

cannot be relied upon until the inspection characteristic can be brought back fully under control through observing the control chart, then reanalyzing the capability plots to verify the state of the process.

It is important to note that in order to guarantee the procurement of raw materials with stable, predictable, and conforming inspection properties indicating a Good Manufacturing Practice (GMP) throughout the production processes, statistical quality monitoring must be established from the outset of the manufacturing process for chemical production. This duty should not be undervalued. When it comes to taking the lead in a competitive market, any respectable business that uses GxP—a typical acronym for quality standards and suggestions that are regarded as “good practice”—must use the system (Eissa & Rashed, 2020). The “x” stands for the various fields in which it might be used. A collection of quality standards is commonly referred to by the acronym GxP. The final dosage forms’ functional values would represent the quality of each individual component. In a world where the number of sick people is always rising, this is vital when it comes to the lives and health of the patients.

The above implemented technique could guarantee the monitoring and management of the inspection properties, but transformation might alter the time series plot’s original shape, which might make extrapolation during investigation more complex and harder. Additionally, more data—and hence, more batches—are needed to create reliable criteria using control charts in order to restore the inspection characteristic under investigation’s quality standards.

CONCLUSION

Based on the non-normally distributed dataset, process-behavior plots were used to illustrate how the manufactured raw material quality fluctuated between batches, exhibiting out-of-control states. Additionally, the process capability monitoring revealed that tightening the differences in the inspection characteristic (assay) between consecutive products is necessary to attain a better performance index level and that performance needs to be improved. The average line is also moved away from

the reference center. In order to reduce the possibility of uncontrollable outcomes that are either above or below the limiting thresholds in the future, the process mean should be moved as close to the center as possible. Other medicinal substances made by the manufacturer should be incorporated in future research investigations along with other inspection characteristics of the pharmaceutical raw material. Additionally, as a crucial component of the quality improvement system, the inquiry would include all the chemicals that the pharmaceutical manufacturer produces.

Compliance with Ethical Standards

Conflict of Interest

The author declares that there is no conflict of interest.

Ethical Approval

For this type of study, formal consent is not required.

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Data Availability

The data that support the findings of this study are available from the corresponding author on request.

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