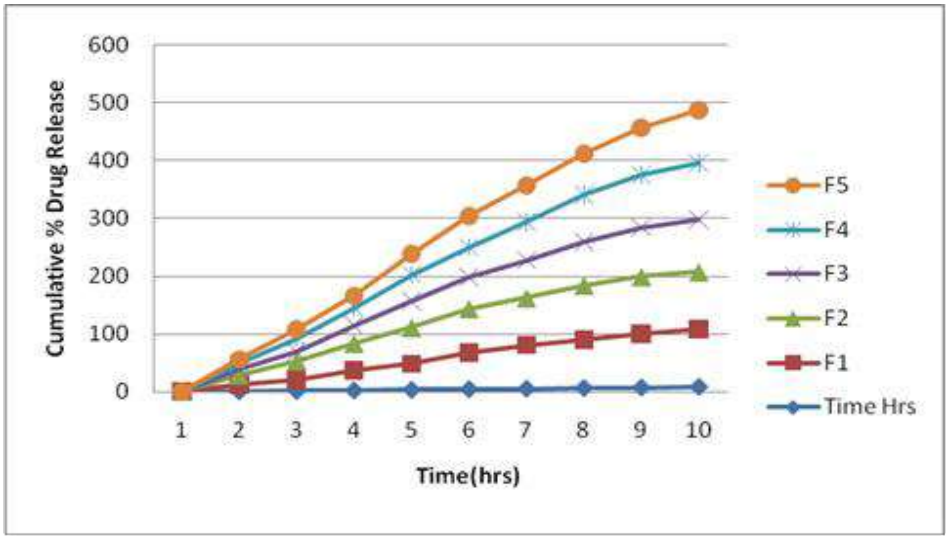
Table No. 23: assessment of Performance parameter of various muco-adhesive buccal patch of Domperidone.

S. No.	Formulation	Performance parameters (Bio-adhesive)		
		Drug Ccontents (mgs) ± SD (n=3)	Surface p^H ± SD (n=3)	In-vitro residence time (min) ± S.D (n=3) (kg/mm2)
1	**F-1**	03.73 ± 00.23	06.30 ± 00.540	320 ± 10.00
2	**F-2**	03.78 ± 00.13	06.40 ± 00.430	350 ± 05.00
3	**F-3**	03.71 ± 00.01	06.60 ± 00.570	490 ± 15.00
4	**F-4**	03.80 ± 00.54	06.50 ± 00.430	420 ± 05.00
5	**F-5**	03.75 ± 00.36	06.40 ± 00.570	450 ±10.00
6	**F-6**	03.69 ± 00.45	06.40 ± 00.570	310 ±10.00
7	**F-7**	03.68 ± 00.98	06.60 ± 00.230	300 ± 10.00
8	**F-8**	03.76 ± 00.21	06.30 ± 00.450	421 ± 15.00
9	**F-9**	03.73 ± 00.11	06.60 ± 00.340	480 ± 05.00
10	**F-10**	03.78 ± 00.78	06.40 ± 00.230	430 ± 10.00

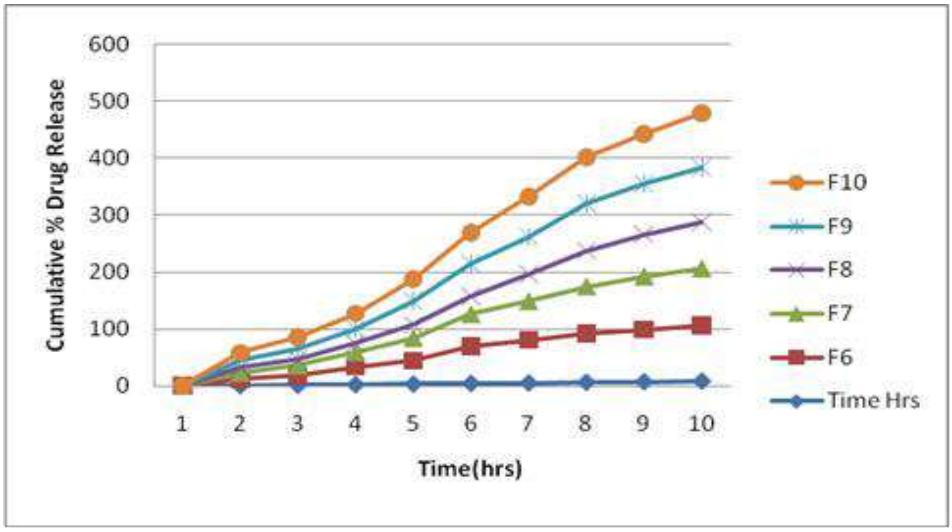
In-vitro drug discharge

In-vitro medicine discharge study was carried out using Keshary-Chien (K-C) cell of 25 ml capacity using 0.22µm cellulose membrane; in acetate buffer saline (ABS) pH 6.6 receptor sections was packed through acetate buffer saline pH 6.6 while a patch of 1cm2 was positioned in the contributor section. Hotness of receptor compartment be maintain at 37±0.50°C with the help of circulate stream bathtub. The Samples (2ml) were withdrawn at ordinary interval & replaced with equal volume of ABS pH 6.6, to continue the sink

situation. Samples were filter through Whatman filter, diluted rightfully by means of analyzed spectrophotometrically at 281nm.



Graph No. 14: Cumulative % drug discharge of formulation F1-F5



Graph No. 15: Cumulative % drug release of formulations F6-F10

The prepared formulations were established to have *in-vitro* discharge in between 7.92 to 99.78 the optimized batch F3 was found to have *in-vitro* release was within limits.

Balance looks at:

stability have a look at of the prepared buccal patch changed into executed by storing the f5 system in a humidity managed oven at room temperature and humidity and 400°c ± 20°c/75% rh ± 5%rh for 90days. A balance examines become completed at the f5 formula for ninety days to expect the degradation that could arise upon long-time period garage at various temperatures and humidity. The outcomes of the stableness look at conducted inside 90day are exposed into Table 24. These outcomes showed a mild lower in the in-vitro launch of the F5 system in comparison to the sparkling F5 formulation. Based totally on these parameters, the shelf lifestyles of the manufactured device changed into calculated.

Table. No. 24: stability have a look at after garage of the selected components (f3) at room temperature (RT) & 40 °c as well as seventy-five% relative humidity.

Storage conditions	No. of Days	Bio-adhesive strength	Invitro dwelling time	Drug contents (mg)	CUM% drug release (10hours)
Room temperature	30	182	421	3.70	99.41
	60	183	423	3.71	99.02
	90	185	425	3.65	98.67
At 400c and 75%RH	30	179	417	3.72	99.45
	60	177	420	3.69	99.08
	90	175	418	3.62	98.12

DISCUSSION

Oral drug transport structures are one of the advanced fields of controlled medicine delivery systems. Such amount paperwork has outstanding advantages in phrases of compliance with the remedy routine by means of the affected person. A managed launch matrix dosage form is described as a shape selected to obtain a therapeutic or comfort intention wherein drug release properties at a time and/or location are now not supplied in conventional dosage bureaucracy". Domperidone acts as a peripheral selective D2 dopamine antagonist. D3 receptors and receptors inside the chemoreceptor-precipitated quarter of the ground of the fourth ventricle, which are used to treat nausea & vomiting because of pills or motion illness to relieve nausea. Consequently, a sustained-launch formulation of Domperidone that releases the medicine over an extended period of a time is effective due to fact the healing attention is continued for a short time frame and for this reason a further dose is needed. In this take a look at, an attempt was made to increase a managed launch Domperidone mucoadhesive buccal patch organized by means of solvent casting the use of diverse ratios of HPMC, Chitosan, PVPC30, PVA and PG to obtain a healing dose that need to be maintained for a long time.

CONCLUSION

Domperidone is a D1, D2 antagonist. Its miles used to treat vomiting because of motion illness. Due to the fact the antique dose releases Domperidone in just a few minutes; the healing attention is maintained for a quick period, requiring an additional dose. Therefore, attempts have been made to keep therapeutic concentrations for longer intervals of time. This has been done via the improvement of managed release drug transport systems. These controlled release buccal mucoadhesive patches are by and large designed to launch the drug over a protracted time frame, 10hours, & to maximize medicine utilization even as warding off useless dosing frequency. For coaching of muco-adhesive buccal patch, HPMC, Chitosan & PVPK30 have been used because matrix formers. Some additional excipient worn is propylene glycol (PG) since a plasticizer. FTIR showed absence of medicine/polymer/excipient relations. A muco-adhesive buccal patch becomes ready by using solvent casting with a charismatic stirrer. Formulated controlled launch buccal mucoadhesive patches had been evaluated for thickness, fold sturdiness, mass trade, bio-adhesive power, medicine content uniformity, shell ph, in-vitro discharge observes, and balance look at. Components F3 confirmed exact bio-adhesion and managed drug release and executed well in everyone other restriction as evaluate to all

different formulation. Therefore, composition F3 is measured as an optimized composition. Balance research had been accomplished for F3 system they'd confirmed suitable stability whilst saved at expanded stability nation as for each the ICH rule & values have been within a allowable limit. It changed into located to facilitate formulations F3 retain medicine launch as much as 24hrs. By means of giving values of distribution proponent (n) inside the variety of 0.60.9 to suggest formula had launch drug by using distribution followed through using erosion mechanism. It was discovered that polymer ratios had tremendous control on medicine launch. For this reason, the conclusion may be made that stable quantity shape may advanced meant for Domperidone for forbidden launch by way of the buccal patches.

ACKNOWLEDGMENTS

Authors would like to be thankful to all the staffs of the Research Laboratory, Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, Vivek College of Technical Education, Bijnor, India, Uttar Pradesh State, for their encouragement, direct technical assistance as well as indirect assistance during this research work.

CONFLICT OF INTEREST

All authors declare that there are no conflicts of interest in this work.

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HOW TO CITE: Gunjan Rani, Sourabh Sharma, Sudhir Kumar*, Formulation And Evaluation of Mucoadhesive Buccal Patch by Natural Polymer Drug Containing Domperidone, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 7, 2051-2073. https://doi.org/10.5281/zenodo.13122963