Review Article

IT Medical Team
https://www.itmedicalteam.pl/

International Journal of Drug Development and Research
0975-9344

2023
Vol. 15 No. 3: 1003

Spray Fluidized-Bed Granulation Method Phase for Drug Development: Control of Particle Quality via Data-Driven, Model-Free Adaptation

Fiona Brien*

Department of Pharmaceutical Technology and Cosmetology, University of Belgrade, Faculty of Pharmacy, Vojvode Stepe 450, 11221 Belgrade, Serbia

Corresponding author: Fiona Brien

fiona@pharmacy.bg.ac.rs

Department of Pharmaceutical Technology and Cosmetology, University of Belgrade, Faculty of Pharmacy, Vojvode Stepe 450, 11221 Belgrade, Serbia

Citation: Brien F (2023) Spray Fluidized-Bed Granulation Method Phase for Drug Development: Control of Particle Quality via Data-Driven, Model-Free Adaptation. Int J Drug Dev Res J, Vol. 15 No. 3: 1003.

Abstract

A novel data-driven model-free adaptive control (DDMFAC) approach is first presented, and then its stability and convergence analysis is provided to show algorithm stability and asymptotical convergence of tracking error. This approach combines the advantages of model-free adaptive control (MFAC) and data-driven optimal iterative learning control (DDOILC). In order to determine the occupied proportions of MFAC and DDOILC in accordance with their diverse control performances in various control stages, fuzzy logic is also used to adaptively adjust the parameters of the suggested approach. The proposed fuzzy DDMFAC (FDDMFAC) approach is utilised to regulate particle quality in the spray fluidized-bed granulation process's drug formulation stage. This approach's control efficiency is contrasted with that of MFAC, DDOILC, and their fuzzy versions, in which MFAC and DDOILC's parameters are adaptively changed using fuzzy logic. The efficiency of the suggested FDDMFAC approach is verified by a number of simulations.

Keywords: Drug Development; Nano crystal; Spray fluidized-bed; Drug formulation; Solubility enhancing technologies

Received: 27-Feb-2023, Manuscript No. ijddr-23-13596; **Editor assigned:** 13-Mar-2023, Pre-QC No. ijddr-23-13596(PQ); **Reviewed:** 16-Mar-2023; QC No. ijddr-23-13596; **Revised:** 23-Mar-2023; Manuscript No. ijddr-23-13596(R); **Published:** 30-Mar-2023, **DOI:** 10.36648-0975-9344.23.15.3-1003

Introduction

In order to convert small particles into larger granules, the spray fluidized-bed granulation process (SFBGP) uses a liquid binding solution that is sprayed onto fluidized particles by a spray nozzle above the powder bed. Because to the advantages of single unit operation, SFBGP has been widely utilised to produce granules intended to increase the power flow capability and physicochemical characteristics of pharmaceuticals. SFBGP's primary objective is to produce uniformly high-quality granules for the following pharmaceutical operations. The manufacture of pharmaceutical solid dosage forms, such as tablets and capsules, requires the use of SFBGP technology. SFBGP particle quality control has important theoretical and practical ramifications as a result [1].

The most crucial factor to control when assessing the particle quality for an SFBGP is granule size. The production yield, drug content, size, density, friability, flow ability, and compressibility are other factors to take into account. MBC methods, which require a priori physical and mathematical understanding of the process, may be the most effective ways to achieve the desired granule size. Previous research developed MBC frameworks and investigated the application of MBC techniques to traditional granulation design [2].

SFBGP is a challenging process that is significantly influenced by both material-related parameters, such as the composition and characteristics of powder particles and binding agents, and process factors. Yet, the numerous changes in prescription during the drug development phase will cause the material characteristics to alter. To learn more, get in touch with us. It is exceedingly challenging to develop accurate process models for an SFBGP whose material properties have already changed and with which we are unfamiliar due to the absence of process operating experience and historical data. Before employing standard MBC methodologies, multiple tests in the actual process should be carried out as long as the prescription is amended in order to

obtain enough process data for precise mathematical modelling. A difficult, time-consuming, and resource-wasting method like this makes MBC techniques unsuitable for quality control work in this activity [3].

In data-driven control, the controller architecture only uses input/output (I/O) measurement data from the controlled plant (DDC). While adopting DDC approaches, a model of a plant is not required, eliminating the modelling process, unmodeled dynamics, and theoretical assumptions. In the literature, DDOILC, virtual reference feedback tuning, lazy learning control, dynamic programming techniques, and many others are examples of DDC approaches with real-world applications in a range of industries. DDC has consequently recently drawn a lot of interest. Notwithstanding this, no report of the study on the use of DDC to SFBGP has, to the authors' knowledge, been published in the literature. In this work, a study on particle quality control based on DDC approaches is carried out in order to meet the practical difficulty of redesigning operating circumstances when prescription and material properties are completely altered [4].

The multiple prescription changes made during the drug development phase will have a range of material effects. For various material grades, the same set of empirical operating parameters will provide entirely distinct IVs of particle quality. The DDC procedures must support various IVs in the practise as necessary. In order to further improve the overall control impact, this work introduces a novel hybrid DDC technique dubbed DDMFAC that combines the advantages of MFAC and DDOILC. Even yet, DDMFAC does not clearly outperform MFAC and DDOILC for all IVs [5]. According to simulation tests, if weighted parameter adjustments are not made in a reasonable way, DDMFAC may not be as effective in controlling particle quality as DDOILC or MFAC. Using the previously completed theoretical analysis for MFAC and DDOILC as well as the subsequent simulation verification, we can summarise the weighted parameter modification methods for DDMFAC. Fuzzy adaptive modification of target weighted parameters is then used to fast converge DDMFAC by completely utilising the benefit of MFAC or DDOILC at various control stages. The last DDC approach we propose in this work is fuzzy DDMFAC (FDDMFAC), and various simulations demonstrate its effectiveness [6].

Materials and Method

The calcareous sand used in this experiment was obtained from the reef on Nansha Island, China. The calcium carbonate content of the calcareous sand, which was composed of broken coral branches and biological debris, reached 90%. Before the test, the calcareous sand was cleaned and left to air dry, as seen in the images of typical calcareous sand particles. The particles larger than 4 mm in size were eliminated in order to lessen the impact of boundary conditions on test results, namely the particle size distribution curve of calcareous sand, which indicates poor gradation. The relative density of the sand sample was ascertained using the pycnometer test [7].

The compression test was carried out using consolidation equipment. 61.8 mm x 20 mm ring knife samples were used to construct the samples. The rate of deformation was kept to a minimum of 0.01 mm per hour, which is considered acceptable (GB/T50123, 1999). The calcareous sand was subjected to tests at seven different vertical stress levels: 50, 100, 200, 400, 800, 1600, and 3200 kPa. The material was sieved after undergoing a 36-hour compression procedure. Particles of calcareous sand smaller than 0.25 mm were not filtered.

It was found that the proportion of coarser particles decreased as the tension rose (while the proportion of finer fraction grew). This showed how the amount of breaking in coarser particles increased along with the stress level. The fraction of particles smaller than 1 mm increased with increasing stress levels, primarily due to the fragmentation of larger particles. While the number of medium-sized particles increased with pressures exceeding 800 kPa, it appeared that the percentage mass of medium-sized particles (size 1-2 mm) changed for strains below 400 kPa. The huge particles were crushed and then compressed into numerous medium- to small-sized particles. The larger particles endure more breakage than the smaller ones [8].

This is due to the fact that they play a crucial role in stress transmission and that the relative scarcity of readily available interparticulate contact surfaces for force-transfer results in the generation of large contact stresses. As particles are reoriented and rearrange under low stress levels below 400 kPa, finer grains occupy the empty spaces around coarser grains, causing grain breakage. Furthermore, because coarse angular particles have developed significant stress concentrations around their asperities, they are more likely to break. It has already been established that particle size and shape are related. The data shown in demonstrate that the coarser particles larger than 2 mm were crushed even at the low stress level of 50 kPa [9].

Due to the increased stress, the higher percentage of the finer fraction implied significant particle crushing. SEM diagrams of calcareous sand particles with a single particle size. It was found that calcareous sands have exterior surfaces with uneven shapes and porous interior structures. This was evident from the compression test findings, which showed that a bigger finer percentage was produced under higher loads. Both the high-stress particle splitting caused by specimen compression and the low-stress particle breaking caused by friction and sliding between particles were caused by specimen compression (refer to the position specified) [10].

Conclusions

The goal of this research was to find a solution to the SFBGP drug development phase's particle quality control issue. Since an accurate process model cannot be obtained, model-based control systems are unable to handle such quality control. Model-free and data-driven control approaches are also considered in this paper. We first compared the properties of MFAC and DDOILC before comparing their abilities to manage particle quality under varied IVs. The simulation results confirmed our theoretical analysis, which let us come to the conclusion that MFAC and DDOILC both benefit under different IVs. In order to overcome these shortcomings, the hybrid solution, FDDMFAC, which combines the benefits of MFAC and DDOILC by adaptively changing each of their weighted components with fuzzy logic, was presented in

this work. We get to the conclusion that FDDMFAC offers greater control performance compared to other ways using a number of simulation findings, which supports the efficacy of FDDMFAC.

Conflict of Interest

None

Acknowledgment

None

References

1 Brown M, Zou Z, Peyyala R, Dziubla T, Puleo D et al (2014) Temporal separation in the release of bioactive molecules from a moldable calcium sulfate bone graft substitute. Curr Drug Deliv 11:605-612.

2 Hengst V, Oussoren C, Kissel T, Storm G (2007) Bone targeting potential of bisphosphonate-targeted liposomes: preparation, characterization and hydroxyapatite binding in vitro. Int J Pharm 331:224-227.

3 Wu P, Grainger DW (2006) Drug/device combinations for local drug therapies and infection prophylaxis. Biomaterials 27:2450-2467.

4 Bennett CF, Mong S, Clarke MA, Kruse LI, Crooke ST et al (1987) Differential effects of manoalide on secreted and intracellular phospholipases. Biochem Pharmacol 36:733-740.

5 Hu L, Wu H, Niu F, Yan C, Yang X et al (2011) Design of fenofibrate microemulsion for improved bioavailability. Int J Pharm 420:251-255.

6 Nazzal S, Khan MA (2002) Response surface methodology for the optimization of ubiquinone self-Nano emulsified drug delivery system. AAPS Pharm Sci Tech 3:23-31.

7 Rane SS, Anderson BD (2008) what determines drug solubility in lipid vehicles: is it predictable? Adv Drug Deliv Rev 60:638-656.

8 Pouton CW, Porter CJH (2008) Formulation of lipid-based delivery systems for oral administration: materials, methods and strategies. Adv Drug Deliv Rev 60:625-637.

9 Pouton CW (1997) Formulation of self-emulsifying drug delivery systems. Adv Drug Deliv Rev 25:47-58.

10 Kim KM, Kim HM, Lee WJ (2014) Surface treatment of silica nanoparticles for stable and charge-controlled colloidal silica. Int J Nanomedicine 9:29-40.