

Research Proposal

Title: Improvement of in-vitro and in-vivo correlations studies on medicinal products to avoid in-vivo Bio-equivalence studies

Background:

Most of the companies spending the lot money to complete the Bio-equivalence studies and many of the healthy volunteers are getting affected one or other reason by exposing all of these drugs used for Bio-equivalence studies. Currently, most of the regulatory agencies are interested to approve the drugs by in-vitro bio-equivalency studies. Few of the drugs approved for Topical products only, in this research would like to extend the similar technology to the other dosage forms to avoid bio-equivalence studies

https://www.accessdata.fda.gov/drugsatfda_docs/psg/Acyclovir_topical%20cream_RLD%2021478_RV12-16.pdf

As part of the research existing medicinal products will be selected and will be compared with in-vitro bio-equivalence and in-vivo bio-equivalency studies in terms of IVIVC correlation.

Research activity will be carrier in following manner

1. Selection of Medicinal product Category
2. Characterization of the Active ingredient
3. Selection of Route of administration
4. Section of Inactive ingredients
5. Experiments for Formulation preparation
6. In-vitro studies (IVPT and IVRT)
7. In-Vivo studies data (if necessary)
8. Results and discussion
9. Conclusion

Based on current industrial experience on research proposed research will be completed in within 2 years of timeframe. Once the admission process is completed I will submit the clear strategy for Research proposal and time line for completion of the activity.

Thanks,

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