



International Journal of Preclinical & Pharmaceutical Research

Journal homepage: www.preclinicaljournal.com

FORMULATION AND EVALUATION OF CALCIUM CARBONATE CHEWABLE TABLETS

Asha Jyothi P^{1*}, Soundharya P², Sravanthi D², Vasavi P², Vijay kushal B²

¹Assistant Professor, Department of Pharmaceutics, KLR Pharmacy College, Palwancha, Telangana 507115, India.

²KLR Pharmacy College, Palwancha, Telangana 507115, India

ABSTRACT

Background: Calcium carbonate is a widely used calcium supplement and antacid, but its large dose and chalky taste reduce patient acceptability of conventional tablets. Chewable tablets improve palatability and convenience. This study aimed to formulate and evaluate calcium carbonate chewable tablets by direct compression. Methods: Five formulations (F1-F5) were prepared with mannitol and sorbitol (sweeteners), PVP K-30 (binder), croscarmellose sodium (disintegrant), flavour and magnesium stearate. Preformulation (organoleptic, solubility, FTIR), blend micromeritics, tablet quality, dissolution and stability were assessed. Results: Calcium carbonate was insoluble in water but soluble in acid, supporting gastric dissolution; FTIR confirmed compatibility. Blends flowed acceptably (Carr's index 19-25%). Tablets had hardness 4.0-4.4 kg, friability <1.1%, disintegration 3.3-4.2 min and drug content 98.7-99.8%. Dissolution exceeded 80% at 30 min, and the formulation was stable under accelerated and long-term conditions. Conclusion: Palatable, stable calcium carbonate chewable tablets meeting quality standards were successfully formulated, providing a patient-friendly option for calcium supplementation.

Keywords: Calcium carbonate; chewable tablet; direct compression; palatability; calcium supplementation.

INTRODUCTION

Adequate calcium intake is essential for bone health, and calcium supplementation is widely recommended for the prevention and management of deficiency states such as osteoporosis. Calcium carbonate is the most common supplemental salt because of its high elemental-calcium content and low cost. However, the large doses required and the gritty, chalky mouthfeel of conventional tablets can reduce adherence, particularly in elderly patients who require long-term supplementation.

Chewable tablets address these limitations by allowing the tablet to be comminuted in the mouth before swallowing, improving palatability, easing administration for those who dislike swallowing large tablets, and promoting disintegration and dissolution. The success of a chewable formulation depends on taste-

masking sweeteners and flavours, on a pleasant texture, and on maintaining acceptable mechanical strength and rapid disintegration.

The present study aimed to develop calcium carbonate chewable tablets by direct compression, using mannitol and sorbitol to impart sweetness and a smooth mouthfeel, croscarmellose sodium to aid disintegration, and PVP K-30 as binder, and to evaluate the preformulation, physicomachanical, dissolution and stability characteristics of the formulations against compendial requirements for chewable tablets.

MATERIALS AND METHODS

Materials and preparation

Calcium carbonate was the active ingredient. Five formulations (F1-F5) were prepared by direct compression using mannitol and sorbitol as sweeteners/diluents, PVP K-30 as binder, croscarmellose sodium as disintegrant, magnesium stearate as lubricant and a suitable flavour (Table 1).

Corresponding Author

Asha Jyothi P

Email: Pattaashajyothi8@gmail.com

Table 1: Composition of calcium carbonate chewable tablet formulations.

Ingredient (mg)	F1	F2	F3	F4	F5
Calcium carbonate	500	450	550	500	525
PVP K-30	30	25	35	40	30
Mannitol	100	120	100	90	110
Croscarmellose sodium	15	18	20	15	17
Sorbitol	100	110	90	95	100
Mg stearate / Flavour	15	15	18	17	20
Total weight	760	760	760	757	802

Evaluation

Preformulation comprised organoleptic examination, solubility testing and FTIR compatibility. Blends were characterised for bulk/tapped density, angle of repose, Carr's index and Hausner ratio. Tablets were evaluated for hardness, friability, disintegration time, drug content and weight variation, and dissolution was determined. Stability was assessed under accelerated (40 deg C/75% RH) and long-term (25 deg C/60% RH) conditions.

RESULTS

Preformulation and micromeritics

Calcium carbonate was a white, odourless powder, practically insoluble in water but readily soluble under acidic (gastric) conditions, which is advantageous because dissolution and calcium release occur in the stomach. FTIR confirmed the absence of drug-excipient incompatibility. Blends showed acceptable flow with Carr's index of 19-25% and Hausner ratio of 1.23-1.33 (Table 2).

Table 2: Micromeritic properties of the chewable tablet blends.

Formulation	Bulk density	Tapped density	Angle of repose (deg)	Carr's index (%)	Hausner ratio
F1	0.45	0.60	25.5	25	1.33
F2	0.48	0.62	24.0	22.5	1.29
F3	0.47	0.58	23.5	19	1.23
F4	0.46	0.59	26.0	22	1.28
F5	0.49	0.61	24.5	19.7	1.24

Tablet quality and dissolution

All tablets had hardness appropriate for chewable products (4.0-4.4 kg), friability below 1.1%, rapid disintegration (3.3-4.2 min) and uniform drug

content (98.7-99.8%) (Table 3, Figure 1). The disintegrant croscarmellose sodium promoted rapid breakdown, and dissolution exceeded 80% at 30 min, ensuring prompt calcium availability for absorption.

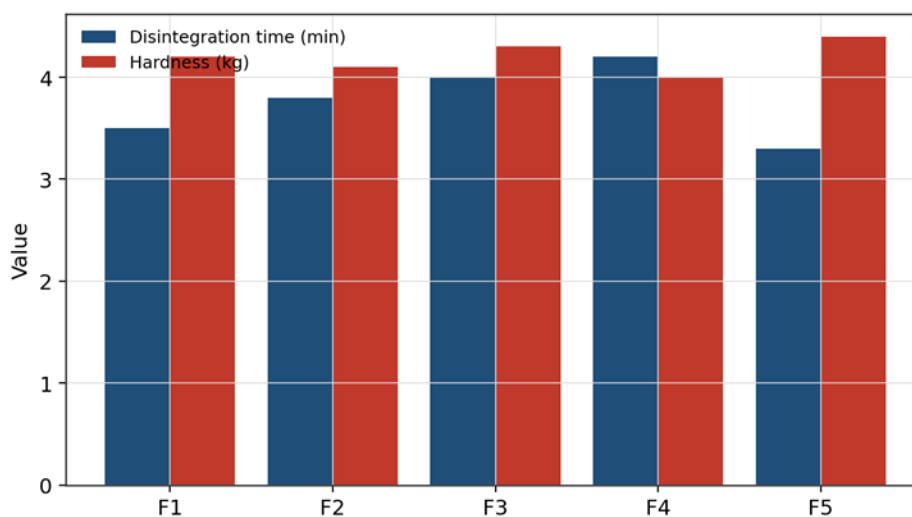
**Figure 1: Disintegration time and hardness of the calcium carbonate chewable tablet formulations.**

Table 3: Post-compression quality attributes of the chewable tablets.

Formulation	Hardness (kg)	Friability (%)	Disintegration time (min)	Drug content (%)
F1	4.2	0.8	3.5	99.5
F2	4.1	1.0	3.8	98.9
F3	4.3	0.9	4.0	99.7
F4	4.0	1.1	4.2	98.7
F5	4.4	0.7	3.3	99.8

Stability

Under both accelerated and long-term conditions the optimised formulation showed no significant change in appearance, drug content (99.2-

99.3%), dissolution (83-84% at 30 min), hardness, friability or disintegration time, all remaining within acceptance criteria (Table 4), indicating good physicochemical stability.

Table 4. Stability data for the optimised chewable tablet formulation.

Parameter	Initial	Accelerated (40C/75% RH)	Long-term (25C/60% RH)	Acceptance
Drug content	99.5%	99.2%	99.3%	90-110%
Dissolution (30 min)	85%	84%	83%	>80%
Hardness (kg)	4.0	3.9	3.8	3-6
Friability	0.5%	0.7%	0.6%	<1%
Disintegration (min)	3.0	3.2	3.1	<5

DISCUSSION

The preformulation results were consistent with a rational chewable design. The insolubility of calcium carbonate in water but ready solubility in acid confirms that dissolution and calcium liberation will occur in the gastric environment, which is the desired site of action for both supplementation and antacid effect. The intact FTIR fingerprint of the blends established excipient compatibility, a prerequisite for stability.

The micromeritic data showed acceptable flow for direct compression, and the resulting tablets met the specific quality expectations of chewable products: a moderate hardness that permits comfortable chewing yet resists handling damage, low friability, rapid disintegration and uniform content. The inclusion of croscarmellose sodium clearly facilitated the short disintegration times observed, while mannitol and sorbitol provided the sweetness and smooth mouthfeel necessary to mask the chalkiness of calcium carbonate.

Dissolution exceeding 80% within 30 min indicates that, once disintegrated, the formulation rapidly releases calcium for absorption. The stability data, with negligible change across accelerated and long-term storage, confirm that the formulation will retain its

quality and performance over its shelf life. Collectively these findings show that a palatable, stable and effective calcium carbonate chewable tablet can be produced by simple direct compression.

Limitations include the absence of formal sensory (taste-panel) evaluation and of in-vivo bioavailability assessment. Future work should include human palatability testing, comparison with marketed products and bioavailability confirmation.

CONCLUSION

Calcium carbonate chewable tablets were successfully formulated by direct compression. Preformulation confirmed acid-favourable solubility and excipient compatibility, blends flowed acceptably, and all tablets met chewable-tablet quality requirements for hardness, friability, disintegration, content uniformity and dissolution (>80% at 30 min). The formulations were stable under accelerated and long-term conditions. The developed chewable tablets provide a palatable, convenient and stable option for calcium supplementation, warranting sensory and in-vivo evaluation prior to scale-up.

REFERENCES

1. Bellini LF. Pharmacokinetics and pharmacodynamics: A biochemical perspective on drug absorption and efficacy. *International Journal of Advanced Biochemistry Research*. 8, 2024, 1146–1149.
2. Idkaidek NMY. Development of successfully physiologically-based pharmacokinetic (PBPK) models. *Jordan Journal of Pharmaceutical Sciences*. 16, 2023, 452.
3. Bereda G. What the body does to a drug: Pharmacokinetics. *Clinical and Experimental Medicine*. 1, 2022, 01–09.
4. Peters S. Applications of physiologically based pharmacokinetic models integrated with drug effect models (PBPK/PD). In: *Physiologically Based Pharmacokinetic (PBPK) Modeling*. 2021. pp. 353–374.

5. Y Q, S M, Z X. DataSheet1.DOCX. *Figshare*. 2022.
6. Upton RN, Hopkins AM, Abuhelwa AY, Hughes JH, Foster DJR. Physiologically based models: Techniques and applications to drug delivery. In: *Drug Delivery and Translational Research*. 2021. pp. 43–73.
7. Mager DE. Breadth of pharmacology modeling: Fundamentals of pharmacokinetics, pharmacodynamics, and mechanistic modeling. *Handbook of Experimental Pharmacology*. 289, 2025, 21–73.
8. S M, P B, F. Table1.DOCX. *Figshare*. 2022.
9. Miller NA, Reddy MB, Heikkinen AT, Lukacova V, Parrott N. Physiologically based pharmacokinetic modelling for first-in-human predictions: An updated model building strategy illustrated with challenging industry case studies. *Clinical Pharmacokinetics*. 58, 2019, 727–746.
10. Yuan Y, He Q, Zhang S, Li M, Tang Z, Zhu X. Application of physiologically based pharmacokinetic modeling in preclinical studies: A feasible strategy to practice the principles of 3Rs. *Frontiers in Pharmacology*. 13, 2022, 895556.