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Research Article

FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF PROCHLORPERAZINE MALEATE USING NATURAL SUPERDISINTEGRANTS

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ABSTRACT

The present study was aimed at formulation and evaluation of mouth dissolving tablets (MDTs) of Prochlorperazine maleate using natural superdisintegrants. Mouth dissolving tablets have gained significant importance due to improved patient compliance, particularly in pediatric, geriatric, and dysphagic patients. Prochlorperazine maleate, a phenothiazine antipsychotic used in the management of nausea, vomiting, and migraine, requires rapid onset of action. MDTs were prepared by direct compression method using dehydrated banana powder, karaya gum, and locust bean gum in different concentrations. A total of thirteen formulations were prepared and evaluated for precompression parameters, weight variation, hardness, thickness, friability, content uniformity, disintegration time, and in vitro drug release. Compatibility studies were performed using FTIR analysis. Dissolution studies were carried out in pH 6.8 phosphate buffer. Among all formulations, F7 was selected as the optimized formulation, showing disintegration time of 16 ± 1.42 seconds and drug release of 98.9% within 10 minutes. Stability studies conducted as per ICH guidelines showed no significant changes. The study concludes that natural superdisintegrants can effectively enhance dissolution and reduce disintegration time of Prochlorperazine maleate MDTs.

Keywords: Mouth dissolving tablets, Prochlorperazine maleate, Natural superdisintegrants, Karaya gum, FTIR.

INTRODUCTION

Drug delivery systems are designed to deliver therapeutic agents to the desired site of action with improved safety and efficacy. Oral administration remains the most preferred route due to convenience and patient acceptance. However, dysphagia is a common problem among pediatric and geriatric populations, affecting nearly 50% of patients (Biradar *et al*., 2002). This limitation has led to the development of mouth dissolving tablets (MD Ts), which disintegrate rapidly in saliva without the need for water (Kuchekar *et al*., 2003). According to USFDA, orally disintegrating tablets are solid dosage forms that disintegrate rapidly when placed on the tongue. MDTs provide advantages such as rapid onset of action, improved bioavailability through pre-gastric absorption, and enhanced patient compliance (Seager, 1998; Lingren *et al*., 2011). Taste masking and mechanical strength remain major formulation challenges (Abd Elbary *et al*., 2015). Several formulation techniques such as freeze drying, sublimation, spray drying, and direct compression have been reported (Chang *et al*., 2000; Fu *et al*., 2004). Among these, direct compression is widely preferred due to simplicity and cost-effectiveness. Prochlorperazine maleate is a dopamine D2 receptor antagonist belonging to the phenothiazine class. It is widely used as an antiemetic and antipsychotic agent with 15% oral bioavailability and 4-8 hours half-life. Rapid disintegration of this drug can improve therapeutic effectiveness. Recent studies highlight the growing importance of natural superdisintegrants such as plantago ovata, karaya gum, and locust bean gum due to biocompatibility and cost effectiveness (Reddy *et al*., 2013; Mohammad Ali Shahtalebi *et al*., 2015; Bhavana Tambe *et al*., 2018). Therefore, the present study aimed to formulate MDTs of Prochlorperazine maleate using natural superdisintegrants and evaluate their performance.

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MATERIALS AND METHODS

Materials

Prochlorperazine maleate was obtained from Yarrow Chem Products, Mumbai. Dehydrated banana powder, karaya gum, locust bean gum, mannitol, aspartame, magnesium stearate, and talc were procured from SD Fine Chem Pvt. Ltd., Mumbai.

Drug–Excipient Compatibility Study

FTIR analysis was performed using Shimadzu 8400S spectrophotometer. KBr pellet method was employed, and spectra were recorded from 4000–500 cm^{-1}.

Analytical Method

Standard curve of Prochlorperazine maleate was prepared in pH 6.8 phosphate buffer. Absorbance was measured at 220 nm using UV-Visible spectrophotometer.

Preparation of Mouth Dissolving Tablets

All ingredients were passed through sieve no. 60. Tablets were prepared by direct compression method using different concentrations of natural superdisintegrants. Powder blends were mixed uniformly and compressed using tablet compression machine.

Precompression Evaluation

Angle of repose, Bulk density, Tapped density, Carr's index, Hausner's ratio.

Post-Compression Evaluation

Weight variation, Hardness (Monsanto hardness tester), Thickness (Vernier caliper), Friability (Roche friabilator), Content uniformity, Disintegration time, In vitro drug release (USP paddle apparatus in pH 6.8 buffer).

Stability Study

Optimized formulation was subjected to accelerated stability studies as per ICH guidelines for 3 months.

RESULTS AND DISCUSSION

By capillary method drug melting point identified.

Table 1. Observed melting points.

Trials	Observed melting point ^0C	Reference melting
1	190	
2	190.5	190-203^oC
3	190	

By FTIR analysis drug and excipient interaction can be identified Kbr pellets were prepared to hold the drug sample. The resultant spectrum was compared with the reference spectrum.

Table 2. FTIR interpretation data of Prochlorperazine maleate.

S.No	Type of stretching	Wave Number as per IP standards (cm^1)	Observed Wave Number (cm^{-1})
1	C-Cl stretching	760-540	755.40
2	N-CH_3 of Secondary Amine	3060-3040	3008.53
3	O-H Alcoholic	3650-3590	3647.20
4	C-N stretching	1360-1310	1357.16

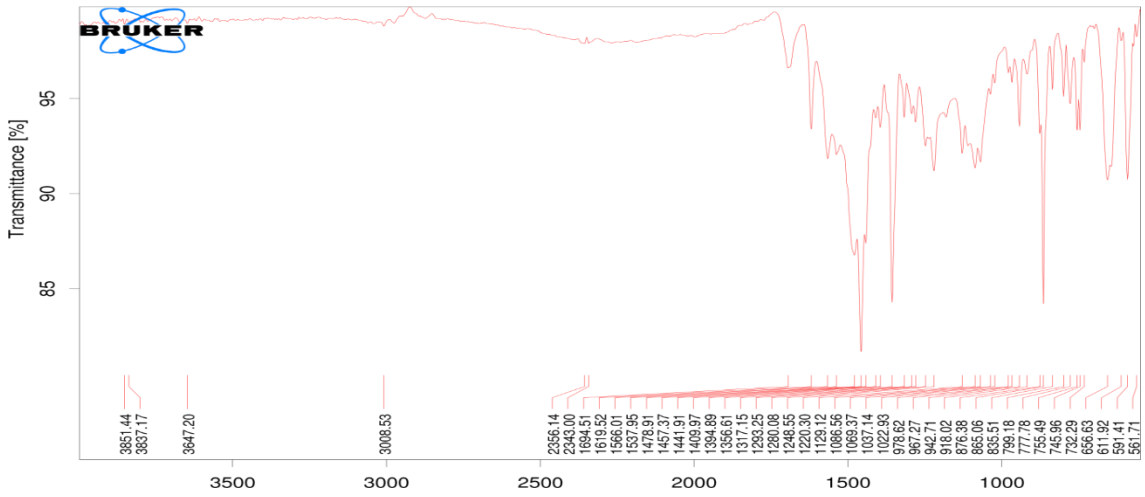

Figure 1. FTIR spectrum of Prochlorperazine maleate.

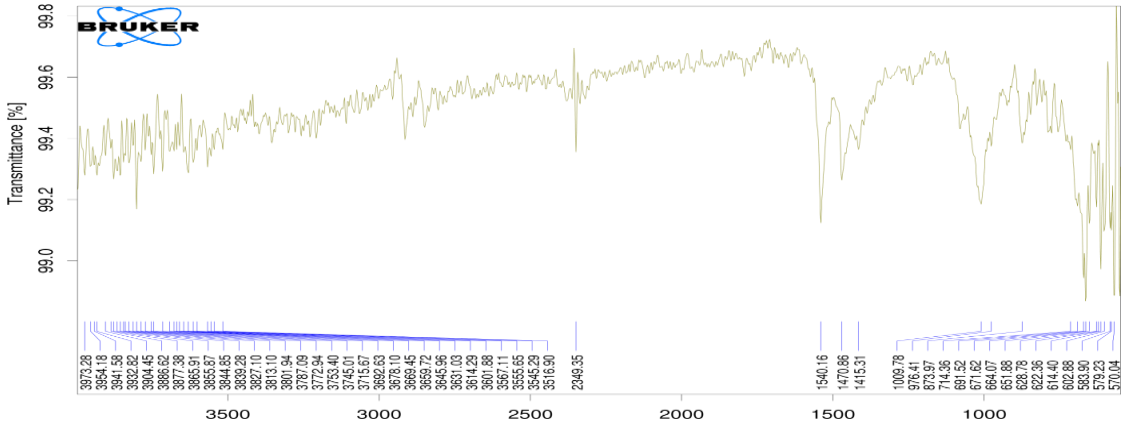

Figure 2. FTIR Prochlorperazine maleate + Dehydrated banana powder.

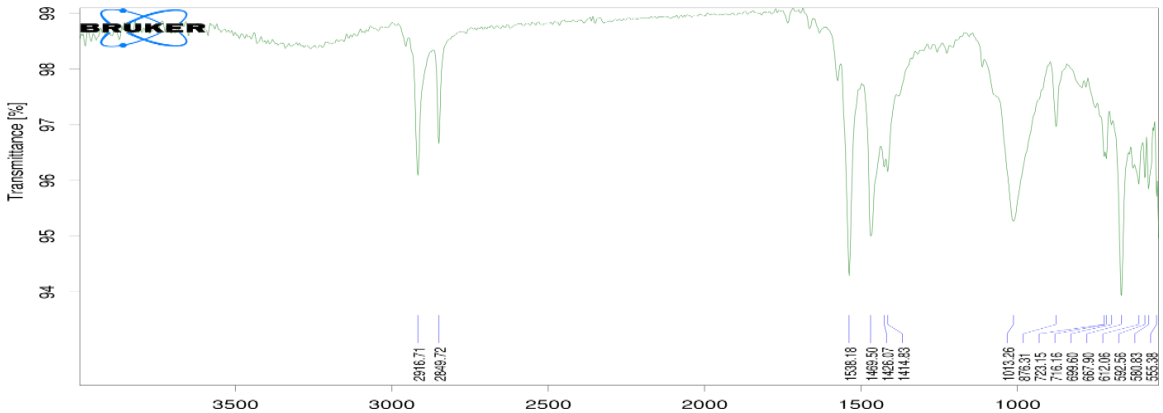

Figure 3. FTIR spectrum of Prochlorperazine maleate + Karaya powder.

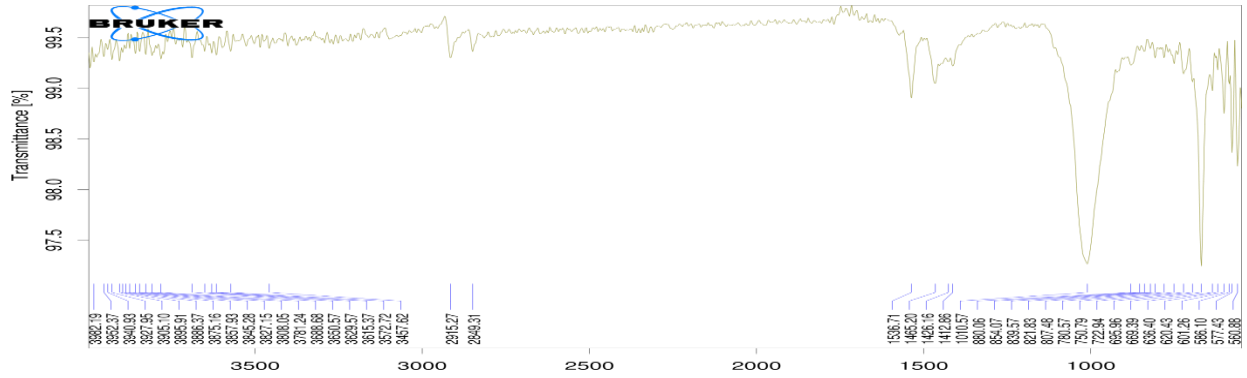

Figure 4. FTIR spectrum of Prochlorperazine maleate + Locust bean powder.

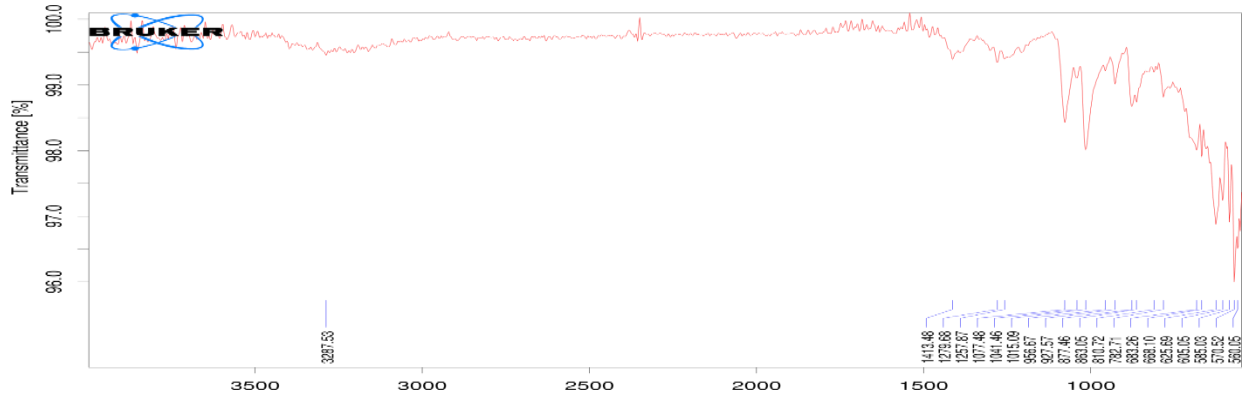

Figure 5. FTIR spectrum of Mannitol.

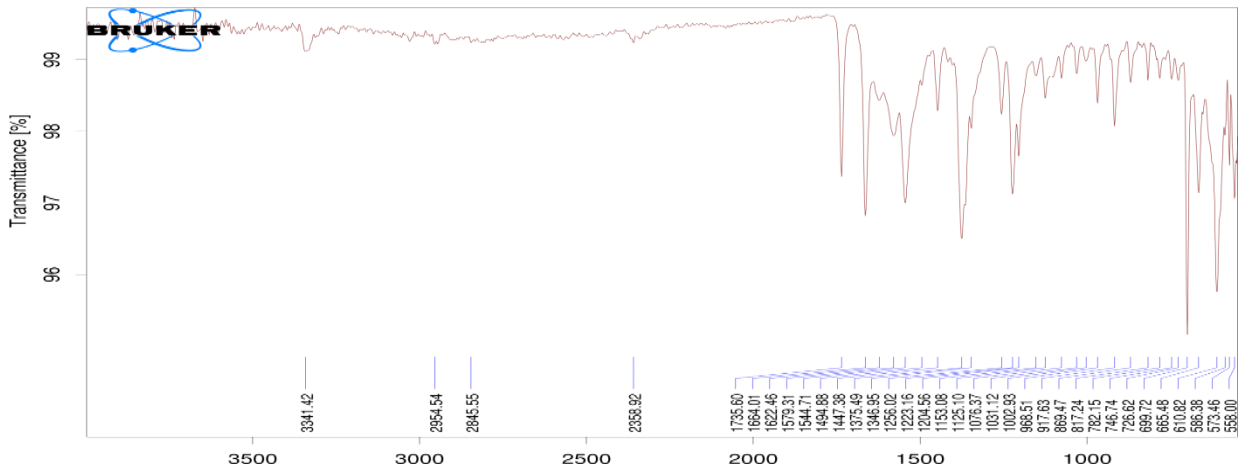

Figure 6. FTIR spectrum of Aspartame.

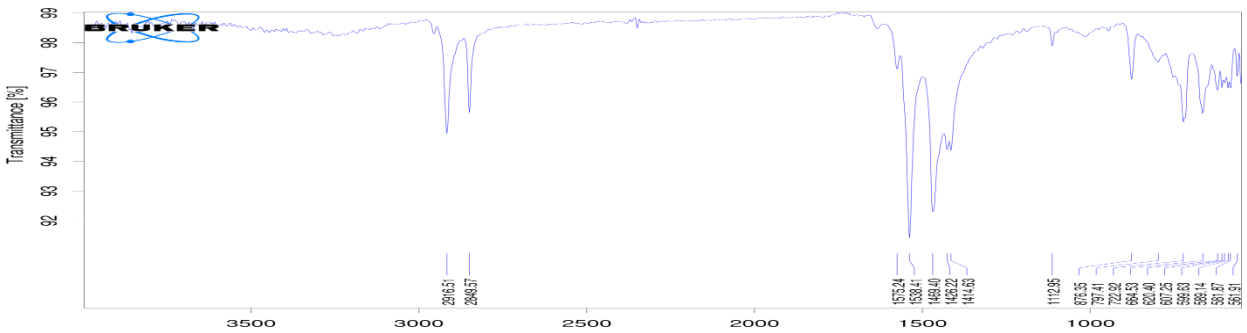

Figure 7. FTIR spectrum of Magnesium stearate.

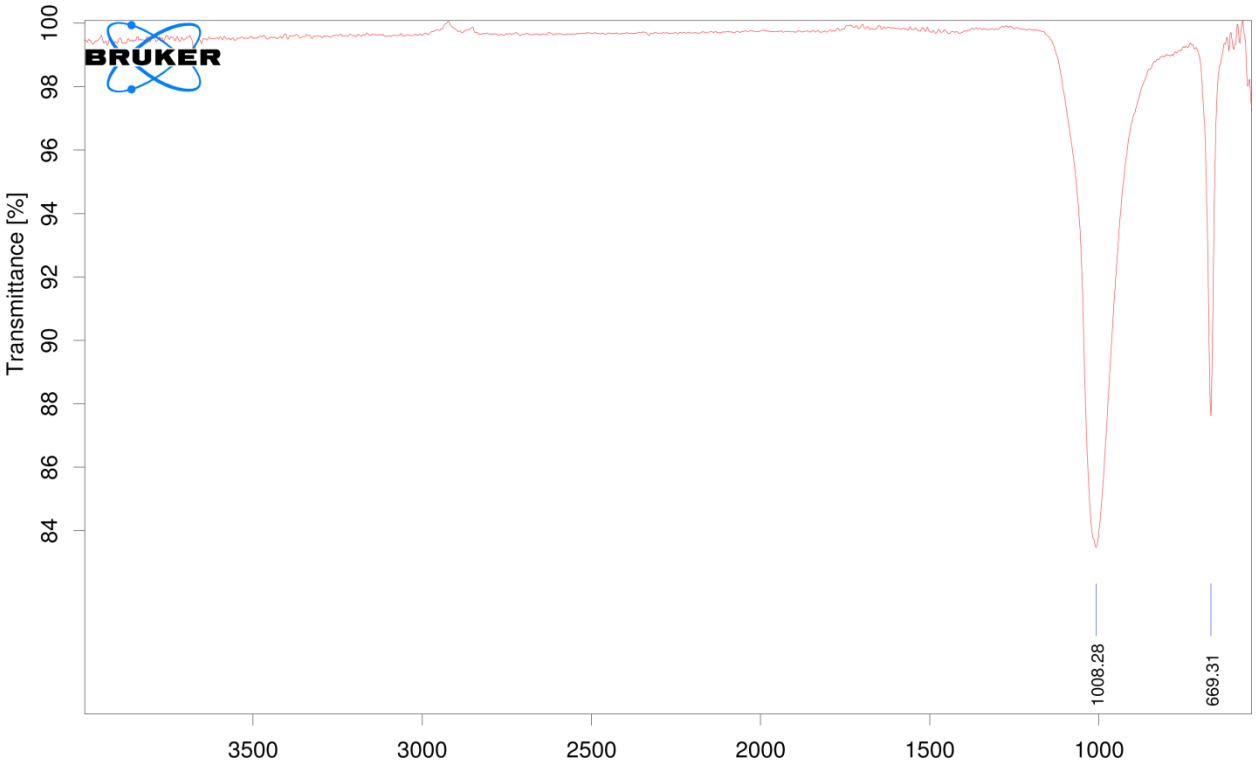

Figure 8. FTIR spectrum of Talc.

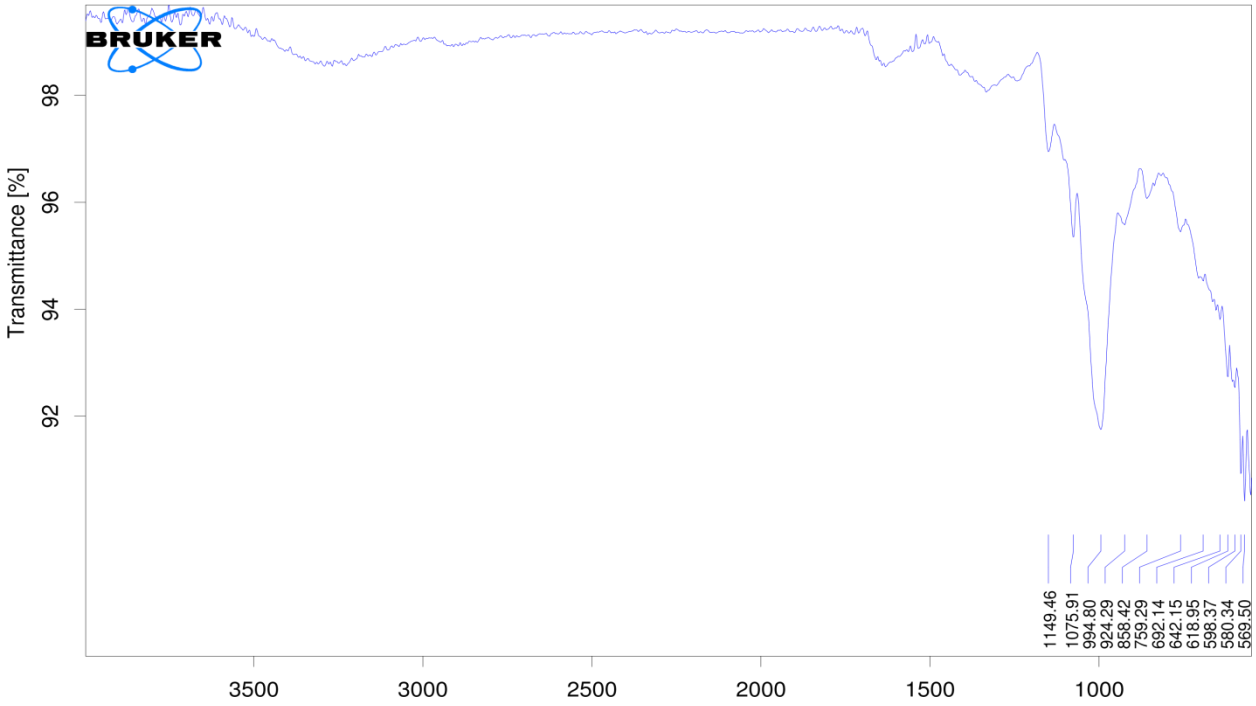

Figure 9. FTIR spectrum of dehydrated banana powder.

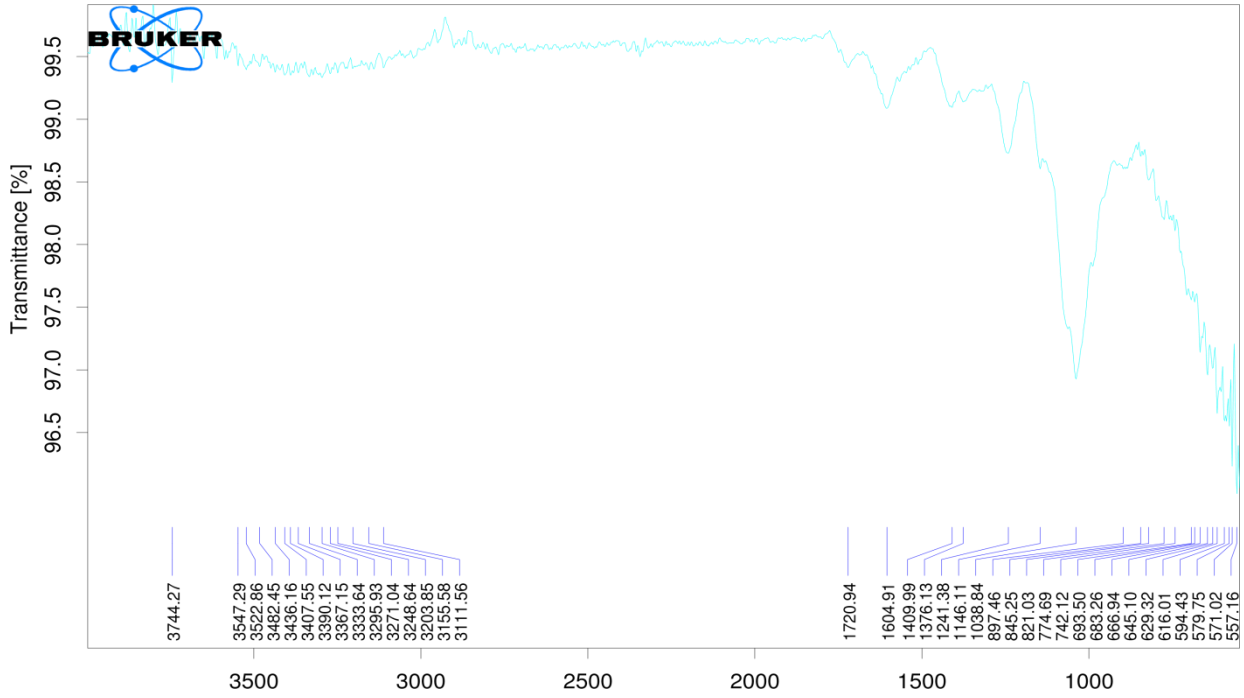

Figure 10. FTIR spectrum of Karaya powder.

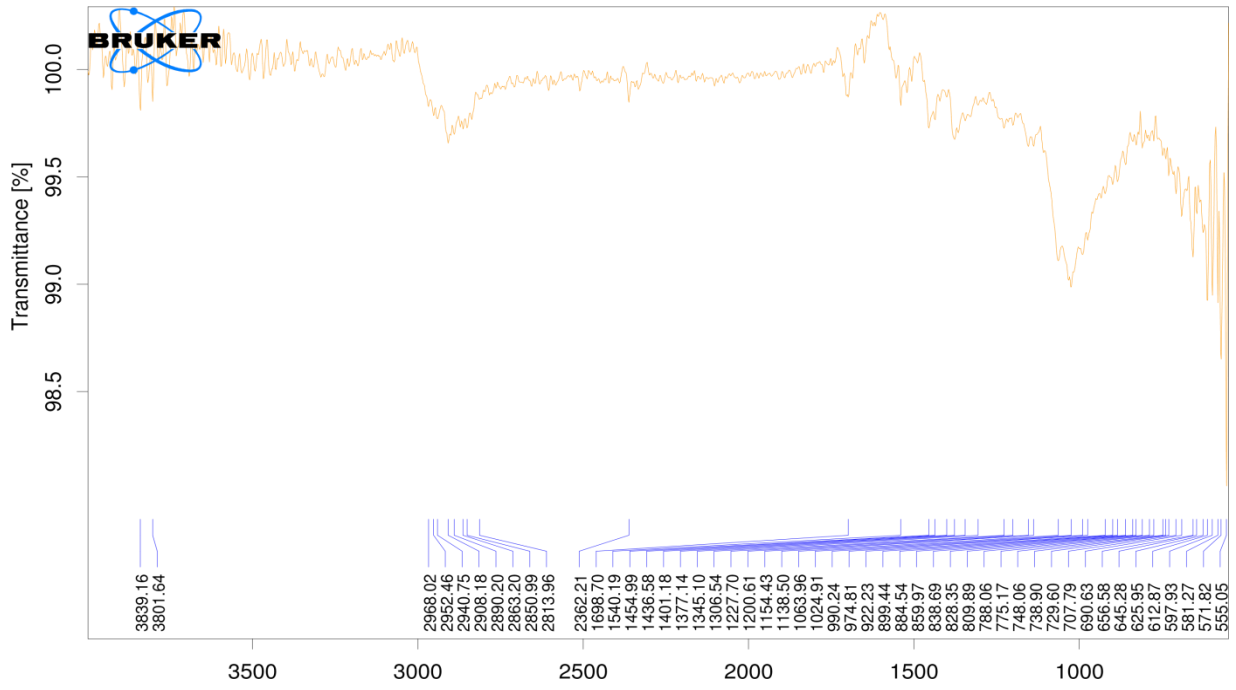

Figure 11. FTIR spectrum of Locust bean powder.

Table 3. FTIR interpretation dataof Optimized Formulation.

S.No	Type of stretching	Wave Number as per IP standards (cm^1)	Observed Wave Number (cm^{-1})
1	C-Cl stretching	2972-2913	2916.72
2	N-CH_3 of Secondary Amine	2855-2765	2849.2
3	CH_3 stretching	760-540	716.6

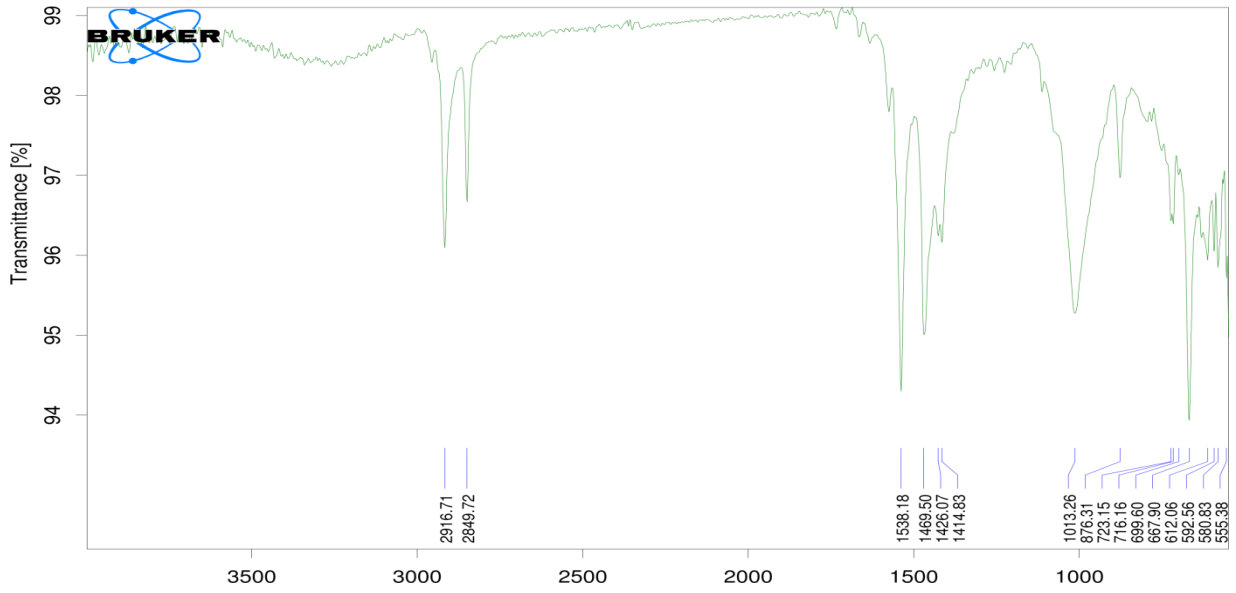

Figure 12. FTIR spectrum of optimized formula.

Standard solutions in the range of 2 to14 mcg/ml were prepared and absorption values were recorded at 220nm against the reference. From this data, the standard curve of Prochlorperazine maleate was obtained by plotting absorbance on Y-axis against concentration on X-axis.

Table 4. Standard curve values of 6.8 Phosphate buffer.

S.No	Concentration (µg/ml)	Absorbance(nm)
1	0	0
2	10	0.595±0.015
3	12	0.595±0.049
4	14	0.699±0.045
5	16	0.799±0.048
6	18	0.898±0.039
7	20	0.999±0.048

All the values are represented as Mean ± SD (n=3)

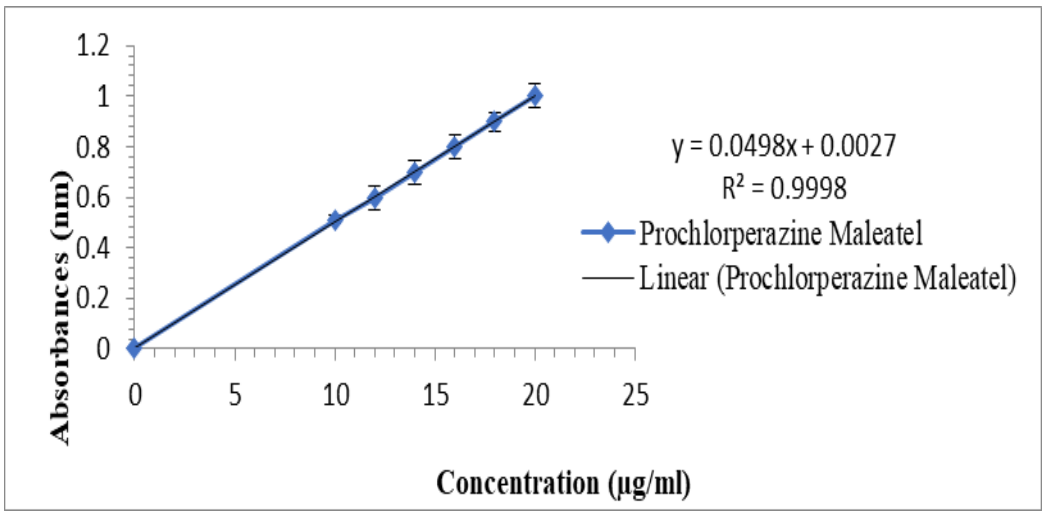

Figure 13. Standard curve of Prochlorperazine maleate.

Table 5. Precompression evaluation tests.

Formulations	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Angle of repose(θ)	Carr's Index (%)	*Hauser's* ratio
F1	0.52±0.007	0.63±0.01	23.47 ± 1.56	11±1	1.15±0.03
F2	0.53±0.007	0.63±0.01	24.12 ± 1.20	11±1.53	1.18±0.04
F3	0.53±0.007	0.64±0.02	22.36± 1.70	12±1.20	1.15±0.03
F4	0.55±0.007	0.65±0.01	23.38 ± 0.88	11±2.51	1.18±0.03
F5	0.50±0.007	0.63±0.01	24.17 ± 1.48	12±1.58	1.14±0.03
F6	0.52±0.007	0.63±0.02	25.38 ± 1.22	11±1.55	1.18±0.04
F7	0.51±0.007	0.58±0.38	20.41± 1.32	11±1.39	1.11±0.04

F8	0.54±0.007	0.65±0.02	25.37± 1.34	12±2.20	1.15±0.03
F9	0.52±0.007	0.62±0.01	24.18± 1.26	11±2.01	1.18±0.03
F10	0.55±0.007	0.65±0.01	24.57 ± 1.20	12±2.12	1.12±0.03
F11	0.54±0.007	0.64±0.02	23.58 ± 1.26	11±1.51	1.15±0.03
F12	0.52±0.007	0.63±0.02	24.63 ± 1.20	11±1.39	1.18±0.03
F13	0.51±0.66	0.64±0.13	23.62±1.35	12±1.18	1.17±0.15

All the values are represented as Mean ± SD (n=3)

Physical appearance: tablets were white in colour with good texture. Plane on one side and debossed on other side, pores are present in the tablet. Weight variation, Hardness, Thickness, Friability, Disintegration time, Content uniformity, *In-vitro* drug release studies These above parameters are presented below the table.

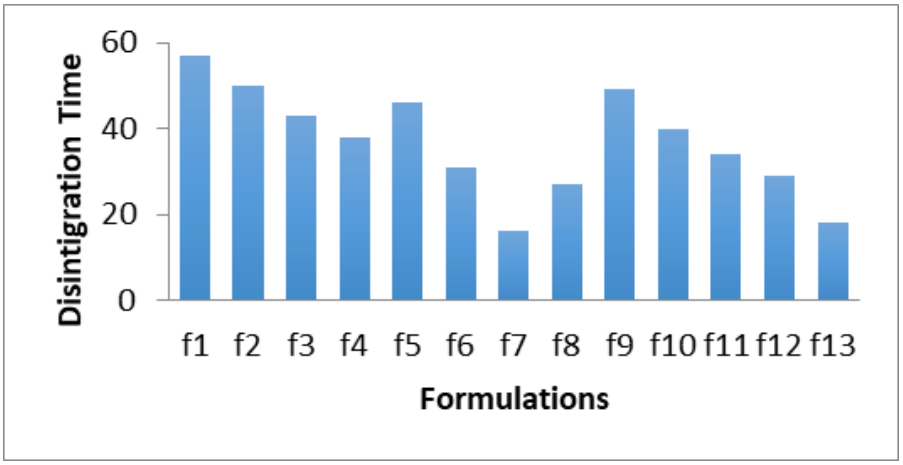

Figure 14. Disintegration time of different formulation (f1-f13).

Table 6. Post compression evaluation tests.

F.No.	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Content Uniformity (%)	98.02±0.61	98.47 ±0.45	97.47±0.21	98.64±0.14	98.1± 0.215	98.73 ±0.21	98.91±0.43	98.37±0.13	98.56 ±0.06	98.28 ±0.13	98.6± 0.347	97.8± 0..49	98.5± 0.51
Disintegration time* (Sec)	57±0.52	50±1.61	43± 1.35	38± 1.52	46±0.577	31±1.137	16±1.42	27±1.42	49±0.54	40±0.577	34±1.527	29±1.63	18±1.57
Friability (%)	0.65±0.03	0.66± 0.05	0.63 ±0.04	0.66 ±0.02	0.69± 0.06	0.65± 0.02	0.65 ±0.02	0.64 ±0.03	0.66± 0.01	0.64± 0.01	0.65± 0.06	0.63± 0.62	0.61± 0.37
Thickness (mm)	1.2±0.063	1.1±0.109	1.2± 0.05	1.2± 0.135	1.1±0.057	1.2±0.152	1.3± 0.045	1.1± 0.115	1.1±0.05	1.3±0.54	1.2±0.06	1.3±0.51	1.3±0.82
Hardness (kg/cm^2)	2.5 ±0.11	2.4 ±0.11	2.4± 0.10	2.6± 0.12	2.4±0.12	2.3±0.10	2.5± 0.15	2.3± 0.21	2.5±0.10	2.5±0.25	2.4±0.10	2.5±0.10	2.5±0.28
Weight variation (mg)	98±0.70	99±0.98	97± 0.84	98± 0.28	99±0.42	98±0.77	99±084	97±0.77	97±0.70	98±0.84	98±0.77	97±0.32	99±0.58

All the values are represented as Mean ± SD (n=3), Weight variation (n=20) Friability (n=20) Disintegration time* (n=6)

Table 7. *Invitro* drug release studies of F1 to F13 formulations.

Formulations	1min	2min	3min	4min	6min	8min	10min
F1	32± 1.25	48±1.47	56±1.24	63±1.78	71±2.44	77±1.78	81±1.89
F2	34±1.24	46±1.11	52±1.78	61±1.78	72±1.44	79±1.26	84±1.25
F3	31±2.25	42±2.29	57±1.75	69±1.52	74±1.52	80±1.86	86±1.77
F4	38±1.52	49±1.16	62±1.25	70±1.19	78±1.27	82±1.28	89±1.58
F5	47±1.88	51±1.15	54±1.78	64±1.75	75±2.28	84±1.19	91±1.32
F6	41±1.88	46±1.15	50±1.78	61±1.75	70±2.28	88±1.19	95±1.32
F7	39±1.57	65±1.45	71±1.22	72±1.63	80±2.210	91±1.590	98.9±1.34
F8	32±1.36	48±1.27	56±1.46	68±1.96	79±1.77	86±1.52	94±1.49
F9	31±2.19	47±2.53	56±1.65	66±1.77	76±1.13	79±1.27	83±1.79
F10	38±1.69	44±1.37	48±1.62	59±1.73	73±1.28	81±1.68	86±1.35
F11	30±1.57	41±1.46	54±1.91	60±1.59	72±2.38	76±1.25	88±1.18
F12	33±1.57	42±1.16	55±1.65	61±1.38	73±2.65	89±1.38	93±1.28
F13	38±1.22	47±1.37	58±1.88	70±1.28	84±1.65	92±1.53	97.6±1.47

All the values All the values are represented as Mean ± SD (n=3)

Table 8. Comparison between F4, F7and, F10formulations.

Formulations	Time in mins Cumulative % drug release						
	1min	**2min**	**3min**	**4min**	**6min**	**8min**	**10min**
F4	38±1.52	49±1.16	62±1.25	70±1.19	78±1.27	82±1.28	89±1.58
F7	39±1.57	65±1.45	71±1.22	72±1.63	80±2.210	91±1.590	98.9±1.34
F10	38±1.69	44±1.37	48±1.62	59±1.73	73±1.28	81±1.68	86±1.35

All the values are represented as Mean ± SD (n=3)

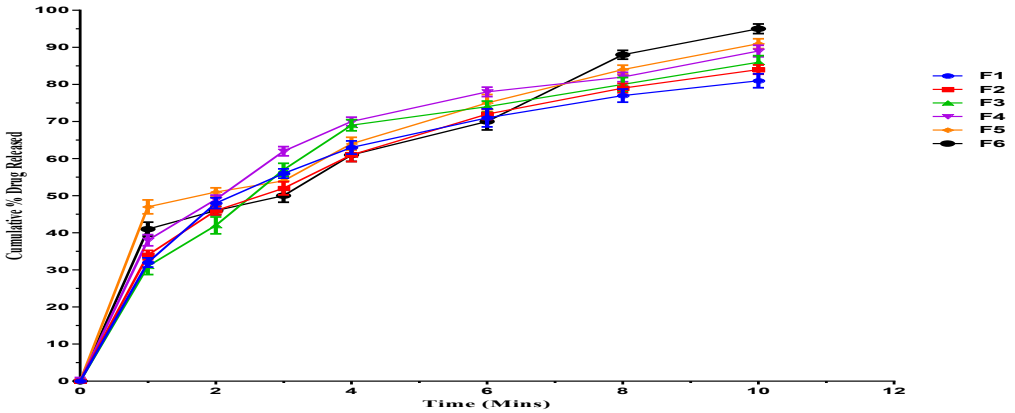

Figure 15. Comparison of %CDR to F1 to F6 formulations.

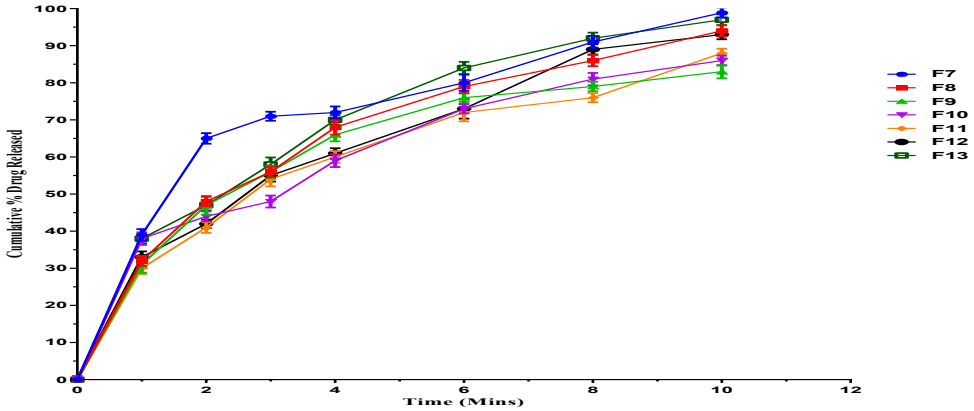

Figure 16. Comparison of %CDR to F7to F13 formulations.

Accelerated stability studies done by conditions 40^0C ± 75 % RH on optimized formulation

Table 9. Acceleratory stability studies.

Parameters	Time in months			
	0 (Initial)	**1st month**	**2nd month**	***3rd month***
Hardness (kg/cm²)	2.5±0.21	2.5±0.20	2.5±0.18	2.5±0.11
Friability (%)	0.64±0.031	0.64±0.029	0.64±0.029	0.64±0.028
Thickness(mm)	1.3±0.45	1.3±0.52	1.3±0.52	1.3±0.52
Disintegration time(secs)	16±0.577	16±0.564	16±0.559	16±0.580
Drug content (%)	99.28±0.13	99.28±0.09	99.28±0.05	99.28±0.01
***In-vitro* drug release (%)**	98.9±0.064	98.9±0.061	98.9±0.058	98.9±0.056

All the values are represented as Mean ± SD (n=3)

The melting point of Prochlorperazine maleate was found to be 190°C, confirming drug authenticity. FTIR studies indicated no interaction between drug and excipients. Precompression parameters showed good flow properties (angle of repose <30°, Carr's index ~11–12%), indicating suitability for direct compression. Post-compression evaluation showed tablets met pharmacopeial limits. Friability was below 1%, indicating good mechanical strength. Content uniformity ranged from 97–99%. Disintegration time varied among formulations. F7 showed rapid disintegration (16 seconds) due to higher concentration of karaya gum. In vitro dissolution studies revealed 98.9% drug release within 10 minutes for F7. Accelerated stability studies confirmed no significant changes in optimized formulation.

CONCLUSION

The present study successfully formulated mouth dissolving tablets of Prochlorperazine maleate using natural superdisintegrants. All formulations complied with pharmacopeial standards. Among them, F7 was identified as the optimized formulation based on rapid disintegration (16 sec) and 98.9% drug release within 10 minutes. The study demonstrates that natural superdisintegrants like karaya gum effectively enhance disintegration and dissolution. The formulation was stable under accelerated conditions. Thus, MDTs of Prochlorperazine maleate prepared by direct compression offer improved bioavailability, rapid onset of action, and enhanced patient compliance.

ACKNOWLEDGMENT

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

FUNDING

This study received no specific funding from public, commercial, or not-for-profit funding agencies.

AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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