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REVIEWER'S REPORT

Manuscript No.: **IJAR-53039** Date: 30-07-2025

Title: ICH Q2(R1)-Guided Validation of a Normal Phase HPLC/UV Method for Thiram in Technical WP Formulations Complying with SANCO QC Standards

Recommendation:
Accept as it is .....YES.....
Accept after minor revision.....
Accept after major revision .....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality			✓	
Techn. Quality			✓	
Clarity			✓	
Significance			✓	

Reviewer Name: Tahir Ahmad

Reviewer's Comment for Publication.

Summary of Content:

The manuscript presents the development and validation of a normal-phase HPLC/UV method for the quantification of thiram in 80% WP formulations. The method adheres to ICH Q2(R1) validation criteria and meets SANCO residue standards (SANCO/12571/2013 rev.3). Using a silica-based normal-phase column with hexane/isopropanol solvent mixtures, the method demonstrates strong retention and sharp UV-detectable peaks at thiram's λ_max (~230–254 nm). Validation parameters include specificity, accuracy, precision, linearity, sensitivity, and robustness. Key findings indicate that the method achieves recoveries between 98–102% across 80–120% spike levels, with correlation coefficients (r^2) ≥ 0.998. Intra- and inter-day RSDs are ≤2% and ≤3%, respectively. LOQ meets or exceeds the SANCO threshold of 0.01 mg/kg for plant matrices. Method tolerance to deliberate variations and stability of processed and standard solutions is confirmed. The validated method is positioned as suitable for routine regulatory analysis of thiram residues in diverse matrices.

Strengths:

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- The study is based on internationally recognized guidelines (ICH Q2(R1) and SANCO), ensuring broad regulatory applicability.
- A detailed description of validation parameters such as specificity, accuracy, and precision is provided, with clear acceptance criteria and supporting results.
- The method demonstrates robust performance across a range of concentrations with excellent linearity and recovery.
- The inclusion of system suitability parameters (retention time, theoretical plates, tailing factor) reinforces the reliability of the method.
- The application scope includes routine regulatory analysis for food/feed and environmental matrices, highlighting the relevance of the work.

Scientific Quality:

The manuscript is well-structured with a comprehensive validation strategy that aligns with standard regulatory practices. The approach covers all critical aspects, including matrix effects, blank and placebo verification, and robustness under minor variations. Stability studies for both samples and standards add further depth to the validation.

Relevance and Impact:

This work is highly relevant to analytical chemists, regulatory agencies, and quality control laboratories involved in pesticide residue monitoring. By addressing sensitivity requirements (≤ 0.01 mg/kg) for dry crops and WP formulations, the method directly supports public health and environmental safety measures.

Overall Evaluation:

The manuscript delivers a robust, validated HPLC/UV method that meets stringent international guidelines for pesticide residue analysis. Its comprehensive validation data and applicability to regulatory frameworks make it a valuable contribution to analytical quality control in agriculture and related industries.