

Abstract

Design, Preparation, and Evaluation of Taste-Masked Dexketoprofen of Orally Disintegrating Tablet by Using QbD Approach [†]

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Abstract: The present investigation was carried out to develop a taste-masked, orally disintegrating tablet containing Dexketoprofen for evaluating the effect of the coating amount on the product's quality attributes via Quality by Design (QbD) systematical roadmap. Dexketoprofen, S(+)-enantiomer of bitter taste ketoprofen, involves an arylalkyl group which is the most frequently used analgesic in the management of acute and chronic pain. To overcome of bitter-taste of the active pharmacological ingredients should apply a taste-masking approach. For this purpose, the bitter taste dexketoprofen particles were coated with a pH-dependent methacrylates polymer in which one of the method of taste-masking approaches. The experimental design was enforced with a four-factor, three-level Box–Behnken method within the framework of response surface modeling (RSM). A ready to use matrix excipient, Eudragit RS 30D, dextrates, aroma, and tablet pressing force were chosen as independent factors, and were assessed on four dependent factors: dissolution rate, disintegration time, tablet hardness, and friability %. Our findings indicate that when tablet pressing force is applied at 250 PSI, the tablets disintegrate within 1 minute, and the friability value is under 1%. Disintegration time increases as the coating amount increases. However, the Pareto charts shows engrossingly that the dissolution rate is affected mainly by tablet pressing force in first, third, and fifth time points, and by matrix excipient and coating in the 10th, 15th, 20th, and 30th time points. It was concluded that the QbD study helped to understand how the coating amount and process variables impacted the dissolution rate, disintegration time, tablet hardness, and friability % of the Dexketoprofen orally disintegrating tablet (ODT) finished product.

Keywords: quality by design; dexketoprofen; dissolution; coating material; tableting

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