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Alternative Reaction Pathways to Metformin Hydrochloride

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Abstract

Metformin Hydrochloride is an important pharmaceutical used for the treatment of type 2 diabetes. The current manufacturing of this product involves a well-known and proven process. The process includes the dissolution and reaction, followed by the precipitation of Metformin Hydrochloride. Although reliable and effective, the current process relies on the use of a solvent; which later needs to be eliminated from the precipitates. The purpose of this project is the investigation of an alternative reaction pathway which will avoid the use of solvents and simplify the final purification stage. The anticipated benefits include reduced costs for the processing and a final product which is closer to meet FDA and quality standards. These steps will eventually result in reducing the final market value of this important pharmaceutical. The investigation of different pathways was conducted using standard thermal characterization and surface analysis instrumentation. Namely, a differential scanning calorimeter (DSC) and a scanning electron microscope (SEM). The DSC was used for thermal characterization of the reactants and product standards; while the SEM was used to examine crystal morphology and elemental composition of reacting mixtures. Preliminary experiments were conducted using micro and laboratory scale solvent-less reacting environments. These experiments allowed identifying the presence of a single chemical reaction. The characterization results suggest that the alternative pathway can successfully synthesize Metformin Hydrochloride. Further characterization and testing protocols are currently being formulated.