

Formulation of amlodipine 5 mg oral disintegrating tablets and evaluation of its physicochemical properties

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Background and Aims: Blood pressure is the reason of death in 13% of people in the world. Amlodipine is one of the main medications used in this condition and is suggested for administration as the first line therapy of blood pressure. The aim of this study is to formulate amlodipine oral disintegrating tablets.

Methods: Different formulations were prepared by mixing all ingredients in geometric order and using direct compression method for its compaction, containing various amounts and types of additives including croscarmellose, sodium starch glycolate and F-melt as the superdisintegrants; Avicel, lactose and calcium carbonate as fillers; Mg Stearate, SLS and sodium benzoate as lubricant; mannitol, aspartame, saccharin, orange flavor, cherry flavor and peppermint as sweetener or flavorant. Tablets were evaluated for weight variation, hardness, friability, drug content, disintegration and dissolution time.

Results: The study revealed that among different additives, Avicel was the best filler and between the different disintegrants used, F-melt was found to be the best, helping to break apart the tablet within 8 seconds. Mg Stearate was found to be the best lubricant, allowing desirable powder flow. Regarding the flavorant/sweeteners used peppermint along side monnitol or aspartame was found to be the best combination for masking the bitter taste of the drug, when evaluation on 10 healthy volunteers. The final formulation also managed to release over 80% of its drug content within 5 minutes.

Conclusions: the Amlodipine ODT tablet prepared is an effective formulation based on its rapid disintegration within the buccal cavity, allowing the ease of swallowing and a fast dissolution rate. It is hoped that following the completion of clinical studies this formulation enters the national drug market.

Keywords: Amlodipine; Oral disintegrating tablets; Taste masking; Superdisintegrants; Formulation study