IMPROVING SYSTEM OPTIMIZATION FOR NEW FORMULATIONS IN TWIN-SCREW WET GRANULATION PROCESS IN PHARMACEUTICAL INDUSTRY

Introduction

Recently the pharmaceutical industry has experienced changes in the way of producing solid oral dosages from traditional inefficient and expensive batch production to continuous. Despite that lately the pharmaceutical industry has not only increased the use of twin screw wet granulation (TSWG) in the manufacturing of solid dosage but has also included tools such as Population Balance Models (PBM), it is necessary to improve the understanding of the physical process within the TSWG and also obtain a better prediction of the characteristics of the product through improvement of current PBM models.

Methodology

Current PBM models have been developed and validated with specific data as a first step to build fundamental process knowledge of TSWG and towards a general PBM for twin-screw wet granulation. Hence, it is essential to test these models with experimental data from different formulations in order to achieve an optimal model capable of controlling the granulation process through understanding the dominating granulation sub-processes and the change in granule size distribution and dynamics along the twin-screw granulator.

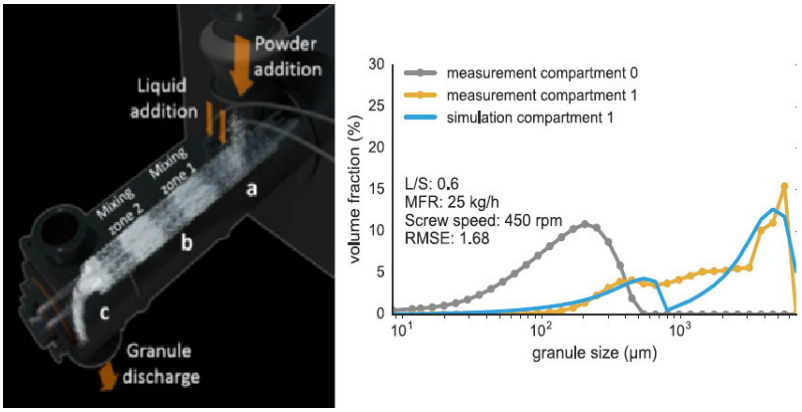

Figure 1 – Example of TSWG and results with current model.

Objectives of the thesis

The proposed study aims to improve the current PBM model in such a way that it can be used for control and optimization in the wet granulation stage in the available manufacturing equipment. The work is part of a project with Janssen Pharmaceuticals, Pfizer and UCB.

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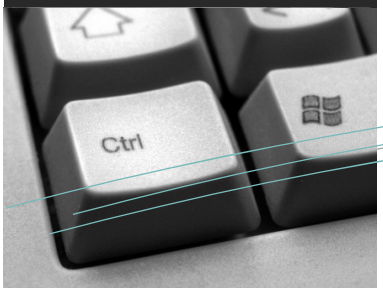

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