**Shipment Validation of Solid and Suppository Dosage Forms on Non-Cold Chain Finished Products in Pharma Industry**

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**Background and aims.** The distribution of pharmaceutical products is a crucial stage in the supply chain. While cold chain products are commonly associated with strict temperature controls, non-cold chain products, such as tablets and suppositories, also require careful environmental monitoring, particularly in tropical regions like Indonesia. Distribution validation for non-cold chain products remains limited in practice. To align with Good Manufacturing Practice and Good Distribution Practice standards, there is an urgent need to implement distribution validation under realistic transport conditions.

**Methods.** This study employed an experimental quantitative approach involving real-time distribution of solid and suppositories products. Worst-case products for each dosage form were selected based on shelf life, storage conditions, and potential degradation risks. Temperature and humidity were monitored using calibrated data loggers during shipment. Post-distribution quality tests were conducted and compared with pre-distribution results to assess product stability.

**Results.** The distribution route with the highest risk score was identified as distributor located in Manado City (North Sulawesi), covering 3,289 km over 23 days via multimodal transport. Temperature profiling identified the hottest point in the container with an average temperature of 31.50 °C. During the actual shipment, data logger readings at this critical point recorded an MKT of 31.78 °C, exceeding the WHO defined Controlled Room Temperature for zone IVb. Post-distribution quality evaluations showed no significant changes in solid dosage forms. However, suppositories showed physical deformation and reduction of the active substance content.

**Conclusion/Discussion.** This study demonstrates that distribution validation for non cold-chain pharmaceutical products is feasible and effective for formulations stable at ambient temperatures. Products with higher thermal sensitivity, such as lipid-based suppositories, are more susceptible to degradation during shipment and require stricter environmental controls. These findings support the implementation of product-specific distribution strategies, including the potential use of isothermal packaging or partial cold chain systems, particularly for thermolabile dosage forms.

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