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Qualitative Risk Assessment in V-Blender Using Bayesian Network

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Abstract
The development of solid dosage is very important in the production process, especially in powder blending. Moreover, the homogeneity of products can be influenced by the performance of powder blending operations that do not conform to the desired specifications and therapeutic effect as regulation by the Food and Drug Administration (FDA) may be detrimental to consumers. In addition, the International Conference on Harmonization (ICH) has also taken initiatives to improve production standards by establishing ICH 9 for Quality Risk Management (QRM). This is why drugs must be manufactured with high quality, safety, and effectiveness to ensure the safety of drug manufacturers as well as consumers. The objective of this research work is to study and investigated the probabilistic relationship between process parameters that can affect the blender performance that led to blending inhomogeneity by using the Qualitative Risk Assessment (QRA) method. QRA method is performed in order to categorize the identification risk level exposed in powder blending with low, medium, and high levels. The method of QRA that has been applied in this study is the Bayesian Network (BN) model. Furthermore, the BN is one of the risk assessment tools that present the parameters and their conditional independence using a directed aversion plot (DAG). The BN was used to verify the process parameters that could cause the failure of blending unit operation are fill level, loading order, blending time, and blending speed. However, from the outcome, the critical process parameters (CPPs) that have a greater risk of affecting homogeneity are a combination of fill level, loading order, and blending speed with 0.62 while the highest probabilities value of failure was a combination of fill volume, loading order and blending time with 0.92. The medium probabilities value of failure was a combination of fill level, blending time, blending speed, and combination of loading order, blending time and blending speed, which was 0.77 and 0.69, respectively. Moreover, it can be concluded that the failure that caused by the related process parameter is 0.75 for a true statement while the false statement is 0.25. This can be concluded that not all of the process parameters can impact the blender operation on the degree of product homogeneity. For further studies, it is possible to address the limitation of the BN in combination with a quantitative risk assessment to confirm the results and minimize the risk of failure by practicing the preventive method.

Keywords: Qualitative Risk Assessment; Blending unit operation; Bayesian network; Risk analysis.