ISSN: (O):3107-7889
Jana Nexus: Journal of Health and Medicine
Publisher's Name: Jana Publication and Research LLP
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REVIEWER'S REPORT

Manuscript No.: JNHM -110

Title: Optimizing Sanitization and Access Control: Lessons from a Cleaning Validation Study.

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

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

Reviewer Id: JPR-347

Reviewer's Comment for Publication.

This manuscript addresses an important aspect of pharmaceutical manufacturing by evaluating microbial contamination during cleaning validation and identifying practical corrective measures to improve sanitization effectiveness. The topic is relevant to current Good Manufacturing Practices (cGMP) and quality assurance in pharmaceutical industries. The work has practical significance, especially for microbiological monitoring and contamination control in non-sterile manufacturing facilities.

Major strengths

1. The study investigates a practical industrial problem with direct relevance to pharmaceutical manufacturing.
2. A systematic root cause analysis was conducted to identify factors contributing to elevated microbial counts.
3. The remediation measures are practical, scientifically justified, and demonstrated improved cleaning validation outcomes.
4. The manuscript provides useful operational recommendations regarding sterilization of templates, use of IPA-soaked lint-free cloths, environmental monitoring, fumigation frequency, and access control.
5. The study follows recognized microbiological testing procedures and references USP <61>.

Minor revisions recommended

1. **Language and grammar**
   - The manuscript requires thorough English language editing. Numerous grammatical errors, awkward sentence structures, spacing issues, and typographical mistakes should be corrected throughout the manuscript.
2. **Statistical analysis**
   - The manuscript states that the results were "not statistically significant with respect to p-value <0.05," but no statistical test is described.
   - The authors should specify:

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- the statistical method used,
- sample size,
- calculated p-values,
- confidence intervals where applicable.

- If inferential statistics are unnecessary because this is a validation study, the statement should be removed.

3. **Methodology**
   - More detail should be provided regarding:
     - sampling rationale,
     - selection of sampling sites,
     - number of replicate samples,
     - validation of the swabbing recovery method,
     - justification of acceptance criteria.
4. **Results presentation**
   - Figures should be presented with higher resolution and consistent numbering.
   - Tables should be reformatted for improved readability and consistency.
   - Mean values should be checked for consistency (the manuscript reports both 8.33 and 8.38).
5. **Discussion**
   - The discussion should compare findings with previous published cleaning validation studies rather than only restating the observed results.
   - The novelty of the findings should be emphasized more clearly.
6. **References**
   - Several references require formatting according to the journal style.
   - Web references should include access dates where appropriate.
   - Some citations are incomplete and should include DOI information where available.
7. **Limitations**
   - The authors should include a brief section discussing study limitations, including:
     - single manufacturing site,
     - single product evaluated,
     - relatively small sample size,
     - limited duration of monitoring.
8. **Formatting**
   - Uniform formatting should be applied throughout the manuscript, including headings, spacing, units, abbreviations, and table captions.

Overall Recommendation

The manuscript presents useful industrial observations and practical corrective actions for improving microbiological cleaning validation. Although the study is not highly novel from a scientific perspective, it provides valuable applied information for pharmaceutical quality assurance. After minor revision to improve language, statistical reporting, presentation, and discussion, the manuscript would be suitable for publication.