Project Scope

- ✓ Patent analysis report of existing formulation and product development plan will be shared with Client
- ✓ Formulation Development with 6M stability studies to be completed by LODAAT.
- ✓ Product development report (PDR) will be done by LODAAT and this report will be shared with Client for approval.
- ✓ Complete analytical method development and validation and forced degradation studies have been completed. Complete validation studies report along with stability protocols will be shared with Client.
- ✓ After the approval of patent analysis reports, PDR and validation reports the technology transfer document (TTD) will be shared with Client.
- ✓ Once the TTD is approved, approval on the travel of scientists from LODAAT to Client will be taken and technology transfer can be initiated.
- ✓ LODAAT and CLIENT shall review technology transfer results and decide action plans, if any.
- ✓ Bio studies Pilot/ Pivotal will be conducted by Client. If required the BE study monitoring can be done by LODAAT at an additional cost.
- ✓ LODAAT/ Client to review the Bio study results. LODAAT will re develop the formulation once if the pilot Bio-study fails in case it fails because of the formulation.
- ✓ LODAAT shall issue development reports (duly signed copy) to CLIENT. These reports will cover all necessary data, records for dossier compilations as per Module 3 of EU CTD format.
- ✓ CLIENT shall compile the dossier and the submission would be done by CLIENT. In case the client decides to get the dossier compiled by LODAAT the same can be done at an additional cost mutually agreed.
- ✓ If applicable, CLIENT to provide relevant deficiency comments, response timelines to LODAAT & Also arrange to provide clarity on relevant points on need basis. LODAAT to provide deficiency related response to CLIENT as per agreed timelines.
- ✓ LODAAT to decide on additional experimentation if required, as per deficiency comments. CLIENT and LODAAT shall discuss and mutually agree on timelines accordingly.
- ✓ CLIENT informs the status of regulatory procedure completion to LODAAT.

Click Here to see a facility implementing our TECH-TRANSFER http://lodaatpharma.co

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