

COMBINING MECHANISTIC AND DATA-DRIVEN MODELS TOWARD REAL-TIME RELEASE TESTING OF TABLET DISSOLUTION

Introduction

Real-time release testing (RTRt) is a system of assuring the quality of all products immediately instead of time-consuming release testing. RTRt has a high potential to improve product quality with process control and reduce cost and process lead time. Tablet dissolution is one of the most critical quality attributes because it is linked to bioavailability but requires a long time to be executed (e.g., 60 mins). Therefore, applying RTRt to tablet dissolution is valuable for the pharmaceutical industry. However, establishing a reliable RTRt needs a lot of experimental data, and a developed RTRt is mostly specific to a particular product.

Methodology

In this project, mechanistic models of dissolution testing will be developed, calibrated and verified using experimental data of dissolution testing for multiple formulations and process settings. This data will further be analyzed via machine-learning techniques, e.g., partial least squares and artificial neural networks. The student will be involved in mechanistic modeling and data analysis of dissolution testing, and he/she is also encouraged to join experimental works using industrial-scale equipment at the Faculty of Pharmaceutical Science.

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BACKGROUND

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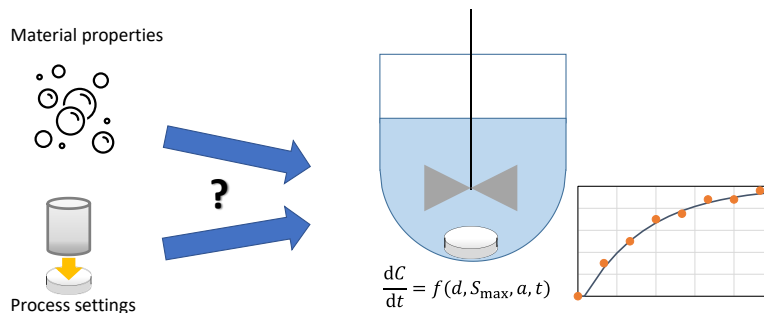


Figure 1 – The overview of the method

Objectives of the thesis

The aim of this project is to apply both a mechanistic model and a machine-learning technique to develop a reliable RTRt-relevant dissolution testing model applicable to continuous direct compression process. Both mechanistic and data-driven approaches will be used for the thesis.

This topic is a part of the project in collaboration with pharmaceutical companies, e.g., Janssen pharmaceuticals and AstraZeneca, and the student will have the chance to present their work to the project partners.

