

An Effort at Improving Reliability of Laboratory Data in Titrimetric Analysis for Zinc Sulphate Tablets Using Validated Spreadsheet Calculators

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Abstract : The requirement for maintaining data integrity in laboratory operations is critical for regulatory compliance. Automation of procedures reduces incidence of human errors. Quality control laboratories located in low-income economies may face some barriers in attempts to automate their processes. Since data from quality control tests on pharmaceutical products are used in making regulatory decisions, it is important that laboratory reports are accurate and reliable. Zinc Sulphate (ZnSO_4) tablets is used in treatment of diarrhea in pediatric population, and as an adjunct therapy for COVID-19 regimen. Unfortunately, zinc content in these formulations is determined titrimetrically; a manual analytical procedure. The assay for ZnSO_4 tablets involves time-consuming steps that contain mathematical formulae prone to calculation errors. To achieve consistency, save costs, and improve data integrity, validated spreadsheets were developed to simplify the two critical steps in the analysis of ZnSO_4 tablets: standardization of 0.1M Sodium Edetate (EDTA) solution, and the complexometric titration assay procedure. The assay method in the United States Pharmacopoeia was used to create a process flow for ZnSO_4 tablets. For each step in the process, different formulae were input into two spreadsheets to automate calculations. Further checks were created within the automated system to ensure validity of replicate analysis in titrimetric procedures. Validations were conducted using five data sets of manually computed assay results. The acceptance criteria set for the protocol were met. Significant p-values ($p < 0.05$, $\alpha = 0.05$, at 95% Confidence Interval) were obtained from students' t-test evaluation of the mean values for manual-calculated and spreadsheet results at all levels of the analysis flow. Right-first-time analysis and principles of data integrity were enhanced by use of the validated spreadsheet calculators in titrimetric evaluations of ZnSO_4 tablets. Human errors were minimized in calculations when procedures were automated in quality control laboratories. The assay procedure for the formulation was achieved in a time-efficient manner with greater level of accuracy. This project is expected to promote cost savings for laboratory business models.

Keywords : data integrity, spreadsheets, titrimetry, validation, zinc sulphate tablets

Conference Title : ICIIP 2021 : International Conference on Industrial Pharmacy

Conference Location : Montreal, Canada

Conference Dates : June 14-15, 2021