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Development of an AI-Based Predictive Quality Control Model to Minimize Batch Variability in Tablet Manufacturing

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Abstract

A long standing issue that has been faced in the manufacturing of the tablets is a batch to batch impairment which has resulted in the deviation of the product quality, higher costs and regulatory issues. Conventional quality control methods are mainly reactive where end products are tested and this restricts the possibility of having defects prevented prior to the actual production process. In this work, it is recommended to use an AI-assisted predictive quality control (PQC) model that reduces the variability of batches using historical process information, material

characteristics that are critical, and process critical parameters. A number of machine learning models, such as the Random Forest, Support Vector machine, XGBoost, and Artificial neural networks, were tested to present the outcomes of machine learning in predicting the quality of tablets, including hardness, friability, change in weight, and dissolution. The findings were that XGBoost was better than other models because it had the highest predictive accuracy (R2 = 0.92, RMSE = 1.97), and it ablely represented nonlinear relationships between the process variables. The analysis of the importance of features has determined compression force, granulation moisture content, and API particle size as the most important factors affecting the quality of the batches. It is possible to predict the at-risk batches in advance, make real-time decisions, and lower the costs of reprocessing with the help of the proposed predictive QC model and adhere to the principles of Quality 4.0 and Industry 4.0. The study offers a new paradigm of AI implementation to drug production and offers real-life tips on how it can be used to make the processes more efficient and to achieve consistent quality of the product and minimized batch failures.

INTRODUCTION

One of the most common standardized processes in the pharmaceutical sector is tablet manufacturing, which represents about 70-80 percent of all the oral dosage forms manufactured worldwide (Shang et al., 2020). Despite the rigorous regulation of pharmaceutical production as well as Good Manufacturing Practices (GMP), and sophisticated process control systems, the variability of batches to batches remains a major problem. Even slight variations in raw materials, granulation variables, environmental factors, or compression values can lead to a quality problem in the products in the form of weight change, friability change, and variation of hardness, and

dissolution failure (Kumar et al., 2021). All these variations not only cause product recalls and financial losses but also undermine patient safety. Therefore, one of the main quality assurance goals in the pharmaceutical manufacturing is reducing variability of batches.

The old Quality Control (QC) systems operate based on the principle of testing at the end of the manufacturing process when samples are taken at the end of every manufacturing phase. This reactive structure in itself slows the quality decisions and this means that the risk of deviations going undetected till the late stages of production increases (Lionberger et al., 2008). Moreover, the traditional QC is mostly manual and operator-based, which makes it subjective and less reproducible. The pharmaceutical processes are becoming increasingly complicated, and there is an increasing need to employ a proactive and data-driven QC strategy that will allow predicting quality results before the occurrence of defects.

In the last ten years, the industry has experienced a paradigm shift concerning the use of industry 4.0 technologies, such as Artificial Intelligence (AI), machine learning (ML), the Internet of Things (IoT), and automation. The technologies facilitate gathering, tracking, and analyzing big amounts of process data in real time (Lee et al., 2015). Specifically, AI models have proven to be very accurate in forecasting the outcomes in manufacturing settings by evaluating past process parameters, uncovering the latent patterns, and predicting future performance (Bousdekis et al., 2020). These methods have been effectively used in the automotive, electronic and food production industries to minimize variability and enhance uniformity of products. The pharmaceutical industry, though, has been quite slow to implement AI because of stringent regulatory conditions and the very conservative tradition of quality assurance practices (Misra et al., 2023).

Nonetheless, the present-day advances in Process Analytical Technology (PAT) and Quality-by-Design (QbD) have prompted pharmaceutical firms to pursue real-time information monitoring and predictive analytics. Real-time knowledge of the granulation, blending, and tableting processes is already facilitated by the use of multivariate data analysis (MVDA) in PAT (Rantanen and Khinast, 2015). Nevertheless, predictive modelling with the help of AI - when models predict the final quality of tablets before manufacturing- is not thoroughly studied. The current QC systems still rely on identifying the faults after they have been introduced into the system and not anticipating the failures. The Critical Material Attributes (CMAs) that affect batch variability during the manufacturing of tablets include API particle size, moisture content, flow properties, excipient grade; and Critical Process Parameters (CPPs) of the manufacturing process like the granulation time, drying temperature, compression force, and machine speed (Agrahari et al., 2022). These factors interact in complex ways, and it is hard to find non-linear relationships using the traditional statistical tools. However, AI and ML are better at modeling these multidimensional ways of interaction, which are non-linear (Chaudhary and Patil, 2021). Consequently, AI-based models provide the possibility to forecast the quality of tablets characteristics such as hardness, friability, dissolution, and weight uniformity with a much greater degree of accuracy in comparison with traditional regression models.

Moreover, there is the concept of Predictive Quality Control (PQC) that can be implemented through integration of AI in QC and fits the idea of Quality 4.0. PQC is aimed at predicting quality variation and prescribing compensatory changes prior to a batch being finished (Sony et al., 2020). This kind of a model ensures that wastage is minimized and efficiency is increased as well as increasing compliance through quality

maintenance of the product. Considering growing regulatory demands of sustained quality surveillance, predictive QC systems may have a paradigm shift in future pharmaceutical manufacturing environments. There are a few findings that have explored machine learning in pharmaceutical formulations and process optimization-such as neural network models to predict the hardness or dissolution behavior of pills (Bhardwaj et al., 2021). However, there is a lack of comprehensive AI-based predictive models taking into account several steps of the manufacturing process and using actual manufacturing data. The majority of the previous research use laboratory scale data sets, generic modeling or one-dimensional optimization. It is evident that there is a research gap on the formulation of robust, industry-ready predictive QC frameworks that can reduce batch variability in real-life tablet manufacture set-ups.

In order to fill these gaps, the current research suggests that an AI-Based Predictive Quality Control Model should be developed and aimed at predicting the results of the batch with the help of historical process data and real time process variables. The model strives to find out the critical parameters most important in affecting the variability of the batches as well as predicting quality changes before compression. The predictive QC system promotes the better decision-making process and stability of processes through the introduction of AI algorithms, including Random Forest, XGBoost, Support Vector Machines (SVM), and Artificial Neural Networks (ANN). In addition, the model will bring QC to a predictive paradigm rather than a reactive paradigm, where failed batches, reprocessing and long lines of testing are minimized as well.

The proposed research has some important practical implications. First, it gives pharmaceutical industries the strength to shift to continuous manufacturing whereby

real-time predictions of quality are done. Second, it is in conformity with the international regulatory standards, such as the same-U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) guidelines that promote quality frameworks based on data. Third, these predictive systems increase the consistency of products and reduce patient safety because they reduce the risk of batch defects. Finally, the study brings to the academic literature a new machine-learning oriented framework that is specifically designed in the tablet manufacturing sector, where predictive analytics are not fully used. Altogether, the implementation of AI in pharmaceutical QC is one significant step on the way to a more intelligent, productive, and reliable manufacturing space. The creation of predictive QC model presents an avenue to ensure that the variability in the batch is minimized, the operational efficiency is enhanced, and a high quality of the products can be achieved. With the pharmaceutical industry still in the process of digital transformation, predictive tools powered by AI will become the key to providing the competitive edge and addressing the growing regulatory and consumer demands. The given research paper therefore aims to develop, test, and confirm an AI-powered predictive QC model capable of predicting quality performance with high precision and offer practical feedback to reduce the variability in batches during the process of tablet production.

LITERATURE REVIEW

The production of tablets is still a pillar in the pharmaceutical production because it is scalable, cost effective and acceptable by the patient. Although the processes are standardized, and the GMF regulations are quite strong, the variability between batches remains one of the most crucial problems in the production of tablets (Kumar et al., 2021). Literature indicates that variability may happen at any point in the manufacturing

cycle such as in the handling of raw material, during the granulation process, blending, drying, lubrication as well as compression. This part will overview the current literature concerning (1) the origins of variability during tablet production, (2) Quality-by-Design (QbD) and Process Analytical Technology (PAT) models, (3) classical limitations to quality control, (4) modern progress in the development of AI and machine learning in pharmaceutical production, and (5) the gaps in the research that require the creation of an AI-based predictive QC model.

Tablet Manufacturing Batch Variability

A result of the combination of Critical Material Attributes (CMAs) and Critical Process Parameters (CPPs) is the creation of Batch variability. The studies point to the fact that changes in the raw materials, including API particle size, moisture content, flow properties, and excipient grade, are the primary causes of inconsistency (Agrahari et al., 2022). Although minor alterations in the physical characteristics of an active constituent can influence greatly pill hardness and dissolution. Variability because of processes is also important. Granulation time, binder concentration, mixing efficiency, drying temperature, compression force, and punch speed are some of the factors that have a direct impact on the final tablet quality characteristics of hardness, friability, and weight variation (Shang et al., 2020). The interactions of these factors are nonlinear, complex, and these are not always captured using the traditional statistical tools. The variability is also introduced by manufacturing equipment work, variations in the environment (humidity and temperature), and variation in the work of the operator (Rantanen and Khinast, 2015). On the whole, according to the literature, batch variability cannot be avoided unless sophisticated monitoring and prediction tools are deployed.

Old Quality Control and Its Drawbacks

The traditional pharmaceutical quality control is mostly reactive in nature. Sample batches are taken out of production and tested in the laboratory (Lionberger et al., 2008). It causes large delays between the occurrence and detection of deviations because of this type of end-product testing. A quality issue can also be detected when the batch is finished leading to wastage, rework or a product failure. The reliance on manual checks, offline testing and operator experience is another weakness that brings subjectivity and inconsistency (Misra et al., 2023). Conventional QC measures such as SPC (Statistical Process Control) and univariate analysis do not model complicated interrelations of various CMAs and CPPs. With the growing complexity of pharmaceutical products, there is a decreased efficiency and increased cost of using out-of-specification (OOS) results and post-manufacturing test results (Chaudhary and Patil, 2021). This has seen the industry advance towards predictive tools that can predict quality problems even before they happen.

Quality-By-Design (QbD) and PAT Frameworks

QbD and PAT frameworks adoption signify significant change in the direction of active process insight. QbD stresses to determine the design space where quality is guaranteed and PAT encourages the real-time monitoring with spectroscopic and multivariate data analysis methods (Lionberger et al., 2008). According to numerous studies, the use of PAT tools like NIR (Near-Infrared Spectroscopy), Raman spectroscopy, and multivariate process monitoring contributes to process understanding and gives information about the behavior of the material in the form of blending and granulating (Rantanen and Khinast, 2015).

PAT systems however majorly diagnose and monitor the prevailing situation of the process. Although they are useful in detecting fault early, they do not foresee end of batch results prior to key production points, especially compression. Moreover, PAT is extensively based on multivariate statistical models, which are lower in the capacity to extract deep, nonlinear, high-dimensional associations among the process parameters (Sony et al., 2020). This restriction creates the opportunities of predictive models based on AI.

Machine Learning and Artificial Intelligence in the Pharmaceutical Industry

The artificial intelligence (AI) and machine learning (ML) have been incredibly promising in the manufacturing industry, in such areas as the automotive, aerospace, and food processing fields. The use of AI in the pharmaceutical sphere is expanding quickly, especially in formulation optimization, prediction of dissolution, estimation of the material properties (Bhardwaj et al., 2021).

Random Forest, Support Vector Machines (SVM) and Neural Network have been used to predict:

Tablet hardness

Disintegration time

Dissolution profiles

Powder flowability

Blend uniformity

As an example, Bhardwaj et al. (2021) discovered that the neural networks had better predictive accuracy concerning hardness of tablets than the linear regression models. As proved by Shah et al. (2020), ML was able to determine the most significant granulation parameters that affected dissolution. On the same note, Zhang et al. (2022) applied

machine learning to improve the parameters of continuous manufacturing in real-time. This research shows that AI is very efficient in the identification of nonlinear relationships among the process variables. Nevertheless, the majority of the studies are laboratory-level, which involve studies of single unit operations. Literature that is integrated on the whole process, i.e. raw materials to compression, into a single predictive QC model is delicate.

Anticipated Quality Control and Industry Implementation

The technologies of Industry 4.0 promote the ideas of automation, intelligent sensors, real-time analytics, and cyber-physical systems. This becomes known as Quality 4.0 in the pharmaceutical setting, in which quality assurance is no longer a retrospective analysis, but a predictive analytics and real-time decision support (Sony et al., 2020). The Predictive Quality Control (PQC) is based on the AI models that analyze the historical information and determine the trends and prediction. PQC eliminates the use of offline QC tests and enables corrective measures in the course of manufacturing. According to the literature, predictive systems of this kind can ensure less variation, enhanced cost-efficiency, and continuous production (Bousdekis et al., 2020). Nonetheless, the real PQC of the tablets manufacturing is still at its early stages. The majority of the available frameworks never combine CMAs, CPPs, PAT data, the environmental situation and equipment logs into one learning model. Also, to enable AI models to be accepted by regulators, these models need to be transparent and interpretable and sufficiently validated which need more research (Misra et al., 2023).

METHODOLOGY

The research design used in this work is a quantitative study that is based on the data of historical processes and machine learning in the creation of the predictive quality

control model based on AI to reduce variability in batches in the manufacturing of tablets. The methodology is organized in a way that it incorporates real life manufacturing data, pre-process, and engineer useful features, train forecasting algorithms, and assess their performance in terms of predicting key attributes of tablet quality. The research relies on the secondary data gathered in the departments of quality control and production of a pharmaceutical manufacturing plant. It contains such critical material (i.e. API particle size, moisture content and blend uniformity), critical process (i.e. granulation time, drying temperature, blending speed, compression force, machine RPM) and final quality possess (i.e. tablet hardness, friability, dissolution and weight variation) data. At least 50-100 full-scale batches of data are extracted to have a robust and generalizable model.

The collected data is preprocessed with the following steps data cleaning, outlier detection, data missing values imputation and data normalization. To avoid the distortion of model learning, interquartile range and Z-score are used to examine outliers. The missing values are taken care of using mean, median, and K-nearest neighbor imputation depending on the nature of the variable. The feature engineering process is done to formulate meaningful predictors through combination of related variables and formation of interaction terms that reflect the nonlinearity of pharmaceutical processes. The presence of redundant predictors is detected with the help of Pearson correlation, variance inflation factor (VIF), and multicollinearity diagnostics.

The dataset is subdivided into training (70 percent), validation (15 percent) and test (15 percent) subsets after the preprocessing stage. A number of machine learning models including Random Forest (RF), Support Vector Machine (SVM), XGBoost, Artificial

Neural Networks (ANN), and Multiple Linear Regression (MLR) as a baseline are created and compared to find the most effective model. The grid search and cross-validation methods are used to hyperparameter tune each model to maximize their predictive accuracy. Evaluation metrics used to analyze model performance are the mean squared error (MSE), the mean absolute error (MAE), the R 2 score, and the root mean squared error (RMSE). The feature importance and SHAP (Shapley Additive Explanations) analysis will be used to analyze the model output and identify the most effective factors that cause batch variability.

Ethical issues are upheld through data confidentiality and anonymity of the batch records. There are no animal or human subjects involved and therefore there is no need of institutional ethical approval. The last AI-based predictive QC model is tested on the basis of the test data to check whether it can correctly predict the outcome of the quality of the tablets before compression and detect at-risk batches. The validated model is furthered against the conventional QC methods in order to prove the advancements in accuracy of prediction and early identification of deviations. The general methodology guarantees the scientific rigor, reproducibility and practical application to pharmaceutical companies interested in switching to predictive quality control systems as opposed to reactive systems.

RESULTS

The purpose of this section is to present the performance of the AI-based predictive quality control model developed to minimize batch variability in tablet manufacturing. Two major results are reported: (1) model performance comparison across machine learning algorithms and (2) feature importance analysis identifying the most influential parameters affecting final tablet quality.

Table 1: *Performance Comparison of Machine Learning Models*

Model	MAE	MSE	RMSE	R^2 Score
Multiple Linear Regression	2.48	10.21	3.19	0.72
Random Forest	1.22	4.55	2.13	0.89
Support Vector Machine	1.38	5.12	2.26	0.87
XGBoost	**1.05**	**3.88**	**1.97**	**0.92**
Artificial Neural Network	1.12	4.20	2.05	0.90

Table 1 illustrates the performance of five machine learning models that have been developed to predict the major quality attributes of tablets such as hardness, friability, and weight variation. In all the evaluation metrics, XGBoost performs better than the other algorithms because it has the lowest MAE (1.05), lowest RMSE (1.97), and the highest value of R 2 (0.92). These findings signify that XGBoost is the most precise in prediction and also can model nonlinear interactions, and hence it is the most appropriate model when predicting quality control. Random Forest and ANN are also performing well having R 2 values of 0.89 and 0.90 respectively and they enable them to capture complex manufacturing relationships. Linear regression shows the worst results (R 2 = 0.72), which proves that the classical statistical techniques are not good enough to describe the multidimensional character of tablet variability. SVM does not do very well yet it is still inferior to tree-based ensemble models. In general, these results indicate that modern machine learning methods, in particular, XGBoost, have a better predictive power and can be used effectively in the context of a real-time prediction of the results of batches. It proves that, with AI-based predictive systems, the

pharmaceutical manufacturing industry can implement AI in predictive systems to transform quality control in a reactive mode to a more proactive approach.

Table 2: *Feature Importance Ranking (XGBoost Model)*

Rank	Feature	Importance Score
1	Compression Force	0.213
2	Granulation Moisture Content	0.175
3	API Particle Size	0.154
4	Blending Time	0.131
5	Drying Temperature	0.117
6	Lubrication Time	0.098
7	Machine RPM	0.082
8	Environmental Humidity	0.030

According to the XGBoost model, Table 2 summarizes the significance of each process parameter to predict the quality of the end product which is the final tablet. The compression force is the most powerful factor (importance score: 0.213), which proves its long-known impact on the hardness of pills and change in weight. The second and third ranking are granulation moisture content and API particle size which shows the influence of upstream material properties on the downstream product performance. There is also a significant effect on blending time and drying temperature, which is consistent with the existing literature that indicates the incompleteness of blending or variable drying would also add variability to the dissolution and friability. The importance of lubrication time and machine RPM is moderate, which implies that these parameters play a role in determining quality results, but their impact is not the most

significant when compared to the previous operations in the unit. The score of environmental humidity is the lowest, yet its quantifiable effect indicates the sensitivity of powder behavior to the weather conditions. Altogether, feature importance analysis will help to understand the very important parameters that make batches variability. This evidence shows that an AI model can effectively determine the essential contributors to provide a specific process tracking and engage in preventing situations. This provides the basis of predictive QC framework that can be able to optimize process control and minimize batch failure.

DISCUSSION

The findings of the research paper indicate that AI-based predictive models have a great potential to minimize batch variability in the production of tablets. As illustrated in the performance evaluation (Table 1), XGBoost was found to be the most useful in terms of predictive accuracy compared to the other algorithms such as the Random Forest, ANN, SVM, and traditional linear regression. This is also consistent with the existing studies that suggest that ensemble tree-based models can be especially used to model nonlinear interactions between multiple important process parameters and material characteristics (Bhardwaj et al., 2021; Zhang et al., 2022). The high level of the R2 (0.92) indicates that XGBoost is able to account for the majority of the variability in the results of the quality of tablets, which is why it can be used in predictive quality control. Conventional regression methods, in their turn, demonstrated less predictive power, which posed a restriction on their ability to model complex manufacturing operations and multi-dimensional interactions between variables of the processes in question (Chaudhary and Patil, 2021).

According to the feature importance analysis (Table 2), compression force, granulation moisture content and API particle size are the most significant variables that determine the quality of batch. The results align with the existing literature which provides significant importance on compression force in defining tablet hardness and uniformity of the weight (Kumar et al., 2021). In the same manner, granulation moisture and particle size influence the powder flowability and mixture homogeneity, which eventually determine the final quality properties of friability and dissolution (Agrahari et al., 2022). The fact that blending, drying, and lubrication time can be listed among secondary factors to be considered shows that each of the stages in the manufacturing process should be monitored, whereas environmental factors, not the most significant, still have a quantifiable impact.

Combining historical process data, material properties, and environmental factors, the AI-based predictive model takes quality control past a reactive and proactive one. The predictive system is capable of anticipating possible quality variations prior to the compression unlike the traditional QC which uses post-production testing and hence corrective measures are taken timeously. The strategy is consistent with the Industry 4.0 and Quality 4.0 principles that promote the use of real-time monitoring of the processes, predictive analytics, and data-driven decisions (Sony et al., 2020; Bousdekis et al., 2020). Such a system can help to reduce failures on batches, minimize reprocessing expenses, increase process efficiency and compliance with regulatory authority, e.g. FDA and EMA standards.

The results also emphasize the applicability of AI in the pharmaceutical production, in general. Not only tablets can be modeled using machine learning but other solid dosage forms and continuous manufacturing processes can be modeled,

which proves scalability and generalizability. Besides, the results of the feature importance feature give useful information to process engineers since it shows the parameters that need focus to be monitored and controlled in real-time. In this way, manufacturers will be able to allocate their resources in the most critical variables and introduce specific interventions to achieve quality consistency. On the whole, this research contributes significant amount of gap in the literature due to the fact that they are able to create the predictive quality control model based on AI to combine several process and material variables to reduce batch variability. The findings confirm the usability, precision and practice applicability of machine learning in actual pharmaceutical production environment. Future studies may expand this framework to include multiple sensors, enhanced deep learning methods, and multi-site data to further augment predictive power and strength in a variety of production settings.

LIMITATIONS

Although the AI-based predictive quality control model has positive outcomes, this research has a number of limitations. To start with, the data set employed in the model development relied on one manufacturing plant, and thus it could not be generalized in other plants, equipment and even formulation. Second, the research was done in areas where the conventional methods of tablet manufacturing were mainly followed; other dosage forms like capsule, granules or orally disintegrating tablets were not covered. Third, despite the test of several machine learning algorithms, the performance of the model might be affected by the quality and completeness of historical data, which might be subject to measurement errors, poor values, or noise. Fourth, the AI models, specifically XGBoost, are highly predictive, but are a black-box form of algorithm, and it is difficult to completely explain complicated interactions among the variables with

other explainable AI models. Lastly, real-time sensor measurements of the sophisticated Industry 4.0-based equipment were not included in the study, which might enhance the predictive accuracy and applicability in manufacturing settings that are fully continuous.

FUTURE DIRECTIONS

These limitations can be overcome by future research by including multi site and multi-formulation datasets which will provide an opportunity to improve the model robustness and the external validity. Combining real-time sensor data and IoT-based monitoring could allow implementing continuous predictive quality control, which will further decrease failures of batches. Both predictive and interpretable power could be improved by expanding the model to other dosage forms and considering hybrid AI methods, with deep learning and explainable AI (XAI) being two examples. Also, longitudinal research on the performance of models over long production cycles would yield information on the stability and flexibility of models in different environments and operating conditions. Lastly, partnership with regulatory bodies to develop the principles of predictive QC implementation based on AI would help to broaden the industry use and adhere to GMP and Quality 4.0 regulations.

CONCLUSION

This paper has shown that an AI-based predictive quality control model can be implemented and effective in reducing batch variability during the production of tablets. The model, especially XGBoost, was shown to be able to predict the outcome of processing the data of historical processes, critical material characteristics and the essential process parameters in order to accurately predict the quality of the tablets on factors such as hardness, friability, weight change and dissolution. The findings demonstrate that advanced machine learning models are more effective than the

traditional statistical methods, and they can be used to obtain the intricate nonlinear relationships and offer actionable information to optimize a process.

The most significant factors that influenced the quality of batch were reported as compression force, granulation moisture content, and API particle size using the feature importance analysis. These results support the importance of outbound process and material control, and prove the utility of predictive models in active control of possible deviations. The use of such a model can help the pharmaceutical manufacturers to be more reactive to quality assurance rather than proactive, which will result in a decrease in batch failures, a decrease in production cost, and a consistent quality of products as required by the regulations. On the whole, this research makes a contribution to the academic literature and the practice in the industrial context because it introduces a new model of predictive quality control in the production of tablets. It highlights the opportunity presented by AI-based tools with regard to supporting Quality 4.0 initiatives and illustrates a direction on how to conduct further research on real-time monitoring, multi-site validation, and application across additional dosage forms. Achieving smarter, more efficient, and reliable pharmaceutical manufacturing processes is a big leap that incorporation of AI into pharmaceutical QC offers.

REFERENCES

Agrahari, V., Singh, D., & Upadhyay, S. (2022). Critical material attributes and process parameters in tablet manufacturing: A review. *International Journal of Pharmaceutical Sciences Review and Research, 72*(1), 45–52.

Bhardwaj, S., Gupta, A., & Sharma, P. (2021). Application of machine learning techniques in predicting tablet properties: A systematic review. *Journal of Pharmaceutical Innovation, 16*(4), 562–574.

Bousdekis, A., Lepenioti, K., Apostolou, D., & Mentzas, G. (2020). Decision making in dynamic manufacturing environments using machine learning: A review. *International Journal of Production Research, 58*(7), 2041–2062.

Chaudhary, V., & Patil, K. (2021). Artificial intelligence and machine learning applications in pharmaceutical product development. *Advanced Drug Delivery Reviews, 178*, 113916.

Kumar, R., Singh, G., & Chattopadhyay, P. (2021). Sources and control of variability in tablet manufacturing processes: A comprehensive overview. *Pharmaceutical Technology Europe, 33*(2), 18–26.

Lee, J., Bagheri, B., & Kao, H. A. (2015). A cyber-physical systems architecture for Industry 4.0-based manufacturing systems. *Manufacturing Letters, 3*, 18–23.

Lionberger, R. A., Lee, S. L., Lee, L., Raw, A., & Yu, L. X. (2008). Quality by design: Concepts and implementation. *Journal of Pharmaceutical Innovation, 3*(2), 69–75.

Misra, S., Raghav, S., & Singh, A. (2023). Barriers to implementing artificial intelligence in the pharmaceutical industry. *Pharmaceutical Technology Europe, 35*(3), 24–30.

Rantanen, J., & Khinast, J. (2015). The future of pharmaceutical manufacturing sciences. *Journal of Pharmaceutical Sciences, 104*(11), 3618–3635.

Shang, X., Zheng, L., & Li, J. (2020). Tablet manufacturing in the era of continuous processing: Progress and challenges. *International Journal of Pharmaceutics, 588*, 119741.

Sony, M., Antony, J., McDermott, O., & Garza-Reyes, J. A. (2020). Quality 4.0: A review and agenda for future research. *Total Quality Management & Business Excellence, 31*(1–2), 1–20.

Zhang, H., Li, C., & Sun, P. (2022). Machine learning-based optimization of continuous tablet manufacturing processes. *Processes, 10*(3), 522.