



Formulation development/studies

In topical products the formulation has a high impact on the performance of the product. An effective drug in an unsuitable formulation can be less successful in the clinic than a less suitable drug in an optimised formulation. It is important to decide upon the final formulation at an early stage. Preclinical and phase I studies will have to be redone at high cost and loss of time unless the final formulation is used.

Zelmic offer the following specific types of formulation studies:

Preformulation

- Solubility studies
- Compatibility with standard and proprietary formulations.

Formulation screening

- Dose finding
- Selection of vehicle type cream, ointment, stick etc.

Initial formulation work

- Formulation compounding
- Stability studies (screening and accelerated studies)
- "In vitro" penetration studies
- Selection of formulation/formulation candidates

Formulation development

- Manufacturing process/method
- Scale up to 8 kg
- Generation of data for regulatory evaluation

Product transfer

- Generation of SUPAC methods
- Transfer of manufacturing method to commercial manufacturers

IP

- Development of patented compositions/products
- Generation of patent applications
- Investigation on patentability/potential infringement

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Formulation development/studies

Zelmic offer to perform individual formulation studies but can also operate as responsible for the pharmaceutical development.

Deliverables

In long term studies the deliverables will be decided from time to time by the client. In general Zelmic will deliver

Monthly report containing

- Status for ongoing work
- All reports generated during the month
- Raw data
- Samples of product(s)

The work will be performed according to Zelmic practices. This means that all data is traceable and that the data is approvable for regulatory use.

If this is of interest to you please contact us at al@Zelmic.se or use the contact details below

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