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RESEARCH ARTICLE OPEN ACCESS

DESIGN AND IN-VITRO EVALUATION OF FAST DISINTEGRATING PROMETHAZINE THEOCLATE TABLETS

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ABSTRACT

Promethazine theoclate, a first-generation H1 receptor blocker, is commonly prescribed for motion sickness and postoperative nausea. Its oral bioavailability is only about 25%, mainly because of poor solubility in water, which delays the onset of action. To overcome this limitation, orally disintegrating tablets (ODTs) of promethazine theoclate were developed. ODTs dissolve quickly in the mouth, improving drug absorption and making them especially useful for patients who have difficulty swallowing.In this study, ODTs were prepared using three different super disintegrantssodium starch glycolate, crospovidone, and croscarmellose sodiumused alone and in combination at different levels. Seventeen trial formulations were designed with the help of Design Expert software. Each formulation was tested for flow properties, hardness, friability, weight variation, drug content, disintegration time, and dissolution performance. Among the prepared formulations, formulation F8 showed the best results, with a rapid disintegration time of 30 seconds and almost complete drug release (99.89%). The optimized blend contained sodium starch glycolate (17.5 mg), croscarmellose sodium (30 mg), and crospovidone (30 mg). FT-IR analysis confirmed no interactions between drug and excipients. Stability testing over 90 days also showed no significant changes in quality or dissolution behavior. Overall, the optimized ODTs of promethazine theoclate achieved rapid tablet breakdown and nearly complete drug release, suggesting faster absorption and quicker relief of symptoms. This dosage form may provide a cost-effective, scalable, and patient-friendly alternative to conventional tablets, with the added benefit of better compliance and improved clinical outcomes.

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INTRODUCTION

For many kinds of medications, oral dosage is still the recommended method of administration since it is easy to use, adaptable, convenient, and well-liked by patients (Van Schaick, 2003). However, swallowing issues with certain oral solid dosage forms, like tablets and capsules are prevalent across all age groups (Masareddy, 2008). Many elderly, paediatric, bedridden, nauseated, and uncooperative patients are reluctant to take these solid preparations because they fear choking (Keny, 2010 and Sudarshan Singh, 2012). Traveling patients without easy access to water and a number of physiological and neurological conditions, such as dysphagia, motion sickness (kinetosis), persistent nausea, sudden episodes of coughing during the common cold, allergic conditions, bronchitis, and hand tremors, also experience difficulty swallowing conventional dosage forms. This results in therapy that is ineffective and noncompliant (Vijay Sharma, 2008; Khan, 2007; Abdelbary, 2004). Orodispersible tablets (ODT) were created to address the aforementioned issue and enhance patient acceptance (Abed, 2010). Other names for ODTs include tablets that dissolve in the mouth, tablets that dissolve quickly, porous tablets, and rapimelts (Aguilar-Díaz, 2012).

A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly, usually within a second when placed upon the tongue," is how the US Food and Drug Administration (FDA) defines ODT (Shah, 2012). ODT disintegration times typically fall between a few seconds to a minute or more. These ODT or fast-dissolving tablets are now recognized by the European Pharmacopoeia. According to the European Pharmacopoeia, ODTs must dissolve in three minutes when put through the standard disintegration test for tablets and capsules (Shukla, 2009). The mouth dissolving tablets release their constituents without mastication or water in less than 60 seconds after coming into contact with saliva, creating a suspension or solution that is simple to swallow (Ibrahim, 2010; Chandrasekhar, 2009). When super disintegrants are used, the tablet dissolves instantly on the tongue, releasing the medication into the saliva. A drug may be taken as a solution to be absorbed from the gastrointestinal tract, which would result in a rapid commencement of action, or it may be absorbed into the systemic circulation from the mouth, throat, and oesophagus as the saliva descends into the stomach (Pabari, 2012; Mutasem, 2006). Among the dosage forms developed for facilitating ease of medication, the orally disintegrating systems have been the favourite of product development scientists. In similar fashion the oral cavity is highly acceptable by patients, the mucosa is relatively permeable with rich blood supply and virtual lack of

langerhans cells makes oral mucosa tolerant to potential allergens (Shojaei, 1998). The development of orally dispersible tablet can be achieved by utilizing appropriatesuper disintegrants, which decreases disintegration time andenhance drug dissolution rate.Promethazine Theoclate, an anti-emetic drug, faces challenges due to extensive first-pass metabolism and low bioavailability when taken orally, which hampers its effectiveness in controlling vomiting. To address this, the goal was to develop mouth-dissolving tablets that ensure rapid absorption, adequate strength, and quick action, ultimately enhancing therapeutic outcomes (Gupta, 2013).

METHODOLOGY

Determination of melting point (*Sharma, 2010*): Melting point was determined by capillary method, a small amount (0.1-0.2g) of pure drug was transferred onto a watch glass. One end of capillary tube of 5cm long was sealed and the solid was introduced into a capillary tube and packed to a height of 3 cm. Then the capillary tube was placed in melting point apparatus and the temperature at which the melting of drug started was noted by using the thermometer placed in the apparatus**.**

Table 1. Formulation design of Promethazine theoclate ODT

FORMULATION	PT	CP	CCS	SSG	MCC (102)	LACTOSE	MANNITOL	TALC	MAGNESIUM STEARATE
F1	25	10	20	5	83	60	40	2	5
F2	25	30	20	5	63	60	40	2	5
F3	25	10	20	30	58	60	40	2	5
F4	25	30	20	30	38	60	40	2	5
F5	25	10	10	17.5	80.5	60	40	2	5
F6	25	30	10	17.5	60.5	60	40	2	5
F7	25	10	30	17.5	60.5	60	40	2	5
F8	25	30	30	17.5	40.5	60	40	2	5
F9	25	20	10	5	83	60	40	2	5
F10	25	20	10	30	58	60	40	2	5
F11	25	20	30	5	63	60	40	2	5
F12	25	20	30	30	38	60	40	2	5
F13	25	20	20	17.5	60.5	60	40	2	5
F14	25	20	20	17.5	60.5	60	40	2	5
F15	25	20	20	17.5	60.5	60	40	2	5
F16	25	20	20	17.5	60.5	60	40	2	5
F17	25	20	20	17.5	60.5	60	40	2	5

PT- promethazine theoclate; CP – crospovidone; CCS –croscarmellose sodium; SSG- sodium starch glycolate

Solubility studies (Sharma, 2010): Solubility of Promethazine theoclate was observed in different solvents such as chloroform, ethanol, water and ether.

Drug and excipient compatibilitystudy (Sharma, 2010): Fourier Transform Infra-RedSpectroscopy (FT-IR) analysis was carried out on pure substances and their physical mixtures. FT-IR spectra of pure drug, excipients and their physical mixtures were taken by direct method between 400-4000 cm^{-1}. The peaks of pure drug, excipient and physical mixtures were compared for incompatibility.

Precompression parameters of powder blend: The powder blend was analysed for bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose.

Formulation of Promethazine theoclate ODT (*Sujit Shinde, 2024*): Accurately weighed quantities of Promethazine theoclate (PT), super disintegrants and MCC102 were taken in mortar and pass-through sieve no 80 to ensure better mixing. Thereafter the formulation weight of mannitol and lactose was mixed with the MCC- disintegrant mixture. Finally, magnesium stearate and and talc was added to the powder blend. After mixing the powder blend was compressed in to tablet using tablet punching machine.

Evaluation of Promethazine theoclate ODT

Thickness (Kuchekar, 2004): Thickness of tablets was measured by using micrometre.

Hardness/Crushing strength (Davesh, 2021): The hardness can be tested using Monsanto hardness tester.

Friability (Shailendra Kumar Singh, 2009): Friability test can be performed to evaluate the ability of the tablets to withstand abrasion during handling and transporting. The test is performed using friability test apparatus. The friabilator consists of a plastic chamber divided into two parts and revolves at 25 rpm.

Weight Variation (Khan, 2007): 20 Tablets were randomly selected and individually weighed and calculated the average weight and compared the individual tablet's weight to the average weight.

***Drug Content* (Gorman, 2011):** Twenty tablets were taken, powdered and the powder equivalent to one dose each was transferred to a 100 mL volumetric flask and phosphate buffer (pH-6.8) was added. The volume was then made up to the mark with phosphate buffer. The solution was filtered and diluted suitably and drug content in the samples was estimated using UV- Visible spectrophotometer at 255 nm.

Invitro drug release (Mahmoud Mahyoub, 2024): The in vitro drug release study was performed for the single unit tablets using USP Type Il dissolution apparatus (Paddle type). Tablet was placed in the dissolution apparatus containing 900 ml of pH 6.8 phosphate buffers and the paddle was rotated at 50 rpm at a temperature of 37±0.50C. Samples of 1 ml were collected at different time intervals up to 10 minutes and analysed by spectrophotometer at 255nm. Then the cumulative amount of drug release from the prepared tablets at different time intervals was calculated.

***Wetting time* (Mohanachandran, 2021):** The wetting time of the tablets can be measured using a simple procedure. A piece of tissue paper (diameter 10 cm) folded twice was placed in a small Petri dish (internal diameter = 10 cm) containing 10ml of ofphosphate buffer (6.5).Methylene blue, a water-soluble dye, is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for phosphate buffer solution to reach upper surface of the tablet is noted as a wetting time**.**

In-vitro Disintegration time (Kuno, 2005): Six tablets were placed in the disintegration test apparatus and the time required for these tablets to completely disintegrate into fine particles was noted. The disintegration test was performedin900 ml distilled water at 37 ± 0.5˚C temperature and at the rate of30 ± 2 cycles/minutes.

***Optimization of formulation using DOE* (Late, 2008):** Statistical design of experiments, a computer-aided optimization technique, was used to identify critical factors, their interactions and ideal process conditions that accomplish the targeted response.The -Box-Behnken

design was used for the designing the formulation. The best formulation was determined using Design Expert Stat Ease Software I. In the study, SSG. CP, and CCS were selected as the three factors and in vitro disintegration time and in vitro drug release were considered as the two responses. Hence, seventeen experimental trials were done. Trials were repeated twice to evaluate experimental errors and increase power ratio. Contour plots were drawn and optimum formulation was selected by optimization criteria.

Drug – excipient compatibility: Compatibility study was done by FT-IR spectroscopic method. During FT-IR studies the peak of Promethazine theoclate was obtained at 3066 cm $^{-1}$,1485 cm $^{-1}$ 1630 cm $^{-1}$, 1300 cm $^{-1}$,730 cm $^{-1}$. There is no significant change in the peak of pure drugin the FTIR spectrum of physical mixture of pure drug with super disintegrantsie. Crospovidone, sodium starch glycolate and croscarmellose sodium.

Table 2. Precompression parameters of different batches of formulation

CONCENTRATION (µg/ml)	ABSORBANCE
0	0.000
2	0.095±0.00407
4	0.188±0.00652
6	0.275±0.005709
8	0.387±0.00897
10	0.485±0.0114

All values expressed as mean of ± SD, n = 3

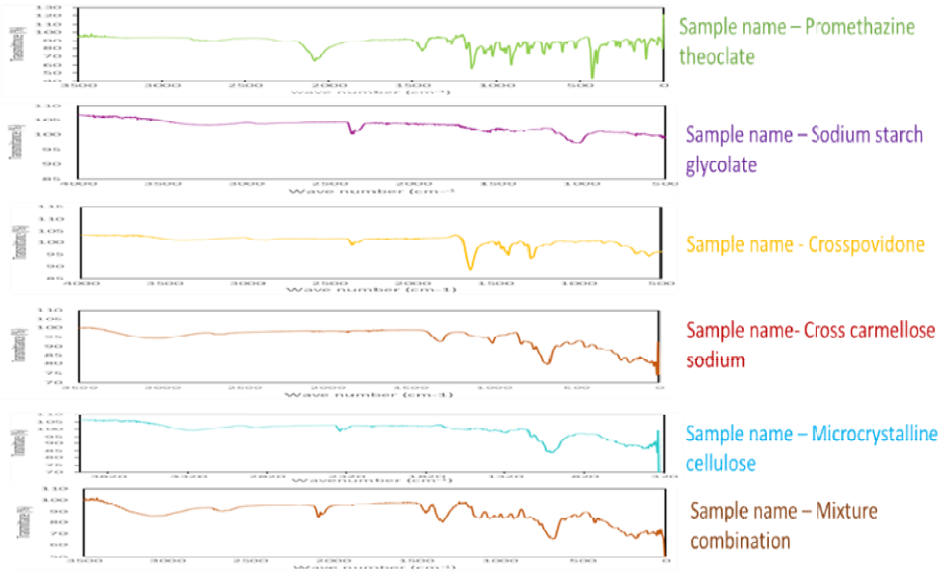

Figure 1. FTIR spectrum of Promethazine theoclate, sodium starchglycolate, crospovidone, croscarmellose sodium and MCC102

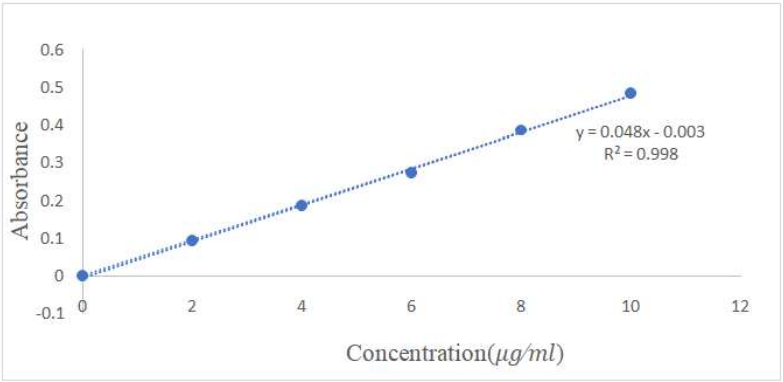

Fig. 2. Standard curve of Promethazine theoclate in Phosphate bufferpH 6.8 at 255 nm

Stability Studies (Shabana Parveen, 2023): This study was carried out at temperature and humidity conditions as per ICH guidelines and the tests were carried out in a stability chamber. The temperature and humidity conditions used were, 40°C ± 2°C at 75% ± 5% RH, 25°C ± 2°C at 60% ± 5% RH, 5°C ± 3°C. Samples were withdrawn at 0 day, 30 days and 90 days' time intervals and evaluated for hardness, friability, drug content, *in-vitro*-disintegration and *in- vitro* drug release.

RESULT AND DISCUSSION

Determination of Melting point: Melting point of Promethazine theoclate was determined by capillary rise method and it was found to be 228 ± 1.5°C (n=3), which complies with official standard.

It indicates that there is no chemical interaction between the drug and the super disintegrants. This shows that Promethazine theoclate was compatible with both the super disintegrants.

Solubility studies: Solubility studies were carried out in different solvents and it was found that Promethazine theoclate was sparingly soluble in ethanol and slightly soluble in water, freely soluble in chloroform& soluble in phosphate buffer pH 6.8 which complies with the pharmacopeial specifications.

Standard calibration curve of Promethazine theoclate: The $\lambda_{max}$of Promethazinetheoclate in phosphate buffer pH6.8 found to be 255 nm. The curve was found to be linear and obeys Beer- Lambert's law

in the range of 1- 10 µg/ml with regression co-efficient 0.9988. The absorbance values are tabulated in the Table 2.

Evaluation of Promethazine theoclate odt

Pre- compression parameter: The precompression parameters of the formulations are shown in the table no.3. All the formulations exhibited good flow properties of powder blend. Bulk density values for all batch beads were obtained in the range from 0.32-0.5 kg/cm^3 and the tapped density values obtained in the range from0.42-0.62kg/cm^3. The angle of repose values range in between 28.2-32.4 indicating that the powder blend has good flow property for compression.Carr's index value for all batch beads was found in the range of 9.2-12.6, indicating excellent to good flow properties for all batches. Hausner's ratio for all batch beads was found between 1.01-1.19 showing excellent flow properties of beads of all batches.

Weight Variation: The weight variation test was performed. The weight variations of the sample were found to be within the range of 243 - 250. All formulations complied with the test for weight variation according to the pharmacopeial specifications.

Wetting time: Wetting time test was performed to find out the time taken for water to wet whole tablet and the wetting time ranges for all batches was found to be in the range of 32-44 sec. Among all the formulation F8 has a wetting time of 32 seconds, a shorter wetting time is generally desirable as it indicate faster disintegration and rapid onset of action.

In-vitro disintegration time: The disintegration time of formulations of tablets were tested by the method described. It was observed that disintegration time of all tablets ranged between 30-50 seconds.

Table 3. Precompression parameters of different batches of formulation

FORMULATION	ANGLE OF REPOSE(°)	BULK DENSITY (g/cm^3)	TAPPED DENSITY (g/cm^3)	CARR'S INDEX	HAUSNER'S RATIO
F1	30.6±0.321	0.5±0.0047	0.6±0.0012	10.12±0.001	1.12±0.008
F2	31.3 ±0.153	0.4± 0.0116	0.58±0.0024	10.1±0.004	1.05±0.004
F3	30.1±0.058	0.34±0.01	0.55±0.031	12.2±0.04	1.16±0.002
F4	31.1±0.082	0.32±0.0058	0.5±0.001	11.56±0.02	1.17±0.04
F5	31.3±0.0047	0.41±0.008	0,62±0.044	9.9±0.0043	1.09±0.01
F6	31±0.057	0.46±0.004	0.58±0.007	10.1±0.004	1.18±0.05
F7	29.03±0.087	0.42±0.020	0.52±0.003	12.2±0.002	1.19±0.01
F8	29.6±0.077	0.33±0.008	0.52±0.006	9.8±0.004	1.10±0.001
F9	30±0.871	0.5±0.012	0.58±0.054	12.6±0.002	1.16±0.003
F10	30.2±0.943	0.42±0.024	0.45±0.003	10.1±0.004	1.07±0.006
F11	32.4± 0.265	0.43±0.004	0.45±0.003	11.85±0.01	1.20±0.03
F12	27.5±0.289	0.41±0.021	0.43±0.031	10.5±0.04	1.14±0.02
F13	28.3±0.025	0.30±0.052	0.41±0.003	9.48±0.01	1.15±0.04
F14	27.2±0.005	0.31±0.031	0.51±0.005	9.9±0.006	1.18±0.01
F15	28.2±0.058	0.32±0.0206	0.42±0.002	9.52±0.05	1.03±0.005
F16	28.2±0.058	0.32±0.0206	0.42±0.002	9.52±0.05	1.03±0.005
F17	28.2±0.058	0.32±0.0206	0.42±0.002	9.52±0.05	1.03±0.005

All values expressed as mean of ± SD, n = 3

Table 4. Post compression parameter of different batches of formulation

FORMULATION	WEIGHT VARIATION (mg)	HARDNESS (kg/cm^2)	THICKNESS (mm)	WETTING TIME (sec)	FRIABILITY (%)	DRUG CONTENT ± SD(%)	IN-VITRO DISINTEGRATION TIME
F1	250±0.72	4.2±0.01	3.1±0.061	44±0.05	0.526±0.11	99.25 ± 0.05	50±0.061
F2	250±0.54	4.5±0.054	3.02±0.113	43±0.30	0.529±0.07	99.42±0.12	48±0.013
F3	249.5±0.68	4.1±0.031	3.01±0.01	42±0.50	0.56±0.02	99.4 ± 0.146	45± 0.06
F4	249±0.72	4±0.11	3.04±0.11	33±0.20	0.59±0.01	99.72± 0.213	54±0.07
F5	250±0.39	4.6±0.13	3.09±0.073	46±0.58	0.51±0.025	99.38± 0.712	46±0.128
F6	247±0.07	4.7±0.07	3±0.073	43±0.40	0.52±0.015	99.49± 0.012	45±0.11
F7	247.5±0.03	4.48±0.16	3.03±0.145	41±0.15	0.54±0.017	99.51± 0.064	43±0.16
F8	248±0.087	4.4±0.113	3.1±0.07	32±0.77	0.56±0.013	99.86± 0.72	30±0.04
F9	244±0.011	4.9±0.154	3.4±0.23	44±0.23	0.58±0.054	99.75± 0.031	47±0.113
F10	249±0.056	4.99±0.04	3.20±0.128	39±0.09	0.51±0.16	99.52± 0.091	40±0.214
F11	248±0.61	4.42±0.15	3.07±0.16	40±0.14	0.51±0.211	99.65± 0.061	42±0.313
F12	243±0.051	4.5±0.17	3±0.04	36±0.40	0.536±0.031	99.43± 0.11	51±0.15
F13	247±0.016	4.23±0.12	3.02±0.20	38±0.25	0.57±0.04	99.56± 0.15	37±0.12
F14	249±0.007	4.22±0.11	3.21±0.13	36±0.51	0.5±0.125	99.54± 0.21	37±0.34
F15	249±0.016	4.21±0.02	3.23±0.420	37±0.02	0.58±0.12	99.5± 0.01	37±0.21
F16	249±0.011	4.22±0.14	3.21±0.21	36±0.13	0.586±0.15	99.6±0.54	37±0.12
F17	249±0.12	4.2±0.23	3.12±0.20	37±0.30	0.54±0.145	99.52±0.15	37±0.43

All values expressed as mean of ± SD, n = 3

Post – compression parameters

Thickness and Hardness: All the formulation showed uniform of thickness of 3- 3.4mm and the hardness of tablets ranged from 4-4.5kg/cm².

Friability: The friability test was performed on the formulations. Friability of all prepared tablets were founded in the range of 0.51%-0.58% indicating the tablet prepared were of sufficient strength.

Drug Content: Drug content of all formulations was tested and was found to be within the pharmacopeial limit. This ranges between 99.25%-99.86%.

time as compared to the other formulations. As the concentration of super disintegrants increased, it showed faster disintegration. Where as formulation F4 had less amount of MCC102 show increased disintegration time of 54 sec. The wetting time and disintegration studies are critical parameters for evaluating the performance of Orodispersible tablets (ODTs), as they directly influence the onset of action and patient acceptability. In the present study, the wetting time for all formulations ranged from 32 to 44 seconds, indicating satisfactory hydration and penetration of water into the tablets. Among all formulations, F8 exhibited the shortest wetting time (32 seconds), which is advantageous as a shorter wetting time generally correlates with faster disintegration and drug release.Similarly, the in-

vitro disintegration time of the formulations was observed to be within 30–50 seconds, complying with pharmacopeial requirements for ODTs. Notably, F8 showed the least disintegration time, confirming its superior performance in comparison to other formulations.

***In- vitro* drug release study:** The dissolution study of Promethazine Theoclate ODTs revealed effective drug release within 10 minutes. Formulation F8, containing 17.5 mg of sodium starch glycolate, 30 mg of crospovidone, and 30 mg of croscarmellose sodium, exhibited the fastest release due to rapid disintegration and particle dispersion. The combination of crospovidone and croscarmellose sodium demonstrated a synergistic effect, while the use of multiple super disintegrants and direct compression further enhanced drug release. The use of multiple super disintegrants in combination was found to be more effective than using them individually, suggesting that their complementary mechanisms of action play a vital role in ensuring rapid drug release.

The direct compression method employed also contributed to maintaining porosity and uniform distribution of excipients, which further enhanced water penetration and tablet breakup. Overall, the results highlight that the rational selection and combination of super disintegrants can significantly influence the disintegration and dissolution behaviour of ODTs. The optimized formulation (F8) thus provides a promising approach for delivering Promethazine Theoclate in a patient-friendly dosage form, ensuring both rapid onset of therapeutic action and improved patient compliance.

Optimization by design expert stat ease software: Box- Behnken design was used to investigate the effect of the two independent variables and their potential interaction. The average values were submitted to multiple regression analysis using Design Expert software (Version 13.0.7.0. Stat- Ease). The numerical optimization tool provided 25 sets of optimal solutions among which 30 mgcrosspovidone,17.5 mgsodium starch glycolate and 30 mg of croscarmellose sodium was selected (by the software) as optimized concentration with desirability of 0.920.

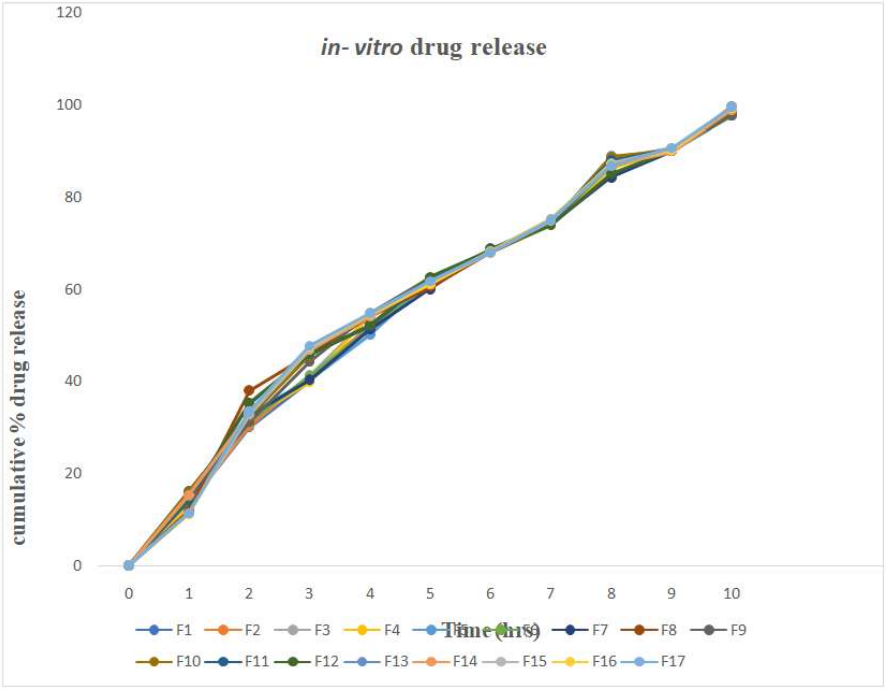

Figure 3. Graphical representations of *in-vitro* drug release indifferent batches of formulation

Table 5. Numerical test results of model adequacy checking for influence of independent variables on response variables

Response	Model	Sequencial p value	R^2	Adjusted R^2	Predicted R^2	Adequate precision	CV %
In-vitro disintegration time	Quadratic	0.0026	0.8976	0.8511	0.7106	12.4820	2.62
Drug release	Linear	0.0543	0.4221	0.0.3835	0.2320	6.8232	3.76

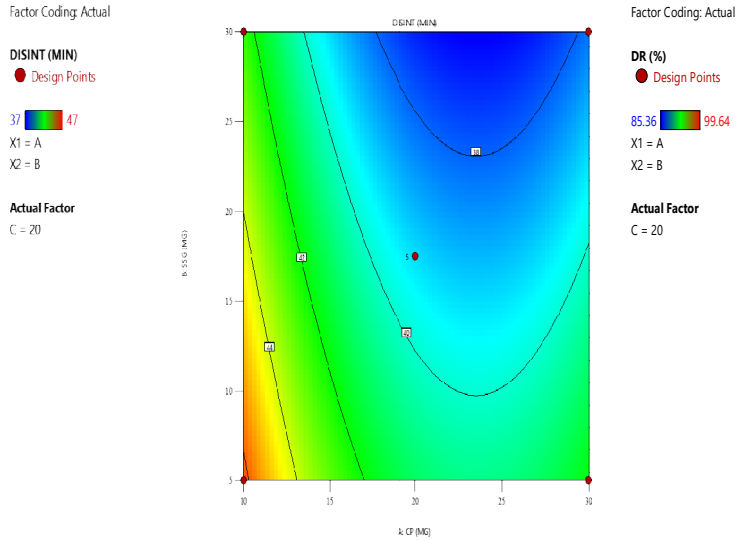

Figure 4. Contour plot forIn-vitro disintegration time

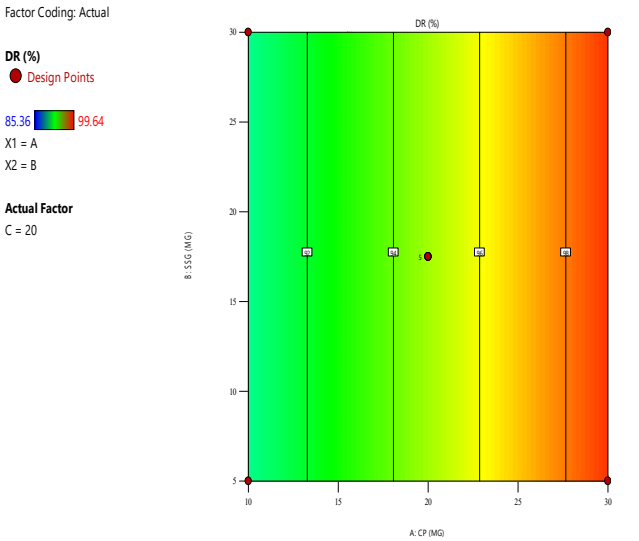

Figure 5. Contour plot forIn-vitro drugrelease

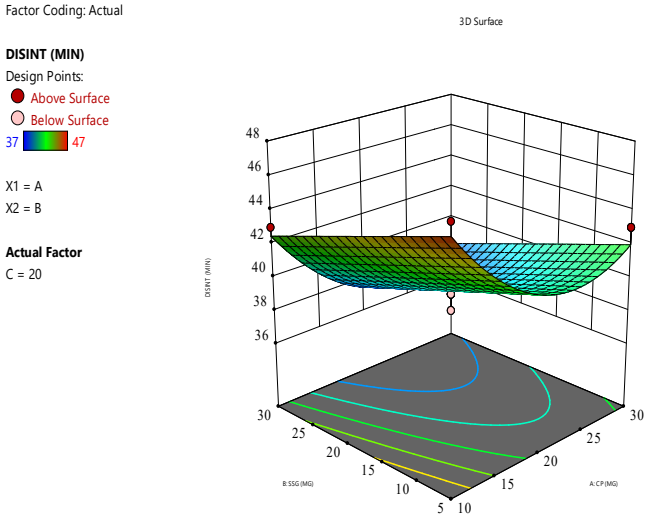

Figure 6. 3D response surface plots for*In-vitro* disintegration time

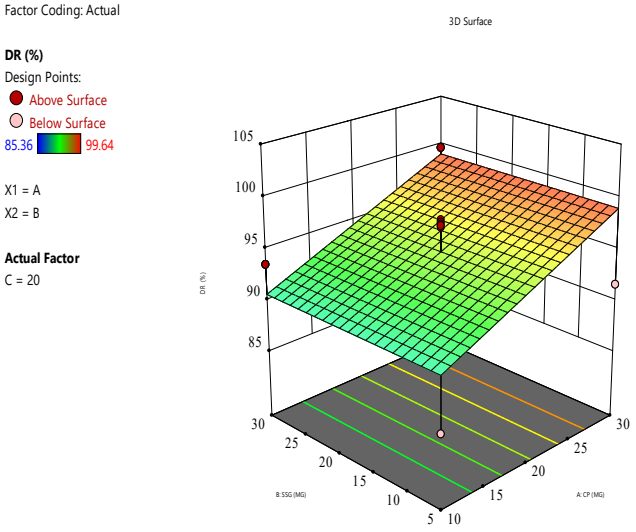

Figure 7. 3D response surface plots for*In-vitro* drug release

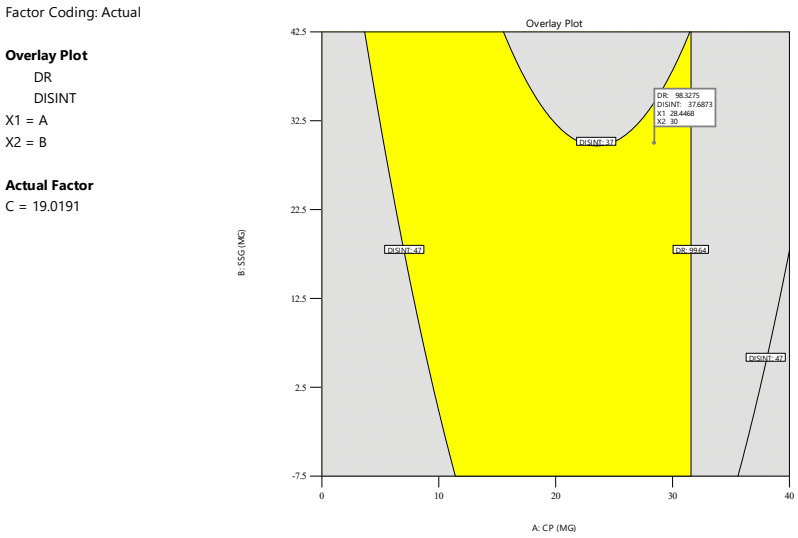

Figure 8 Overlay plot of optimized formulation of Promethazine theoclate ODT

Table 6. Resultof stability studies

STORAGE CONDITION	SAMPLING INTERVAL	HARDNESS (kg/cm^2)	FRIABILITY (%)	DRUG CONTENT (%)	*IN-VITRO* DRUG RELEASE (%)	*IN-VITRO* DISINTEGRATION TIME (sec)
40˚C ±2˚C at 75%±5% RH	Initial Study	4.4±0.13	0.56±0.013	99.86± 0.72	99.89±0.21	30±0.04
	30 days	4.4±0.23	0.56±0.02	99.57± 0.031	97.9±0.112	30±0.113
	90 days	4.4±0.39	0.561±0.01	99.25± 0.091	96.89±0.21	30±0.214
25˚C ±2˚C at 60%±5% RH	Initial Study	4.4±0.42	0.56±0.025	99.65± 0.061	99.32±0.31	30±0.313
	30 days	4.4±0.17	0.56±0.015	99.43± 0.11	99.21±0.01	31±0.15
	90 days	4.4±0.25	0.56±0.017	98.63± 0.15	98.1±0.37	31±0.12
5˚C ±3˚C	Initial Study	4.4±0.21	0.56±0.013	99.31± 0.15	99.1±0.13	30±0.34
	30 days	4.4±0.14	0.56±0.054	99.36± 0.15	98.4±0.161	31±0.21
	90 days	4.4±0.11	0.562±0.16	98.42±0.15	97.3±0.161	31±0.12

All values expressed as mean of ± SD, n = 3

Figure 9. Optimized formulation (F8)

Stability studies: The optimized formulation was subjected for stability studies as per ICH Guidelines 3 months. It showed that the prepared tablets passed stability studies with not much significant changes in hardness, friability, drug content, *in-vitro* drug release*, in-vitro* disintegration time.The results of stability data were shown in Table 6.

CONCLUSION

The present study focused on developing orally disintegrating tablets (ODTs) of promethazine theoclate to overcome the limitations of its poor aqueous solubility and low oral bioavailability. Seventeen formulations were designed using sodium starch glycolate, croscarmellose sodium and crospovidone as super disintegrants either individually or in combination. Among the developed batches, formulation F8 was identified as the optimized formulation, demonstrating a disintegration time of just 30 seconds and an in vitro drug release of 99.89%. The study demonstrates that orally disintegrating tablets of promethazine theoclate, formulated with an optimized combination of sodium starch glycolate, croscarmellose sodium, and crospovidone, achieve rapid disintegration and enhanced drug release. These improvements suggest a potential increase in oral bioavailability and faster therapeutic action compared to conventional tablets. The formulation is particularly useful for patients who require quick relief from nausea, vomiting, or allergic symptoms and for those who experience difficulty in swallowing. In addition to its clinical advantages the method of preparation is straightforward, stable and suitable for scale-up making it a practical and patient-friendly alternative to existing solid dosage forms.

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REFERENCES

Abdelbary G et al. *The preparation of orally disintegrating tablets using a hydrophilic waxy binder. International Journal of Pharmaceutics*. 278; 2004: 423–433. DOI:10.1016/S0378-5173(04)00209-1

Abed etal.*Formulation and Optimization of Orodispersible Tablets of Diazepam. AAPS PharmSciTech.* 11(1); 2010: 356–361. DOI:10.1208/s12249-010-9387-y

Aguilar-Díaz JE et al. Predicting orally disintegrating tablets formulations of ibuprophen tablets: An application of the new SeDeM-ODT expert system. European Journal of Pharmaceutics and Biopharmaceutics. 80; 2012: 638–648. DOI:10.1016/ j.ejpb.2011.12.012

Chandrasekhar R et al. *The role of formulation excipients in the development of lyophilized fast-disintegrating tablets. European Journal of Pharmaceutics and Biopharmaceutics.* 72; 2009: 119–129. DOI:10.1016/j.ejpb.2008.11.011

Davesh S Jire et al *Mouth DissolvingTablet : A Novel Drug Deliverys,Asian Journal of Pharmaceutical Research 2021:*11(3), 101-107.`DOI: 10.52711/2231-5691.2021.00033

Gorman EA et al.*An evaluation of croscarmellose as a tablet disintegrant in direct compression systems. Drug Dev Ind Pharm*2011; 8(4): 397–410.DOI:10.3109/03639048209022108

Gupta M et al. *Mouth dissolving tablets: a review.Journal of Drug Delivery and Therapeutics,* 2013; 3(2):207-214. DOI: 10.52711/ 0975-4377.2025.00015

Ibrahim et al. *Valsartan Orodispersible Tablets: Formulation, in vitro in vivoCharacterization. AAPS Pharm Sci Tech*. 11(1); 2010: 189-196.DOI:10.1208/s12249-009-9354-7

Keny RV et al. *Formulation and evaluation of Rizatriptan benzoate Mouth dissolving tablets. Indian J.Pharm.Sci*. 72(1); 2010: 79-85. DOI: 10.4103/0250-474X.62253.

Khan S et al: *Taste masking of ondansetron hydrochloride by polymer carrier system and formulation of rapid disintegrating tablets. AAPS Pharm Sci Tech* 2007; 8(2)DOI: 10.1208/pt0802046

Khan S et al. *Taste Masking of Ondansetron Hydrochloride by Polymer Carrier System and Formulation of Rapid-Disintegrating Tablets. AAPS PharmSciTech*. 8 (2); 2007: E1–E7.DOI:10.1208/pt0802046

Kuchekar BS et al: *Mouth dissolve tablets of salbutamol sulphate: a novel drug delivery system. Indian Drugs* 2004; 41(10): 592 598.DOI10.52711/2231-5691.2021.00033.

Kuno Y et al. *Evaluation of rapidly disintegrating tablets manufactured by phase transition of sugar alcohols. J. Control Release* 2005; 105: 16-22.DOI:10.1016/j.jconrel.2005.01.018

Late SG, et al. *Effect of disintegration promoting agent, lubricants and moisture treatment on optimized fast disintegrating tablets. Int. J Pharm* 2008; 365: 4-11.DOI:10.1016/j.ijpharm.2008.08.010

Mahmoud Mahyoub et al. *Formulation and Evaluation of Rivaroxaban Orodispersible tablet, World Journal of Pharmacy and Pharmaceutical sciences* 2024;13(2);2066-2092 DOI10.20959/wjpps20242-26698

Masareddy et al. *Development of mouth dissolving tablets of Clozapine using two different techniques. Indian J.Pharm.Sci.* 70(4); 2008: 526-528.DOI: 10.4103/0250-474X.44611

Mohanachandran. P.R et al.*Formulation and evaluation of mouth dispersible tablets of amlodipine, Asian Journal of Pharmaceutical Research Vol 11, Issue* 3, 2021. DOI: 10.52711/2231-5691.2021.00033

Mutasem M et al. *Fast-disintegrating Sublingual Tablets: Effect of Epinephrine Load onTabletCharacteristics. AAPS Pharm Sci Tech*.7 (2); 2006: 1 – 7.DOI:10.1208/pt070241

Pabari et al. *Disintegration mechanism on Wetting, water absorption, and Disintegration time of Orodispersible tablets. Journal of Young Pharmacists*. 4; 2012: 157-163.DOI:10.4103/0975-1483. 100021

Shabana Parveen et al. *Revolutionary Advancements in Fast Dissolving Tablets: An In-Depth Exploration Int. J. in Pharm. Sci.,* 2023, *Vol 1, Issue* 9, 427-446.DOI: 10.5281/zenodo.8381942

Shah et al. *Formulation and evaluation of microsphere based Orodispersible tablets of Itopride Hcl. DARU Journal of Pharmaceutical Sciences*. 2012: 20-24.DOI:10.1186/2008-2231-20-24

Shailendra Kumar Singh et al. *Fast disintegrating combination tablets of omeprazole and domperidone. Asian Journal of Pharmaceutical and Clinical research Vol*.2 *issue 3, September* 2009, 1-9. DOI 10.52711/2231-5691.2021.00033

Sharma S et al. *Optimization of promethazine theoclate fast dissolving tablet using pore forming technology by 3-factor, 3-level response surface-full factorial design. Arch Pharm Res*. 2010 Aug;33(8):1199. DOI:10.1007/s12272-010-0810-4.

Shojaei A etal. *Buccal mucosa as a route for systemic drug delivery: a review. J Pharm. Pharmaceut. Sci.* 1 1998, 1: 15–30.DOI:10.1007/978-3-030-51519-5_12-1

Shukla D et al. *Mouth Dissolving Tablets II: An Overview of Evaluation Techniques. Sci Pharm.* 77; 2009: 327–341. DOI:10.3797/scipharm.0811-09-02

Sudarshan Singh et al. *Development and Characterization of Mouth Dissolving Tablet of Zolmitriptan. Asian Pacific Journal of Tropical Disease*. 2012: S457-S464.DOI:10.1016/S2222-1808 (12)60203-5

Sujit Shinde et al. *Formulation and Evaluation of Fast Dissolving Sodium Diclofenac Sodium Tablet Int. J. of Pharm. Sci*., 2024, *Vol* 2, *Issue* 5, 1761-1774.DOI: 10.5281/zenodo.11400826

Van Schaick EA et al. *Pharmacokinetic Comparison of Fast-Disintegrating and Conventional Tablet Formulations of Risperidone in Healthy Volunteers. Clinical Therapeutics. 25(6); 2003: 1687-1699*.DOI: 10.4103/0250-474X.44611.

Vijay Sharmaetal *Modified Polysaccharides as Fast Disintegrating Excipients for Orodispersible Tablets of Roxithromycin. AAPS PharmSci Tech*. 9(1); 2008: 87–94.DOI: 10.1208/s12249-007-9026-4

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