

Proceedings

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 taste-masked orally disintegrating tablet containing Dexketoprofen for evaluating the effect of the coating amount on product's quality attributes via Quality by Design (QbD) systematically roadmap. Dexketoprofen, S(+)-enantiomer of bitter taste ketoprofen, involves in arylalkil group which is the most frequently used analgesic in the management of acute and chronic pain. Bitter-taste active pharmacological ingredients should involve taste masking approach. For this purpose, the bitter taste dexketoprofen particles were coated pH-dependent methacrylates polymer in which one of the methods of taste-masking as a taste-masking agent. The experimental design was enforced with four-factor three-level Box-Behnken method within the framework of response surface modeling (RSM). Ready to use matrix excipient, Eudragit RS 30D, dextrans, aroma, 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 as 250 PSI, the tablets disintegrate below 1 minute and friability value's is under 1%. Disintegration time increases as the coating amount increases. However the pareto charts shows engrossingly that the dissolution rate is affected mostly by tablet pressing force in first, third, fifth time points, and by matrix excipient and coating in tenth, fifteenth, twentieth, thirtieth time points. It was concluded that QbD study helped to understand hoe coating amount and process variables impacting the dissolution rate, disintegration time, tablet hardness and friability of Dexketoprofen orally disintegrating tablet (ODT) finished product.

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

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