

Publication

Hydroxychloroquine immediate release tablets: Formulation and evaluation of a solid dosage form

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Hydroxychloroquine (HCQ) is a quinoline derivate used for the treatment of malaria and rheumatoid disorders. During early phases of the SARS - CoV2 (COVID - 19) pandemic, preliminary and later not substantiated reports suggested that HCQ might benefit COVID - 19 patients. This had sparked a worldwide and rapidly rising demand for HCQ drug products. Consequently, patients with pre - existing rheumatic diseases in Switzerland were confronted with an acute drug shortage . We have therefore designed, produced and characterized a generic HCQ drug formulation. The proposed HCQ formulation can be manufactured by using a minimal number of operation steps (mixing, wet granulation, sieving , blending, compression) and readily available pharmaceutical excipients. HCQ tablets were manufactured by granulation of the active pharmaceutical ingredient (API) , blending with the external phase and compaction using a non instrumented single punch tablet press. Analytics and identification of the API was performed by a combination of NMR, ESI - MS, FT IR and HPLC. HCQ tablets met the quality criteria for an immediate release HCQ dosage form. We hope that free access to non - proprietary protocols covering analytical procedures, formulation design, and manufacturing instructions for HCQ tablets will help to bridge existing and future supply chain gaps.

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