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Short communication

The Importance of overall equipment effectiveness (OEE) in demonstrating control and consistency of pharma packaging process

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Introduction

Pharmaceutical manufacturers continually strive to improve the quality of their products along with improving their production operations. Regulatory agencies in their guidelines require that product manufacturers should not only validate their production and packaging processes, but also demonstrate control and consistency. The efficiency of equipment as an important part of a manufacturing system directly affects the quality and cost of the product and the productivity of a company (Chikwendu et al., 2020).

This paper focuses on calculating the overall equipment effectiveness (OEE) of a packaging line that is used for packaging of solid dosage forms in the pharmaceutical industry as one of the most important key performance indexes of the packaging process.

Materials and methods

Overall equipment effectiveness was calculated for the following products: Amlodipin Alkaloid tablets 30 x 5 mg and 10 mg; Biprez® film coated tablets 30 x 2,5 mg, 5 mg and 10 mg; Citeral® film coated tablets 10 x 500 mg, Blokmax forte Rp® coated tablets 20 x 400 mg, Caffetin menstrual® film coated tablets 10 x 200 mg, Skopryl® tablets 30 x10 mg and 20 mg and Skopryl® plus tablets 30 x (20+12,5) mg that are primary and secondary packed on the packaging line IMA C80/A81.

Blister packaging machine IMA C80, cartoner machine IMA A81, labeling and checkweigher machine INEL PV1800 and stretch banding machine IMA MS 250 A are integrated in the packaging line IMA C80/A81.

As one of the key performance indicators (KPI`s) for each batch produced and packed on the packaging line IMA C80/A81 during 2021, an overall equipment effectiveness was calculated. The results have been analyzed on a monthly and quarterly period as by the internal procedure for following of the key performance indicators is required.

In this paper manufacturing productivity is analyzed by overall equipment efficacy metric and potential room for improvement has been defined.

Results and discussion

In the manufacturing site of Alkaloid d.o.o., located in Belgrade, a new packaging line IMA C80/A81 was installed and put into operation during 2020. The process of primary and secondary packaging has been validated and after the validation has been completed, a continued process verification is being performed and its Overall Equipment Effectiveness has been monitored.

Overall Equipment Effectiveness is a tool related to monitoring the efficiency of a plant, a machine or at a general level, the production system. It is a percentage indicator that represents the overall performance of a productive resource or a set of resources, during the time in which they are available to produce (Slack et al., 2016). It covers and analyzes both human or technical factors that can influence the final efficiency. Therefore, the OEE investigates all types of inefficiencies that lead to lower productivity: lack of materials, poor planning, setups, downtime, micro-stops, long failures, rework, non-conformities, etc. In particular, any inefficiency is limited to three factors: availability, performance, and production quality (Muhammad et al., 2020).

OEE can be measured by obtaining the product of performance efficiency of the process, the availability of equipment, and rate of quality products.

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OEE = Availability x Performance efficiency x Quality Rate

In order to calculate OEE, first the ideal time for packaging of each product had been calculated. All products were grouped into 4 groups according to the size parts, blister size and the number of the blisters in the final packaging.

Availability, performance efficiency and the quality rate were calculated considering: batch sizes, downtimes, planned breaks, number of total produced units and number of rejected units.

The obtained results showed that the process is consistent and the following OEE values were calculated for each calendar quarter for 2021 prospectively: 67.61%; 66.02%; 73.86% and 54.39%. In periods were the production campaigns were organized in a way to have as less change overs as possible, the calculated OEE values were higher. The time for downtimes solving has a huge impact on the final OEE score. Also, the results were analyzed between different groups of products and it was noticed that the OEE values depended on the type of size parts as well. The following OEE values were calculated: 64.14%; 60.96%; 63.77% and 85.55% for groups of products A, B, C and D prospectively.

Batch size also has an influence on the results and as bigger the batch size is, a better OEE values are gained.

Products from group B have the lowest values for OOE due to their specific shape and problem with the feeding system on packaging line. It leads to a higher rework ratio, compared to the products of other groups. In order to improve the process and to gain a better OEE results for the products from group B the current vertical feeding unit will be replaced with a new universal brush feeding system. After validating the new feeding system, a comparison of effectiveness between two different type of feeding for the same products will be done.

Conclusion

In the current economic conditions of high competition, all aspects of production costs must be approached with care. In this environment, it is necessary to consider appropriate methods that manufacturers can use to produce the product at minimum cost. Overall Equipment Effectiveness (OEE) is a method that meets this goal. By collecting a real - time data on a daily level it helps in diagnosing the loses and gives a direction to implement corrective actions and improvements in order to gain a highly productive process with a high-quality finished product.

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