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Research Article

Formulation and Evaluation of Mouth Dissolving Film of Chlorpromazine

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ABSTRACT

In the present research work an attempt has been made to optimized, formulate and evaluate Mouth dissolving film of Chlorpromazine. The solvent casting method was used to formulate and evaluate Mouth dissolving film of Chlorpromazine. Above results it was found that the formulation F3 was found to be optimized formulation from the data obtained. It is observed from the formulation F3 which shown disintegration time 18 sec. and percentage cumulative drug release shown 96.39% within 180 second. Thus, it can be concluded that the drug given in the form of Mouth dissolving films should be advantageous for patients suffering from nausea and vomiting, providing better patient compliance and an effective mode of treatment.& It is useful treats mental health conditions, like schizophrenia and bipolar disorder

INTRODUCTION

The oral route is one of the most favoured routes of drug administration about 60% of all the formulations are solid dosage form. Tablet is the most preferred dosage form due to ease of transportation, as it is more suitable, cost effective, and ease of administration leads to high degree of patient compliance. However, peroral administration of drugs has demerits like liver degradation and enzymatic degradation within the gastrointestinal tract, that disallow oral administration of various types of drugs especially peptides and proteins. Within the oral mucosal cavity, the buccal area seems to be one of the preferred routes for delivery of drug systemically. It provides benefits like prevention of hepatic first pass metabolism within the gastrointestinal tract, also provides improved enzyme flora for absorption of drugs. [1] Fast dissolving drug delivery system was developed belatedly in 1970s to beat swallowing problems linked with tablets and capsules for children and elderly sufferers. Oral mucosal drug delivery is vital route of drug administration. Several bioadhesiveoral mucosal

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dosage forms have been invented, which includes mucoadhesive tablets, gels, ointments, patches, and the use of films for buccal delivery, also known as oral thin strips. [1]

Buccal cavity is made up of stratified squamous epithelium i.e separated from the lamina propria and sub mucosa. The penetrability of buccal mucosa is 4-4,000 times larger than the skin, and is less than that of the intestine. Therefore, the buccal delivery is an outstanding platform for absorption of molecules with poor skin penetration. The prime obstacle to permeability in oral mucosa is the outcome of intercellular objects generated from the 'membrane covering granules' which is present at the topmost 200 µm layer. These oral film strips have a shelf life of 2-3 years, based on the active pharmaceutical ingredient but are tremendously responsive to environment humidity. [2]

MATERIAL AND METHODS

Chlorpromazine was obtained as Yarrow chem. pvt. Ltd. HPMC, Glycerol, Mannitol, Citric acid was obtained from loba chemicals

EXPERIMENTAL WORK

PREFORMULATION STUDY

Determination of wavelength using UV-visible spectroscopy:

10 mg of Chlorpromazine was weighed and dissolved into 10 ml ethanol to prepare a 1000µ g/ml stock solution from which a 10µg/ml dilution was prepared. Baseline correction was performed using ethanol and sample was scanned between 200- 400nm and wavelength of maximum absorbance (λmax) was determined.[52]

Determination of Melting Point:

Melting point of drug sample was determined by using melting point apparatus. Drug sample was taken and placed in a thin walled capillary tube; the tube was approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was recorded. [45]

Determination of solubility:

Preparation of calibration curve of Chlorpromazine:

The calibration curves of Chlorpromazine were prepared in distilled water and phosphate buffer pH 6.8 by using Shimadzu 1800 UV visible spectrophotometer. Accurately weighed 50 mg of Chlorpromazine was transferred into a 50 ml volumetric flask and the volume was made up by using co solvent with distilled water to obtain a 1000µg/ml stock solution of Chlorpromazine. From the stock solution 1 ml was taken and transferred into a 10 ml volumetric flask and rest of the volume was made up with solvent to obtain a 100µg/ml of solution from which further dilutions were prepared. Same procedure was followed for phosphate buffer pH 6.8 to prepare calibration curve.[53]

Determination of solubility of Chlorpromazine in various medium:

The solubility of Chlorpromazine in various medium was determined by equilibrium solubility method. In this method 5 ml of each solvent was taken into a separate vial and excess amount of Chlorpromazine was added in to vials containing distilled water and phosphate buffer pH 6.8. The vials put on magnetic stirrer at 37±20C for 12 hrs. The solutions were allowed to equilibrate for next 24 h. The solution was transferred into eppendr off tubes and centrifuged

for 5 min. at 2000 rpm. The supernatants of each vial were filter through 0.45micron membrane filter, make appropriate dilutions and analyzed by UV visible spectrophotometer (UV-1800 Shimadzu ,japan) at 255 nm, the studies was performed in triplicate.[54]

Drug-excipient interaction study:

The compatibility of the drug was assessed by drug-excipient interaction study. The drug was mixed with various excipients in a 1:1 ratio in glass vials which were properly sealed and kept undisturbed at 40°C temperature for 14 days. After 14 days incompatibility (if a vomiting, ny) was confirmed by TLC.[55]

Preparation of Mouth dissolving film by Solvent casting method:

Method for preparation of film containing drug Chlorpromazine:

Mouth dissolving films were prepared by solvent casting method as per the composition shown in table 6.4.In this method, the required quantity of water soluble polymer HPMC was dissolved in distilled water in a beaker (covered with aluminium foil) with continuous stirring on magnetic stirrer to make required percentage of polymer solution and then the weighed quantity of ingredients like as drug and glycerol as plasticizer, citric acid as saliva stimulating agent, Mannitol as Sweetening agent was dissolved in distilled water in another beaker and then this mixture was added to the polymer solution. After continuous stirring for 2 hours the solution was left undisturbed for 12 – 16 hours to remove all the air bubbles. This polymeric – drug solution was then poured on to the mould, allowed to air dry , packed in aluminum foil or a Zip Polybag and then stored in desiccators until use.

Optimization of Mouth Dissolving Film Formulation using two factor three level Designs:

A two factor three level factorial design (32) was used for the formulation optimization of Mouth dissolving film of Chlorpromazine and experimental trials are performed at all 9 possible formulations. In which the amount of HPMC, Glycerol were selected as independent variables (factor) varied at three different level: low (-1), medium (0), and high (+1) levels. The drug release and disintegration time used as dependent variables (response).

Table No. 1: Composition Of Chlorpromazine Mouth Dissolving Film.

BATCH NO. INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
Chlorpromazine(mg)	10	10	10	10	10	10	10	10	10
HPMC (mg)	300	300	300	250	250	250	200	200	200
Glycerol (ml)	0.05	0.1	0.075	0.05	0.1	0.075	0.05	0.1	0.075
Citric acid (mg)	20	20	20	20	20	20	20	20	20
Mannitol (mg)	20	20	20	20	20	20	20	20	20
Distilled water (ml)	10	10	10	10	10	10	10	10	10

Evaluation of Mouth dissolving film:

- **Weight of films:**

The mouth dissolving film of area 2×2 cm2 was cut and weighed on analytical balance and average weight was determined for each film. It is desirable that films should have nearly constant weight. It is useful to ensure that a film contains the proper amount of excipients and API.[58]

- **Film thickness:**

The thickness of the film was measured by micrometer screw gauge (Acculab) at three different places; averages of three values were calculated. This is essential to ascertain uniformity in the thickness of the film this is directly related to the accuracy of dose in the film. [29]

- **Folding endurance:**

The folding endurance is expressed as the number of folds (number of times the film is folded at the same place, either to break the specimen or to develop visible cracks). This test is important to check the ability of the sample to withstand folding. This also gives an indication of brittleness. The folding endurance of the strips was determined by repeatedly folding one film at the same place till it broke. [29]

- **Drug Content Uniformity:**

Drug content was determined by dissolving the prepared and the mouth dissolving film of area 2×2 cm2 was cut mouth dissolving film (MDF) of Chlorpromazine drug in 100 ml of phosphate buffer pH 6.8.The aliquot of 1ml was taken and diluted to 10ml with distilled water. Then solution was filtered through whatmanfilter paper and solution was analyzed on UV spectrophotometer at desired wavelength to calculate the amount of drug present in the film. [35]

- **In- vitro disintegration test:**

The in vitro disintegration study of the mouth dissolving film was carried out using 10 ml of water at 36ºC and it was placed in a petridish of 10 cm diameter. Each MDF was carefully kept at the centre of the petridish and the time required for the MDF to completely disintegrate was noted.

- **In- vitro Dissolution test:**

The dissolution study of the Mouth dissolving film was determined in Electrolab Dissolution Apparatus type II following USP Paddle method. Each film area 2×2 cm2 film was cut and fixed to a piece of metal wire slab and placed at the bottom of the dissolution vessel. All tests were conducted in 250 ml of Phosphate buffer pH 6.8.The dissolution medium was maintained at 37±0.5ºC with paddle rotation speed at 50rpm. Aliquot of 5ml was withdrawn at specific intervals and were immediately filtered through Whatman filter paper and analyzed spectrophotometrically. The absorbance values were transformed to concentration by reference to a standard calibration curve obtained experimentally measured on UV spectrophotometer. [29]

- **Stability Studies**

Stability studies were conducted on prepared films to assess their stability with respect to their physical appearance, drug content and drug release characteristics after storing them at 40° C/65 % RH for 2 months. Samples were withdrawn at 0, 30, and 60 days. [60]

RESULT AND DISCUSSION:

Identification study of drug

U.V. Spectroscopy

The UV spectrum of Chlorpromazine shows prominent absorbance maxima at wavelength 255 nm (fig No. 7.1) which is similar to the standard peaks therefore confirmed the identity of sample drug as Chlorpromazine. Reported absorbance maxima were Chlorpromazine were λ max at 255nm.

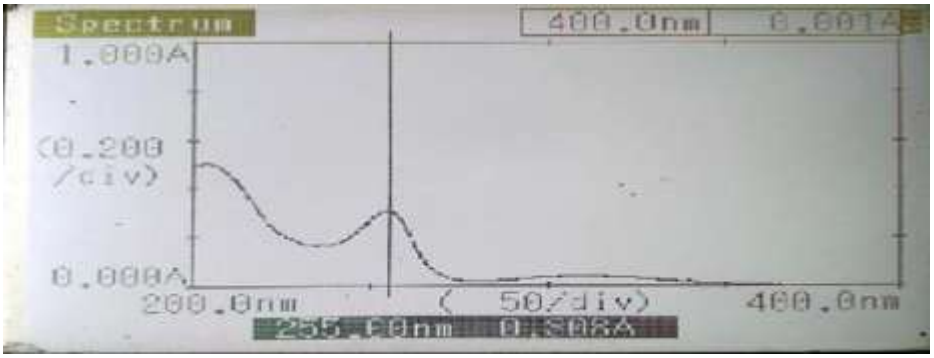

Fig.No.1: UV Spectrum of Chlorpromazine

Melting point determination:

The melting point of Chlorpromazine was found to be 200-2290C which is same as reported in literature

Determination of solubility:

Preparation of calibration curves: The calibration curves of Chlorpromazine in various solvents e.g. Distilled water, 6.8 pH phosphate buffers were prepared and shown in Table No. 7.1 &7.2

Table: 2 Absorbance data of Chlorpromazine in distilled water for preparation of calibration curve, at 255nm

S. No.	Concentration (µg/ml)	Absorbance
1	5	0.233
2	10	0.454
3	15	0.666
4	20	0.902
5	25	1.062

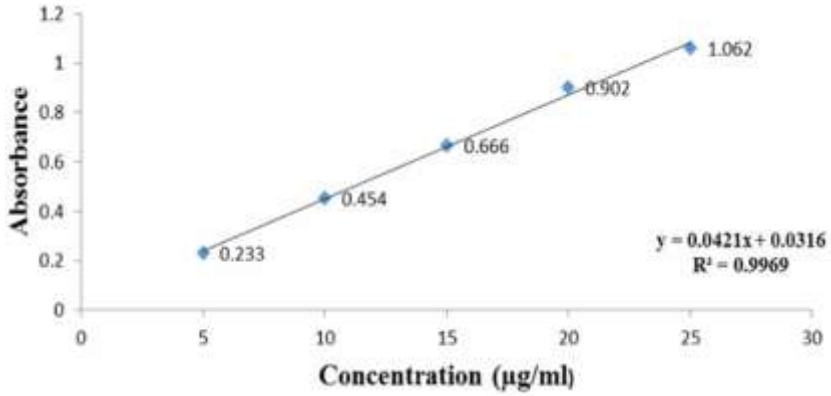

Figure 2: Calibration graph of Chlorpromazine in distilled water at 255.0nm

Table: 2 Absorbance data of Chlorpromazine in phosphate buffer pH 6.8 for preparation of calibration curve, at 255 nm.

S. No.	Concentration (µg/ml)	Absorbance
1	5	0.220
2	10	0.457
3	15	0.762
4	20	1.055
5	25	1.247

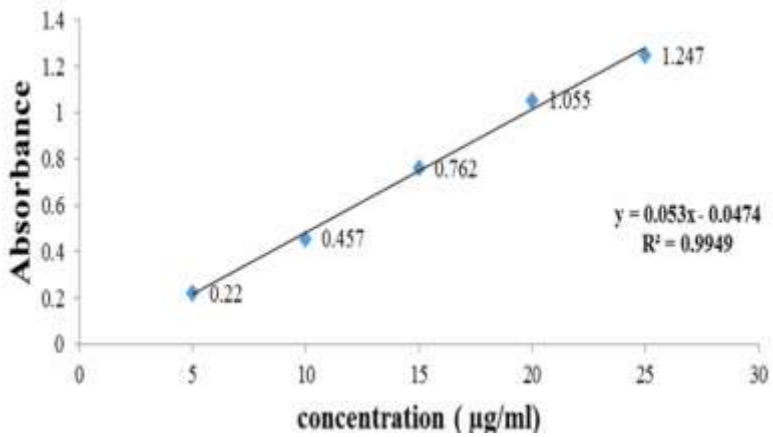

Figure 3: Calibration graph of Chlorpromazine in phosphate buffer pH 6.8 at 255.0nm

Determination of solubility of Chlorpromazine in various medium: The solubility of Chlorpromazine in various mediums was studied and the results of study were shown in below table:

Table:3 Solubility data of Chlorpromazine in different mediums

Sr. No.	Solvent	Solubility (mg/ml) Mean ± SD
1	Distilled water	4.135±0.00
2	Phosphate buffer pH 6.8	16.195±0.87

Drug-excipient interaction study: The drug (Chlorpromazine) was found to be compatible with various excipients which were selected for formulation of fast dissolving film. The compatibility was assessed by TLC and the retention factors of all ratios found similar.

Table :4 Data of drug-excipient interaction study

Sr. No.	Drug/ drug+ Excipient Ratio (1:1)	Physical appearance (initial)	Present Day (Rf)	Physical appearance (final)	After 15 Days (Rf)
1.	Drug (Chlorpromazine)	White	0.59	White	0.59
2.	Pure Drug + HPMC	Light brown	0.50	White	0.56
3.	Pure Drug + Glycerol	White	0.48	White	0.49
4.	Pure Drug + Mannitol	White	0.52	White	0.51
5.	Pure Drug+ Citric acid	White	0.54	White	0.56

Evaluation of parameters of Mouth dissolving film:

The Mouth dissolving films of Chlorpromazine were evaluated like weight variation, thickness, disintegration time, drug content and folding endurance. The results of the studies were shown in below table

Table:5 Weight variation, Thickness, Folding endurance, Drug content & Disintegration Time Ratio of Formulation F1-F9.

Formulation	Weight variation(mg) Mean ± SD	Thickness (mm) Mean ± SD	Folding endurance (Times)	Drug Content (%)	Disintegration Time (sec) Mean ± SD
F1	48.9±0.02	0.1±0.07	142	85.1	36

F2	34.5±0.05	0.08±0.04	126	86.6	30
F3	29.8±0.04	0.09±0.02	151	97.4	18
F4	31±0.06	0.07±0.08	124	86.6	20
F5	39±0.04	0.09±0.4	141	93	31
F6	49±0.09	0.1±0.09	130	92.2	35
F7	34±0.08	0.09±0.06	137	92.3	36
F8	47.8±0.05	0.08±0.07	145	87.7	32
F9	35±0.07	0.07±0.05	140	86.4	35

In-vitro drug release study for Mouth dissolving film:

The results of In vitro dissolution study are (shown in Table). The film formulations with different batches (F1-F9) showed good % Drug Release within 3 minutes time. This indicates fast drug release from the thin film delivery system.

Table :6 Percentage drug release data of F1 to F9 formulation of Mouth dissolving film.

Sr. No.	Time (in Sec.)	% Drug Release data								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2.	30	24.57± 0.12	23.80± 0.70	24.23± 0.09	23.22± 0.12	22.05± 0.12	23.58± 0.90	22.08± 0.84	23.07± 1.23	24.40± 0.14
3.	60	34.42 ± 0.31	34.02± 0.24	36.56± 0.22	33.3± 0.12	33.12± 0.25	31.05± 0.12	34.39± 0.12	35.87± 0.70	34.87± 0.06
4.	90	41.50 ± 0.25	41.31± 0.025	42.23± 0.091	39.69± 0.12	41.05± 0.39	38.79± 0.12	41.68± 0.39	39.09± 0.42	41.04± 0.12
5.	120	51.48± 0.25	52.32± 0.45	58.57± 0.26	52.15± 0.07	52.41± 0.07	56.14± 0.78	52.69± 0.70	53.30± 1.43	52.69± 0.19
6.	150	65.09± 1.53	68.65± 0.91	68.24± 1.75	66.46± 0.60	67.68± 0.63	74.17± 2.55	71.15± 0.70	70.69± 0.72	74.56± 0.19
7.	180	89.68± 2.10	91.83± 0.23	96.39± 0.12	89.28± 0.50	90.78± 0.00	92.52± 0.12	93.94± 0.91	90.48± 1.81	91.98± 0.89

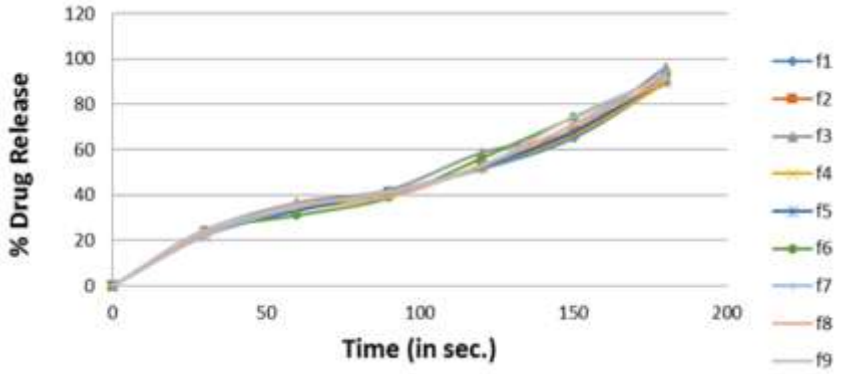

Figure 4: Percentage Drug Release from Mouth dissolving film Formulation.

Stability Studies

The formed films were charged for stability at 40° C/75 % RH for 2 months .Table 7.8 shows the

stability data. The data indicates that the drug product falls well within the proposed stability specification. The data indicates that there is no physical or chemical change indicating that the formulation would maintain its efficacy and quality throughout its proposed shelf life.

Table: 7 Stability study of Mouth dissolving film:

Evaluation Parameters	Before stability	After 1 month storage	After 2 months storage
Thickness	0.08mm	0.08mm	0.087 mm
Disintegration time	18 sec	18 sec	18 sec
Weight variation	30 mg	30mg	32.79 mg
Drug content	97.41%	97.39%	97.23%

SUMMARY AND CONCLUSION

In the present research work an attempt has been made to optimized, formulate and evaluate Mouth dissolving film of Chlorpromazine. The solvent casting method was used to formulate and evaluate Mouth dissolving film of Chlorpromazine. Above results it was found that the formulation F3 was found to be optimized formulation from the data obtained. It is observed from the formulation F3 which shown disintegration time 18 sec. and percentage cumulative drug release shown 96.39% within 180 second. Thus, it can be concluded that the drug given in the form of Mouth dissolving films should be advantageous for patients suffering from nausea and vomiting, providing better patient compliance and an effective mode of treatment.& It is useful treats mental health conditions, like schizophrenia and bipolar disorder.

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