QbD Assisted Systematic Review for Optimizing the Selection of PVP as a Ternary Substance in Enhancing the Complexation Efficiency of Cyclodextrins: a Pilot Study

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Aims and scope

Submit manuscript

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Abstract

Inclusion complexes require higher concentration of Beta cyclodextrins (βCD) resulting in increased formulation bulk, toxicity, and production costs. This systematic review offers a comprehensive analysis using Quality by design (QbD) as a tool to predict potential applications of Polyvinylpyrrolidone (PVP) as a ternary substance to address issues of

inclusion complexes. We reviewed 623 documents from 2013 to 2023 and Eighteen (18) research papers were selected for statistical and meta-analysis using the **QbD** concept to identify the most critical factors for selecting drugs and effect of PVP on inclusion complexes. The QbD analysis revealed that Molecular weight (MW), Partition coefficient (Log P), and the auxiliary substance ratio directly affected complexation efficiency (CE), thermodynamic stability in terms of Gibbs free energy (ΔG), and percent drug release. However, Stability constant (K_s) remained unaffected by any of these parameters. The results showed that low MW (250), median Log P (6), and a **βCD**: PVP ratio of 2:3 would result in higher CE, lower G, and improved drug release. PVP improves drug solubility, enhances delivery and therapeutic outcomes, and counteracts increased drug ionization due to decreased pH. In certain cases, its bulky nature and hydrogen bonding with CD molecules can form non-inclusion complexes. The findings of the study shows that there is potential molecular interaction between PVP and β-cyclodextrins, which possibly enhances the stability of inclusion complexes for drug with low MW and log P values less than 9. The systematic review shows a comprehensive methodology based on QbD offers a replicable template for future investigations into drug formulation research.

Graphical Abstract