

Review Form 1.6

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| Journal Name: | Journal of Pharmaceutical Research International |
| Manuscript Number: | Ms_JPRI_80868 |
| Title of the Manuscript: | Protocol of Comparative Evaluation of Efficacy of Kulattha Gutika with Atorvastatin in the Management of Dyslipidemia (Medoroga) |
| Type of the Article | |

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

<https://www.journaljpri.com/index.php/JPRI/editorial-policy>

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PART 1: Review Comments

| | Reviewer's comment | Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here) |
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| Compulsory REVISION comments | <ol style="list-style-type: none"> 1. In the abstract-Group A (Interventional) patients will be treated with <i>KulatthaGutika</i> 1 gm thrice a day after meal with warm water for 45 days and Group B (Experimental group) will be given Tab, Atorvastatin 10mg at bedtime with warm water for 45 days. Here, intervention should be changed to an experimental or test group and experimental group should be changed to a standard or positive control group. 2. In abstract- Aim and objectives-Comparative—it is comparative 3. In the title it was given that ---Comparative Evaluation of Efficacy of Kulattha Gutika with Atorvastatin in the Management of Dyslipidemia... Please rephrase the title. 4. In Research Gaps Analysis..... Nephrolithic-----???? 5. Type of trial--. It will include, a 45 days treatment period, and a 15th, 30th 45th day week follow-up period—whole sentence is future tense.... Change the tense... further it is not clear that follow up will be after 45 days of therapy???? Please rephrase the sentence for a better understanding of the readers. 6. Methodology....Allocation ratio.....This should be changed to sample size and grouping and also mention and justify the sample size calculation. Furthermore, the sample size is 60.. So it should be under the pilot study category. 7. Further need details of ethical clearance and CTRI registration which are missing in the manuscript. 8. In addition to this study design, the manuscript lacks the duration, study site, inclusion and exclusion criteria, consent form, and consenting procedures. 9. Allocation ratio – Total 60 patients will be selected for the study which will then be equally divided into two groups. Group A is experimental group whereas Group B is standard control. Please see the controversy surrounding this sentence and the corresponding sentence in the abstract. 10. Table I .. It was given as.... 1 Part... To be more specific... 11. Also briefly mention the preparation of the drug so that others can reproduce it without referring to other manuscripts. 12. In the manuscript, please try to use standard clinical trial terminologies like study site, inclusion and exclusion criteria, and subject selection criteria. 13. Always use English terminology in the brackets of Sanskrit or Ayurvedic words. 14. In eligibility criteria, whether measuring the body weight, BMI, abdominal circumference etc. 15. In case of investigation criteria, whether measuring physical values like weight, height, BMI etc. and vital such as BP, HR, PR etc. 16. We will measure quantity of Gutika for the consumption of appropriate dose for assessment and to | |

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| | <p>check drug adherence during treatment the subject will be followed up..... How? Whether by the pill count method?</p> <p>17. Follow up- whether diet chart is provided or planned to collect the subjects' notes</p> <p>18. Enrolment and interventions time schedule: So the total; study period in 45 days. I doubt that the clear effectiveness in dyslipidemia can be accurately measured in 45 days. Because it is such a short period, the data cannot be clearly measured.</p> <p>19. Ethical clearance details should be mentioned in the abstract also.</p> <p>20. Also, please mention the details of drugs in the discussion section. Try to correlate your results with the experimental proof via published literature regarding the dyslipidemia properties of the active ingredients.</p> <p>21. I also found several spelling and grammatical errors, especially in tense. Please pay special attention to the English language service before sending the revised files.</p> | |
| Minor REVISION comments | | |
| Optional/General comments | | |

PART 2:

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| | Reviewer's comment | Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here) |
| Are there ethical issues in this manuscript? | <i>(If yes, Kindly please write down the ethical issues here in details)</i> | |

Reviewer Details:

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|----------------------------------|-----------------|
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