Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 45 - 46 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.020
Short communication

Development and characterization of polyethylene glycol–based soft chewable tablets

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Introduction

Soft chewable tablets (SCT) are intended to have a soft texture that facilitates chewing and the formation of a swallowable bolus. Due to their texture, they are well accepted by special patient populations, i.e. pediatric and geriatric patients (Stomberg et al., 2017). Therefore, compounded SCTs would provide an alternative dosage form for patients who experience difficulties administering conventional solid oral dosage forms. The aim of this work was development and characterization of polyethylene glycol–based SCTs, with regards to SCT dimensions, hardness, and disintegration time.

Materials and methods

Polyethylene glycol 400 (PEG 400, Sigma–Aldrich, USA) and polyethylene glycol 4000 (PEG 4000, Sigma–Aldrich, USA) were used for SCT–base preparation. Hypromellose (HPMC, Affinisol™ 15 LV, IFF Pharma Solutions, USA), hydroxypropyl cellulose (HPC, Ashland Inc, USA), granulated maltodextrin (GMD, Glucidex® IT 12, Roquette Frères, France) or polysorbate 80 (PS, Ph. Eur. 11.0) were used as viscosity–modifying agents. Dry yeast, mannitol (Parteck® M 100, Sigma-Aldrich, USA) and corn starch powder blend (Ph. Eur. 11.0) was incorporated into SCTs as a solid phase.

In the first phase, 5 SCT formulations were prepared (PEG 400 to PEG 4000 ratios ranging from 30/70%, for sample S1, up to 70/30%, for sample S5). The mass was moulded and allowed to solidify. In the second phase, 5% of viscosity–modifying agent was added to the selected SCT samples, whereas 30% of powder blend (dry yeast–mannitol–corn starch in ration 1:1:1) was incorporated in the third phase to assess the possibility of solid phase incorporation in the developed SCTs. Prepared SCTs were assessed with regards to thickness, using a caliper, and mass uniformity. SCT hardness was evaluated by texture analyzer (EZ universal tester, Shimadzu Corporation, Japan), with the 1000 N–load cell and a cylindrical probe (diameter 7 mm, speed: 2 mm/s). The force required to break the tablet was recorded as hardness and Chewing Difficulty Index (CDI) was calculated as a product of SCT hardness and thickness (Gupta et al., 2015). Disintegration testing was conducted according to the uncoated tablet disintegration testing protocol and apparatus (Erweka ZT 52, Erweka, Germany), as suggested in the FDA guideline (FDA, 2018).

Results and discussion

Critical quality attributes of chewable tablets include mechanical properties and disintegration, as well as tablet dimensions and palatability, as these factors can influence patient acceptance and chewing

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performance (FDA, 2018). SCT mass ranged from 3.05–3.08 g, whereas thickness was 7.66–7.95 mm. Their hardness and CDI ranged from 15.9 N and 0.13 Nm (S5, 70/30% of PEG 400 and PEG 4000) to 34.0 N and 0.29 Nm (S1, 30/70% of PEG 400 and PEG 4000), indicating the impact of the PEG 4000/PEG 400 ratio on the SCT mechanical properties. Analogously, SCT disintegration time ranged from 11.8 min (S5) to 16.9 min (S1). Assuming that the solid phase incorporation would increase SCT density and mechanical strength, formulations S4 and S5 (60/40% and 70/30% of PEG 400/PEG 4000, respectively) were selected for the further development, due to the lowest hardness among the investigated SCT samples.

SCTs prepared with the HPMC, HPC, GMD or PS, as viscosity–modifying agents, exhibited mass in the range 3.03–3.22 g and thickness 7.05–8.02 mm. These samples exhibited lower thickness when compared to S4 and S5, indicating higher SCT base density. The addition of viscosity–modifying agents generally improved mechanical properties of S4–based samples, but did not notably impact the S5–based sample hardness. The hardness and CDI of SCTs with viscosity–modifying agents ranged from 11.5 N and 0.09 Nm (S13, containing 70/30% of PEG 400/PEG 4000 with 5% PS) to 28.8 N and 0.24 Nm (S6, containing 60/40% of PEG 400/PEG 4000 with 5% HPMC). S4–based samples were brittle and prone to break, while the probe penetrated through the softer S5–based samples. The addition of PS generally decreased SCT hardness.

The addition of viscosity–modifying agents led to prolonged disintegration time to some extent, ranging from 11.9 (S13) to 15.2 min (S6). Samples S6 and S13 were selected for solid phase (P) incorporation, due to the highest and lowest values of mechanical strength and disintegration time.

Sample S6 with solid phase incorporated (S6–P) did not break during the hardness test and second indentation cycle was required, indicating the need for two chewing cycles. On the other hand, sample S13–P exhibited somewhat higher hardness to the S13 (14.2 N and 11.5 N, respectively). However, the results were highly variable. The disintegration time of the SCTs with solid phase incorporated was 18.1 min (S13–P) and 22.9 min (S6–P), indicating an increase compared to corresponding S6 and S13 samples (15.2 and 11.9 min, respectively). This may be attributed to the high solid phase content (30%). The obtained disintegration time exceeded 15 min, corresponding to the Pharmacopoeial requirement for uncoated tablets. However, both SCT hardness/CDI and disintegration time were comparable with those reported for the marketed chewable tablets (45.3 to 306.8 N and 10.58 to more than 240 min, for the hardness and disintegration time values reported, respectively) (Gupta et al., 2015; Lanz et al., 2014).

Conclusion

Soft chewable tablets with acceptable dimensions, hardness, and disintegration properties were successfully prepared using the appropriate PEG 400/PEG 4000 ratio and a viscosity–modifying agent. The SCT properties remained acceptable even at high solid phase content incorporated. Due to relatively simple formulation composition and preparation method, these dosage forms may represent a promising compounding alternative.

Acknowledgement

This research was funded by the Ministry of Science, Technological Development, and Innovation of the Republic of Serbia through grant agreements with the University of Belgrade – Faculty of Pharmacy (Nos. 451-03-33/2026-03/200161 and 451-03-34/2026-03/200161).

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