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Formulation, Preparation, and Evaluation of Coated Desloratadine Oral Disintegrating Tablets

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Abstract : Orally disintegrating tablets (ODTs) are gaining importance as new drug delivery systems and emerged as one of the popular and widely accepted dosage forms, especially for the pediatric and geriatric patients. Their advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bed-ridden and patients who do not have easy access to water. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market. These dosage forms dissolve or disintegrate in the oral cavity within a matter of seconds without the need of water or chewing. Desloratadine is a tricyclic antihistaminic, which has a selective and peripheral H1-antagonist action. It is an antagonist at histamine H1 receptors, and an antagonist at all subtypes of the muscarinic acetylcholine receptor. Desloratadine is the major metabolite of loratadine. Twelve different placebos ODT were prepared (F1-F12) using different functional excipients. They were evaluated for their compressibility, hardness and disintegration time. All formulations were non sticky except four formulations; namely (F8, F9, F10, F11). All formulations were compressible with the exception of (F2). Variable disintegration times were found ranging between 20 and 120 seconds. It was found that (F12) showed the least disintegration time (20 secs) without showing any sticking which could be due to the use of high percentage of superdisintegrants. Desloratadine showed bitter taste when formulated as ODT without any treatment. Therefore, different techniques were tried in order to mask its bitter taste. Using Eudragit EPO resulted in complete masking of the bitter taste of the drug and increased the acceptability to volunteers. The compressible non sticky formulations (F1, F3, F4, F5, F6, F7 and F12) were subjected to further evaluation tests after addition of coated desloratadine, including weight uniformity, wetting time, and friability testing.. Fairly good weight uniformity values were observed in all the tested formulations. F12 exhibiting the shortest wetting time (14.7 seconds) and consequently the lowest (20 seconds) disintegration time. Dissolution profile showed that 100% desloratadine release was attained after only 2.5 minutes from the prepared ODT (F12) with dissolution efficiency of 95%.

Keywords : Desloratadine, orally disintegrating tablets (ODTs), formulations, taste masking
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