ISSN(O): 2320-5407 | ISSN(P): 3107-4928

ISSN NO. 2320-5407

International Journal of Advanced Research

Publisher's Name: Jana Publication and Research LLP

www.journalijar.com

REVIEWER'S REPORT

Manuscript No.: IJAR-57703

Title: DETERMINATION DE LA CONFORMITE DU PARACETAMOL 500mg COMPRIME AU LABORATOIRE NATIONAL DE LA SANTE,

Recommendation:

Accept as it is .....

Accept after minor revision.....

Accept after major revision .....YES

Do not accept (*Reasons below*) .....

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

Reviewer's ID: JPR-094

Detailed Reviewer's Report

Reviewer's Report

 # Overall Evaluation

The manuscript addresses an important public health issue related to the quality control and conformity assessment of paracetamol tablets in Mali. The topic is relevant, particularly in low- and middle-income countries where substandard and falsified medicines remain a major concern. The study employs standard pharmacopeial analytical techniques including TLC, UV-Visible spectrophotometry, FTIR, disintegration testing, and visual inspection.

However, the manuscript contains several methodological inconsistencies, data interpretation errors, language deficiencies, formatting problems, and reference inaccuracies that significantly affect its scientific quality. Major revision is required before the manuscript can be considered for publication.

 # Strengths

1. **Relevant Public Health Topic**

*** The study addresses the critical issue of medicine quality and counterfeit pharmaceuticals in resource-limited settings.**

2. **Use of Standard Analytical Methods**

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*** Application of recognized analytical techniques:**

*** Thin Layer Chromatography (TLC/CCM)**
*** FTIR spectroscopy**
*** UV-Visible spectrophotometry**
*** Disintegration testing**
*** Visual inspection**

*** Use of British Pharmacopoeia (BP 2025) specifications strengthens methodological credibility.**

3. **Practical Laboratory-Based Study**

*** Real-world sampling from the Pharmacie Populaire du Mali (PPM) increases practical significance.**

4. **Comprehensive Physicochemical Evaluation**

*** Multiple quality parameters were assessed instead of relying on a single test.**

5. **Regional Importance**

*** Provides useful preliminary data on medicine quality surveillance in Mali and Sub-Saharan Africa.**

 # Weaknesses

Major Weaknesses

1. Serious Data Inconsistency in Table III

*** Sample **23-P11DC** shows:**

*** 98.3% assay**
*** 418.6 mg/comprimé**

*** The stated acceptable BP range is:**

*** 475–525 mg/tablet**

*** Therefore, this sample is clearly **non-compliant**.**
*** However, the manuscript incorrectly states that all samples were compliant.**

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2. Contradictory Conclusions

*** The conclusion claims:**

> "aucune autre non-conformité n'a été détectée"
*** This contradicts the assay table results.**

3. Small Sample Size

*** Only 20 batches were analyzed.**
*** Sample representativeness is insufficient to draw broader conclusions about the national market.**

4. Incomplete Method Validation

The manuscript lacks:

*** calibration curves,**
*** precision studies,**
*** accuracy,**
*** repeatability,**
*** limit of detection,**
*** limit of quantification,**
*** validation of UV analytical method.**

5. Statistical Analysis Missing

*** No statistical treatment of data:**

*** mean ± SD,**
*** confidence intervals,**
*** variability analysis,**
*** comparative statistics.**

6. Weak Discussion Section

*** Discussion is mostly descriptive.**
*** Limited critical comparison with previous studies.**
*** No explanation for regulatory non-compliance.**
*** No risk assessment regarding missing manufacturing dates.**

7. Reference Quality Problems

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Several references are:

*** incomplete,**
*** improperly formatted,**
*** duplicated,**
*** outdated,**
*** non-scientific (Wikipedia, web pages).**

 # Key Points / Major Comments

1. Correct Assay Result Interpretation

*** Recheck Table III values.**
*** 418.6 mg/tablet is outside BP limits.**
*** Either:**

*** the calculation is incorrect,**
*** or the conclusion must be revised.**

2. Improve Scientific Writing

The manuscript contains:

*** grammatical errors,**
*** spacing inconsistencies,**
*** typographical mistakes,**
*** formatting issues,**
*** inconsistent French and English usage.**

Examples:

*** "BIBLOGRAPGIQUES"**
*** "choisit" instead of "choisie"**
*** inconsistent spacing around punctuation.**

Professional language editing is strongly recommended.

3. Clarify Sampling Strategy

Authors should specify:

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*** sampling method,**
*** selection criteria,**
*** batch origin,**
*** manufacturer information,**
*** randomization procedure.**

4. Improve Methodological Details

The following are missing:

*** preparation of standard solutions,**
*** instrument calibration,**
*** number of replicates,**
*** environmental conditions,**
*** acceptance criteria for FTIR similarity.**

5. Figures Require Improvement

*** Spectra and chromatograms are poorly described.**
*** Figures lack:**

*** resolution,**
*** labeling,**
*** axis descriptions,**
*** interpretation.**

6. Reference Formatting

The reference section should follow a uniform journal style:

*** Vancouver,**
*** APA,**
*** or journal-specific format.**

 # Scientific Significance

The study has moderate scientific and public health significance because:

*** counterfeit and substandard medicines are a major issue in Africa,**
*** paracetamol is one of the most consumed medicines worldwide,**

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*** quality surveillance studies are limited in Mali.**

The work could contribute useful baseline surveillance data if methodological and analytical weaknesses are corrected.

 # Novelty

*** The study has **limited novelty** scientifically because similar paracetamol quality evaluation studies have already been conducted in:**

*** Cameroon,**
*** Ethiopia,**
*** East Africa,**
*** other African regions.**
*** However, the Mali-specific dataset provides some regional value.**

 # Recommendation

Recommendation: MAJOR REVISION

The manuscript should not be accepted in its current form due to:

*** inconsistent analytical data,**
*** incorrect interpretation,**
*** lack of statistical analysis,**
*** methodological insufficiencies,**
*** language and formatting problems.**

The authors should:

1. Correct all inconsistencies in assay data.
2. Reanalyze non-compliant samples.
3. Add statistical analysis.
4. Improve discussion and interpretation.
5. Revise references thoroughly.
6. Perform professional English/French editing.
7. Clarify methodology and validation procedures.

After substantial revision, the manuscript may be reconsidered for publication.

Major Revision Justification with Issues and Reasons (Line by Line)

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Line No.	Issue Identified	Reason for Major Revision
5–9	Introduction in abstract is too broad and repetitive	The background excessively discusses counterfeit medicines generally but does not specifically justify why paracetamol 500 mg in Mali requires investigation.
10–11	Objective poorly written ("étaitd'évaluerla")	Formatting and spacing errors reduce readability and scientific professionalism.
12–16	Methodology lacks validation details	No mention of sample size justification, analytical validation parameters, calibration procedures, precision, specificity, or accuracy of methods used.
14	Use of BP 2025 specification only	The manuscript does not explain why BP standards were selected over USP or Ph. Eur., reducing methodological justification.
15–16	Analytical parameters incomplete	Dissolution testing, hardness, friability, and assay validation are absent although essential in tablet quality evaluation.
17–18	Regulatory non-conformity poorly analyzed	Authors mention missing manufacturing date but fail to discuss legal implications, pharmacovigilance concerns, or traceability risks.
19–20	Contradictory findings	One batch (23-P10DC = 472.2 mg) and another (23-P11DC = 418.6 mg) are below BP limits (475–525 mg), yet authors claim all batches were compliant. This is a major scientific inconsistency.
23–38	English abstract contains grammatical errors	Several language problems reduce clarity and scientific quality. Example: "People's Pharmacy of Mali" and "Disintegration" phrasing is awkward.
41–42	Unsupported claims	Statements regarding toxicity and publications require updated references and clearer context.
48–50	Weak rationale	The importance of medicine quality evaluation is generic and not linked specifically to Mali's pharmaceutical surveillance system.
53–58	Poor sentence construction	Grammatical structure is weak and difficult to understand scientifically.
59–65	Statistics not critically	WHO statistics are cited without critical

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Line No.	Issue Identified	Reason for Major Revision
	discussed	interpretation or relevance to local prevalence in Mali.
66–73	Literature review insufficiently synthesized	Previous studies are merely listed without comparing methodologies or analytical outcomes with the current study.
74–75	Weak study justification	Claiming paracetamol is "most prescribed" is insufficient to justify study novelty.
77–80	Study design incomplete	No mention of ethical approval, sampling strategy, inclusion/exclusion criteria, or study limitations.
82–84	Sampling methodology unclear	Authors do not explain whether sampling was random, stratified, convenience-based, or representative of the market.
85–94	Excessive instrument details	Listing serial references of instruments is unnecessary and distracts from scientific content.
96–99	Visual inspection subjective	Organoleptic examination lacks standardized evaluation criteria or scoring method.
100–104	Disintegration method incomplete	Rotation speed, medium volume, apparatus type, and acceptance criteria are missing.
107–118	TLC methodology insufficient	Mobile phase composition, plate specifications, and reference standard preparation are absent, making reproducibility impossible.
117	Incorrect Rf formula usage	Rf values are dimensionless ratios and should not be expressed as percentages in this context. Formula application appears scientifically inaccurate.
119–126	FTIR method lacks spectral interpretation	No characteristic peaks or wave number assignments are discussed adequately.
128–138	UV method incomplete	Standard preparation concentration, calibration curve, linearity, and validation data are absent.
137–138	Formula formatting corrupted	Equation presentation is unclear and improperly formatted, affecting reproducibility.
141–142	Grammar error ("choisit")	Indicates insufficient language editing.
145	Table formatting poor	Tables are not properly aligned and column

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Line No.	Issue Identified	Reason for Major Revision
		headings are unclear.
146–150	Contradiction in visual inspection results	Authors state all samples were compliant while simultaneously reporting non-conformity in 7 batches.
153–155	TLC interpretation weak	Authors only describe "violet spot" without providing chromatograms, retention comparison images, or standard deviations.
166–168	Statistical analysis absent	No statistical treatment of Rf variability or confidence intervals.
170–171	Major data inconsistency	Batch 23-P10DC (472.2 mg) and 23-P11DC (418.6 mg) fail BP specifications, yet discussion and conclusion claim 100% conformity. This invalidates conclusions.
173–175	Incorrect conclusion	Statement of complete conformity is scientifically false based on presented data.
183–197	UV spectra poorly interpreted	Spectra are described superficially without discussing absorbance specificity, interference, or wavelength justification.
198–208	Uniformity of mass methodology absent	Number of tablets tested and acceptance calculations are not described.
203–208	No statistical descriptors	Mean, SD, RSD, or confidence intervals are absent.
215–217	FTIR interpretation weak	Authors do not identify functional groups corresponding to observed peaks.
219–257	Discussion lacks critical depth	Results are mainly repeated rather than critically analyzed scientifically.
223–224	Incorrect percentage calculation	Authors state "7 lots sur 13 = 53.8%," but total analyzed lots were 20. This creates confusion and suggests calculation inconsistency.
228–232	Inadequate comparison with literature	Comparative discussion lacks analytical rigor and does not explain observed differences.
244–250	Major contradiction repeated	Discussion again claims all batches complied despite numerical non-compliance in Table III.
258–265	Conclusion unsupported	Final conclusion ignores non-compliant dosage values and overstates conformity.
267	Typographical error	Indicates insufficient proofreading.

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	("BIBLOGRAPGIQUES")	
272	"Acetaminohen Toxicity" misspelled	Reference quality is poor.
Multiple references	Inconsistent referencing style	References mix French and English styles, incomplete journal details, missing DOI, inconsistent capitalization, and formatting errors.
Multiple sections	Absence of statistical analysis	No inferential or descriptive statistical analysis provided throughout the study.
Entire manuscript	Language quality poor	Numerous grammatical, typographical, and formatting errors reduce publication quality.
Entire manuscript	Lack of novelty	Study largely confirms expected pharmacopeial compliance without introducing methodological innovation or broader epidemiological significance.
Entire manuscript	Figures of poor scientific value	Figures are not adequately labeled, discussed, or interpreted quantitatively.
Entire manuscript	No study limitations	Authors fail to discuss limitations such as sample size, geographic restriction, or lack of dissolution studies.

Overall Recommendation: MAJOR REVISION

Main Reasons

Serious contradiction between assay data and claimed compliance.

Incomplete analytical methodology and lack of validation.

Absence of statistical analysis.

Weak scientific discussion and interpretation.

Significant language, formatting, and referencing problems.

Unsupported conclusions inconsistent with presented results.

Important pharmacopeial tests such as dissolution and hardness are missing.

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The manuscript requires substantial scientific correction, methodological clarification, statistical analysis, language editing, and revision of conclusions before reconsideration for publication.