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Formulation and physicochemical evaluation of rizatriptan orally disintegrating tablet

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Background and Aims: The aim of this study was to prepare a rizatriptan, a novel 5-HT1D/1B agonist for relief of migraine headache orally disintegrating tablet formulation. These tablets are capable of turning quickly into a liquid form in contact with the saliva, hence a quicker onset of action and a greater bioavailability would be expected.
Methods: 6 Different groups of rizatriptan (10mg) tablet formulations were prepared. This Formulations were examined in terms of different physicochemical tests including powder/granule flowability, appearance, thickness, uniformity of weight, taste, hardness, friability, disintegration and dissolution time.
Results: Rizatriptan powder had an awfully bitter taste, poor flow and inappropriate compressibility, needing the use of suitable additives and various taste-masking agents. Series A to D formulations were prepared in order to determine the type and amount of required filler and super-disintegrant. Results showed that avicel in an amount of 80% was the most desirable filler and sodium starch glycolate in an amount of 5% was the most appropriate super-disintegrant. The final formulation in these series disintegrated within 10 seconds and released more than 80% of its drug content within 5 minutes. More over, the amount of active ingredient (assay) was 99/7 (HPLC method). In series E, formulations the appropriate type and amount of sweetener were investigated. Results showed that aspartame in an amount of 0.1% was suitable. In series F, using the selected formulation F12 from series E was used to determine the appropriate type and amount of flavoring agents. Based on the opinion of ten young healthy volunteers it was found that peppermint and menthol in an amount of 0.1% could mask the bitter taste of drug.
Conclusions: The final formulation F18 containing rizatriptan, avicel, sodium starch glycolate, aspartame and menthol showed the most desirable taste and passed all the physicochemical tests conducted.

Keywords: Rizatriptan; Orally disintegrating tablet; Sodium starch glycolate; Disintegration time; Taste-masking