Development Studies for the Surgicel SNoW Load Increase in the Dehumidification Chamber

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Abstract *— A medical device company was facing a significant downtime related to "waiting for material". Due to the high processing time and small loads in the dehumidification process, the next operation (Sealing) was being impacted. Development studies were conducted to three batches of different sizes by increasing the load size and analyzing the impact in the loss on drying (LOD) testing. Results showed that the dehumidification process can consistently produce LOD results of less than 5.5% with the proposed quantities.*

Key Terms *— development, load on drying, overall equipment increase, loss efficiency.*

INTRODUCTION

Surgicel SNoW (Structure Non-Woven) is an approved topical hemostatic agent for use during surgical procedures. It forms a physical barrier that blocks blood flow while providing a large surface area for the rapid formation of a fibrin clot. This product is manufactured in a medical device company dedicated to the wound closure industry.

The product comes in a large sleeve that undergoes certain processes until it transforms into a gauze with dimensions of 1x2, 2x4, and 4x4. One of the most critical parameters is the relative humidity. For SNoW products, the relative humidity cannot be more than 5.5%. In order to be able to achieve this parameter, the product is placed in a dehumidifier (DH) with fixed temperature, pressure, and vacuum time.

Each product code has a validated number of pieces that can be placed in the dehumidifier. That is because those were the minimum and maximum pieces that could withhold the relative humidity requirement at that size and at that moment in time with the current technology. After the product is dehumidified (approximately 5 hours), it goes to the Sealing process. Due to the constraint of the relative humidity for this product, it must be taken out of the dehumidifier only when the next process is ready. Due to the high processing time of the DH, the sealing process is often waiting for material, and this affects the Overall Equipment Efficiency (OEE).

The objectives for this project are to maximize the load increase in the dehumidification chamber and to minimize downtime related to "waiting for material", which will improve the OEE.

LITERATURE REVIEW

Production planning aims at providing efficient and effective utilization of production resources, while meeting sales demand for products, and taking into consideration all significant variables that affect the manufacturing environment [1]. A study was made about evaluating the production by its yield, cost, price, demand, and production capacity. It was found that evaluating the competitiveness of a product with its yield is a reasonable idea. By monitoring and controlling the input and output of a manufacturing system is very efficient to optimize the production and the system objectives [1]. In this study, to improve machine utilization, they used:

$$Utilization = \frac{Average\ Output\ Rate}{Maximum\ Capacity} x100\% \quad (1)$$

This utilization rate indicates the need for adding extra capacity or eliminating unneeded capacity [1]. Another factor is the capacity cushion. It is defined as the amount of reserve capacity a process uses to handle sudden increase in demand or temporary losses of production capacity [1]. Having found these values, they were able to calculate the optimum parameters to run the machine, as well as the percentage of improvement that can be achieved.

A study was made to investigate the impact of batch sizes on effective production capacity. There are two types of batches, sequential and continuous. Sequential batches are produced one after the other, while continuous is determined by the number of products that can be produced together [2]. In this study, the impact of the batch size was expected to have a positive impact on the diversity of products that could be produced. On the other side, lower effective production capacity was expected to result in lower total production output [2].

Another study was made to find the Economic Manufacturing Quantity (EMQ) for a production run, considering raw material & finished goods inventory and manufacturing setup cost. They developed an expression for the general cost function that may be used to determine an optimal batch size for the production run [3].

A Dehumidifier with different loading condition was studied. Desiccant Dehumidification cooling system is widely used in conventional purpose and dehumidifying the evaporative air comes from evaporative cooler [4]. Higher loading conditions resulted in higher latent capacity.

A study was made to achieve a set of strategies that can be adopted to increase capacity in production systems [5]. Toyota System of Production (TSP), Total Productive Maintenance (TPM) and Theory of Constraints (TOC) where some of the strategies used to achieve the goal. They suggest that to reduce the preparation time, to improve the feed of the machines and avoid the time lost in the bottleneck typically require low investments [5]. The implementation of Six Sigma methodology is highly recommended.

METHODOLOGY

The methodology used for this project was a development where the batch size was doubled and loss on drying testing was performed to confirm that changes on the quantity of pieces per batch didn’t affect the critical to quality parameters. Execution of three batches of Surgicel SNoW sizes 1x2, 2x4, and 4x4 inches were manufactured as per proposed quantities. Once the filling process was completed, each batch was dehumidified in the dehumidification chamber following the proposed revisions to current process specifications. Once the dehumidification cycle was completed and verified, each batch continued the manufacturing process through sterilization. During the sealing process, samples for LOD testing were taken at random, sent to the QA Laboratory for LOD testing.

RESULTS

Batch 1 of size 1x2 was successfully dehumidified at minimum parameters in the dehumidification chamber. LOD results for the batch ranged between 1.27-2.29% with an average of 1.75% and a Ppk of 3.83. As such, the batch dehumidification was found to be successful.

Batch 2 of size 2x4 was successfully dehumidified at minimum parameters in the dehumidification chamber. LOD results for the batch ranged between 0.92-2.13% with an average of 1.63% and a Ppk of 3.83. As such, the batch dehumidification was found to be successful.

Batch 3 of size 4x4 was successfully dehumidified at minimum parameters in the dehumidification chamber. LOD results for the batch ranged between 0.53-1.85% with an average of 1.31% and a Ppk of 6.53. As such, the batch dehumidification was found to be successful.

All results are presented in Table 1. These results provide confirmation that the dehumidification chamber dehumidifies SNoW product codes using the proposed quantities and minimum parameters.

Table 1
Summary of LOD Testing

Batch	Size (in)	Maximum LOD (%)	Ppk	Pass/ Fail
1	1x2	2.29	3.83	Pass
2	2x4	2.13	3.83	Pass
3	4x4	1.85	6.53	Pass

CONCLUSION

As a result of this testing activity, it is concluded that the dehumidification process has successfully passed Development testing based on the acceptance criteria specified in the protocol. This Development has established by objective evidence that the dehumidification process, under anticipated conditions, can consistently produce LOD results of less than 5.5%, which meets all predetermined requirements.

REFERENCES

[1] Abu Jadayil, W., Khraisat, W., & Shakoor, M. (2017). Different strategies to improve the production to reach the optimum capacity in Plastic Company. *Cogent Engineering*, *4*(1), 1389831. https://doi.org/10.1080/23311916.2017.1389831.

[2] Mussche, H. (2019, March). Determining the impact of batch sizes on the effective ... Retrieved April 1, 2022, from https://feb.studenttheses.ub.rug.nl/22917/1/Thesis_3272753.pdf.

[3] Sarker, B. R., & Parija, G. R. (1994). An Optimal Batch Size for a Production System Operating Under a Fixed-Quantity, Periodic Delivery Policy. The Journal of the Operational Research Society, 45(8), 891–900. https://doi.org/10.2307/2584013.

[4] Tripathi, Ram Ji & Verma, A. (2022). PERFORMANCE EVALUATION OF DESICCANT DEHUMIDIFIER WITH DIFFERENT LOADING CONDITION. Available https://www.researchgate.net/publication/357700503_PERFORMANCE_EVALUATION_OF_DESICCANT_DEHUMIDIFIER_WITH_DIFFERENT_LOADING_CONDITION.

[5] Augusto, D., Pergher, I., Fernando, C., & Scwenberg, C. (2013, October 19). View of strategies for increasing productivity in production systems: Independent Journal of Management & Production. View of Strategies for increasing productivity in production systems | Independent Journal of Management & Production. Retrieved April 1, 2022, from http://www.ijmp.jor.br/index.php/ijmp/article/view/134/380.