Development and Characterization of Fast Disintegrating Tablets Containing Low Dose Model Drug

Objective
For fast disintegrating tablets, quick disintegration is desired. Sodium starch glycolate (SSG), a cross-linked sodium carboxy methylated (potato) starch, is widely used as super-disintegrant for oral solid dosage forms. The aim of this work was to examine the functionality of different sources of SSG in developing fast disintegrating tablets of a low dose model drug.

Experimental
Low dose alprazolam tablets (1 mg/tablet) were produced by direct compression, carried out using 9 x 4.5 mm standard concave capsule shaped punches at two hardness settings on a rotary compression machine (batch size 10,000 tablets). Six different sources of SSG were compressed at 2% along with spray dried lactose monohydrate, microcrystalline cellulose, and magnesium stearate. The blends were characterized by standard quality control analysis for various physical properties such as density and flowability. The tablets were evaluated for weight variation, content uniformity, disintegration time and dissolution.

Results and discussion
Physical properties of the blend showed excellent compactibility of SSG with the other selected excipients. The six different sources of SSG exhibited minimal effect on the physical characteristics of the blend (Figure 1). All blends exhibited “passable” up to “good” flow properties, as defined by Hausner ratio and Carr’s index. The content uniformity of all batches complies as per USP except for one (in batch A one of the tablets showed content of 72% out of 10 tablets and the other 9 tablets showed content above 90%). The dissolution for all the six batches of alprazolam tablets complies as per USP except for one (in batch A one of the tablets showed content of 72% out of 10 tablets and the other 9 tablets showed content above 90%). The dissolution for all the six batches of alprazolam tablets complies as per USP except for one (in batch A one of the tablets showed content of 72% out of 10 tablets and the other 9 tablets showed content above 90%). The dissolution for all the six batches of alprazolam tablets complies as per USP except for one (in batch A one of the tablets showed content of 72% out of 10 tablets and the other 9 tablets showed content above 90%).

Conclusion
For development of fast disintegrating tablets, SSG was found to be a suitable disintegrating agent. This fast disintegration can be explained by the powerful swelling due to rapid uptake of water resulting in fast disintegration of the tablet and release of active ingredient. In this study, excipient source has found to have a significant effect on disintegration characteristic of finished product.

The tablets composition (mg/tab):
- Alprazolam: 1.00 mg
- Sodium starch glycolate (SSG) 
- Magnesium stearate: 1.20 mg
- Docusate sodium: 0.12 mg
- SuperTab® 14SD: 76.0 mg
- Pharmacel® 102: 39.88 mg

Tablet properties:
- Weight variation (g): 0.5
- Tapped density (g/ml): 1.0
- Bulk density (g/ml): 1.5

Figure 1: Effect of six different sources of SSG on the physical characteristics of the blend (Carr’s index and angle of repose) and the tablets (weight and thickness) containing low dose alprazolam.

Figure 2: Disintegration time as a function of tablet hardness (left) of tablets with different sources of SSG, and a comparison of disintegration time versus friability of the tablet (right). Dots indicate minimum/maximum range of hardness (H) and disintegration time and friability at two hardness settings (low and high).

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