Mango peel pectin as a superdisintegrating agent

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Received 01 February 2010; revised 01 July 2010; accepted 05 July 2010

This study presents extraction and evaluation of mango peel pectin as superdisintegrant agent. Tablets of mango peel pectin had comparatively lesser release of drug as compared to sodium starch glycolate for a specific period of time. Therefore, mango peel pectin cannot be used as a promising superdisintegrant, but due to its good solubility in biological fluid and better swelling index, it can be used to prepare fast dispersible tablets.

Keywords: Fast dispersible tablet, Mango peel pectin, Sodium starch glycolate, Superdisintegrant

Introduction
Dispersible tablets contain natural and synthetic disintegrants in formulations1-5. Pectin of natural origin is preferred over semi-synthetic and synthetic substances because pectin is comparatively cheaper, abundantly available, non-irritating and nontoxic6,7. European Pharmacopoeia8,9 defines oro-dispersible tablets as “uncovered tablet for buccal cavity, where it disperses before ingestion”. Active moiety can rapidly dissolve in saliva and so absorbed through buccal mucosa10. Freeze drying, sublimation, moulding or direct compression are techniques used to prepare this type of tablets11-15.

In this study, mango peel pectin (MPP) was extracted using simple wet granulation method to develop fast dispersible tablets of a model drug, Diclofenac sodium, and effect of MPP as superdisintegrant was compared with synthetic superdisintegrant, sodium starch glycolate (SSG). Diclofenac is a non-steroidal anti-inflammatory drug16.

Experimental Section
Material Procurement
Mango peel was obtained from a juice shop of Meerut, India. Diclofenac sodium was obtained as a gift sample from Alchem Laboratories, Baddi, India. Other materials used include microcrystalline cellulose (MCC, fine powder), talc and magnesium stearate (RANKEM Limited, New Delhi).

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Pectin Isolation and Preparation of Tablets
Dried mango peel powder was used for extracting pectin using Soxhlet apparatus. Round bottom flask containing acidified water [water acidified (pH 2) using 0.5 N citric acid] was heated continuously at 75°C for 7-8 h after start of first siphon cycle. Powder to solvent ratio was 1:8. After heating period was over, mixture was passed through two fold muslin cloth and cooled to room temperature. Double amount of ethyl alcohol was added to solution with continuous stirring for 15 min. Mixture was kept for 2 h without stirring. Pectin was precipitated and filtered through 4-layered muslin cloth. Precipitate was washed 2-3 times by ethyl alcohol, to further remove any remaining impurity. Finally, precipitate was kept for drying at 35-40°C in hot air oven, sieved (#80) and stored in desiclator until use17,18.

Tablets were prepared in 4 batches (MPP - M1, M2, M3, M4; SSG - S1, S2, S3, S4). Each batch among 4 batches of MPP and SSG under formulation of fast disintegrating tablet contained: drug, 50; talc, 6; and magnesium stearate, 4 mg. Superdisintegrants (Batch M for MPP and batch S for SSG respectively) in 4 batches were as follows: M1/S1, 5; M2/S2, 10; M3/S3, 15; and M4/S4, 20 mg. Similarly, MCC in 4 batches was as follows: M1/S1, 135; M2/S2, 130; M3/S3, 125; and M4/S4, 120 mg. Tablets were prepared in two steps: i) weighed quantities of all ingredients were mixed as per varying concentration, and then granulated using water as granulating agent; and ii) weighed quantities of
granules were compressed by Cadmach Punching Machinery using 8 mm punch at 0.5 tonne pressure.

Technological Parameters

Weight variation (USP XXIV monograph), friability (Roche Friabilator), hardness [Digital Force Gauge (Model: EL=500N, Electrolab) tester] and thickness (vernier calipers) were determined\textsuperscript{19,20}. Drug content was calculated by measuring absorbance using buffer (pH 6.6) and measured at 276 nm wavelength (Shimadzu UV-2450, Japan). Wetting and de-aggregation time were calculated by placing tablets from each batch in 10 ml distilled water (in petridish of 10 cm diam). Wetting time necessary for complete wetting of tablet was carried out in triplicate. De-aggregation time (European Pharmacopoeia IV Ed.) is required to de-aggregate tablet into small fragments, when immersed in water at room temperature, without stirring\textsuperscript{21}. In vitro dissolution study was performed in 900 ml phosphate buffer (pH 6.6) at 37°C using paddle method at 100 rpm (Lab India Disso 2000, India). Medium (5 ml) was collected at specified time interval and filtered. Filtrate was analyzed at 276 nm by UV spectrophotometry.

Results and Discussion

Formulated tablets met United State Pharmacopoeial (USP) requirement of weight uniformity. In case of use of MPP, weight variation (mg) was 200.4(0.11), 201.2(0.12), 200.1(0.23) and 199.8(0.43) respectively from M1 to M4. Similarly, readings (mg) ranged from 199.8(0.10) to 201.3(0.08) using SSG. Hardness (Newton) for each batch from M1 to M4 was found 20.0(0.12), 19.1(0.17), 13.9(0.12) and 9.4(0.36) respectively. For S1 to S4, hardness values were 26.30(0.03), 22.80(0.02), 19.90(0.04) and 18.50(0.03) respectively. Percentage friability was between 0.05(0.12) to 0.53(0.09), for batches containing MPP; whereas range for batch with SSG was between 0.05(0.05) to 0.15(0.06). Relative study of thickness (mm) ranked between 2.50(0.09) to 2.87(0.16) for tablets compounded with MPP and between 2.50(0.02) to 2.53(0.03) for tablets compounded with SSG.

Thus tablets compressed using SSG were harder than that with MPP. Average wetting and deaggregation time indicated that tablets compounded with MPP took more time in comparison with SSG. Friability study showed that tablets compounded using MPP were more friable than those formulated with SSG. As concentration of gum increases, swelling index of tablets increased proportionally\textsuperscript{22,23}. Drug content in all batches of two polymers was quite uniform. In vitro dissolution study, carried out at pH 6.6, reveals that batch M2 gives best release (92.12%) in 90 min (Fig. 1) in comparison to batch S1 (cumulative release of 99.47%).

Conclusions

Naturally obtained mango peel pectin stands as a good candidate to act as superdisintegrant though, not as stronger as synthetic sodium starch glycolate but although due to its good solubility and higher swelling index, it may be used in formulation of fast dispersible formulations.

References


