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RESEARCH ARTICLE

Formulation Development and Optimization of Oral Dispersible Tablets of Antihypertensive Drug

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Abstract: ***Background:*** This study aimed to formulate oral dispersible tablets that rapidly dissolve in the mouth by employing a tasteless complex of Kyron T-314 and propranolol hydrochloride, utilizing the Quality by Design (QbD) approach.

Methods: The QbD methodology was used to acquire more insight into the process and expand the design area. This involved utilizing a quality target product profile (QTPP) and critical quality attributes and performing risk assessments. The project's ultimate goal was to use orally disintegrating tablets (ODTs) to speed the beginning of action of propranolol hydrochloride. A 3^2-factorial design with a central composite approach was used to develop oral dispersible tablets (ODTs) containing propranolol hydrochloride. In this design, two independent variables, HPMC as a binder and Kyron T-314 as a super disintegrant, were used at each level. As part of the analysis, response surface plots, R^2 (goodness of fit), Q2 (goodness of prediction), reproducibility and model validity were reported. Several pre- and post-compression parameters were evaluated and techniques were utilized for the characterization of drug and prepared tablets through Fourier transform infrared (FTIR) spectroscopy, differential scanning calorimetry (DSC), and X-ray diffraction (XRD), all of which were thoroughly reported.

Results: Direct compression methods were used to prepare oral dispersible tablets. UV spectroscopy revealed the maximum of propranolol hydrochloride at 228 nm. The substance existed in its pure form in an infrared spectroscopy (IR) compatibility analysis, and no significant interactions with other polymers were discovered. The drug's crystalline nature with distinct peaks was confirmed through DSC and XRD analyses. An overlay plot was created with specified values for WT (0.11 – 0.43 sec), Fr (0.39 – 0.96), and Q_{15} (91.55 – 95.49 %).

Conclusion: The validation of the optimization study demonstrated the predictive solid capability of response surface methodology. Using the Quality by Design (QbD) methodology, the study demonstrates how to formulate propranolol hydrochloride-containing orally disintegrating tablets (ODTs) most effectively.

Keywords: Quality by design, critical quality attributes, drug resin complex, critical material attributes, propranolol hydrochloride, risk-assessment analysis, response surface methodology.

1. INTRODUCTION

QbD (Quality by Design) is a strategic method utilized in a wide range of industries, including medicines, manufacturing, and product development, to ensure consistent delivery of top-quality products. It incorporates a methodical and proactive approach to include quality concerns across every stage of the product lifespan, from design to manufacture. This approach is facilitated by planning strategically and leveraging existing data. Despite its focus on risk management, QbD has demonstrated its efficacy in reducing final product variability and increasing the likelihood of regulatory approval [1, 2]. Quality by Design (QbD) principles are elucidated in ICH guidelines like Q8, Q9, and Q10. These guidelines serve as foundational frameworks for understanding QbD. They emphasize the importance of scientific principles, risk assessment, and managing the product life cycle through various methodologies [3]. When a product goes from the early stages of research and development to the late stages of production, it can be very unpredictable. This is usually because people do not fully understand why things

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