PLAN OF WORK & METHODOLOGY

1.4.1 Selection of a product to work on.
Product marketing team, International Export team, experts & Buyers provide the name of Product which is required for export & marketing there according to the demand of the drug product in prevalent disease condition & profitability in that geographical area.

1.4.2 Literature Search:
Study & collect of information regarding formats & guidelines available for the CTD, EU-CTD & CIS Countries & background of proposed research.

- To Study the format of CTD, European Common Technical Document (EU-CTD) and for CIS Country-Russia

Collect the information about the Tianeptine sodium (Compendial Testing methods, SPC, PIL, Label etc)
The Common Technical Document is organized into five modules.

1.4.2.1 Requirement for module 1
1.4.2.2 Requirement for module 2
1.4.2.3 Requirement for module 3
1.4.2.4 Requirement for module 5

1.4.3 Drug Procurement, Characterization & Identification:

- Selection of Vendor (For API)
- Characterization of Tianeptine (By IR, Mass spectrum, GC)
- Identification by IR absorption spectrophotometry.
- Impurities & Related Substances: By Gas chromatography & Liquid Chromatography.
- Assay by Potentiometric titration.

1.4.4. Drug substance, Excipients & Packaging material compatibility studies.

1.4.5. Preparation of Tianeptine sodium 12.5 mg Capsules:

- Optimization of Product (Tianeptine sodium 12.5 mg Capsule)
- In order to ‘best optimized’ product 9 different formulation will be prepared (F1 to F9) taking by varying different key Excipients ratios, Average fill, Uniformity of weight & Dissolution as major testing parameters.
Evaluation of capsule properties after filling it by different Pharmacopoeial & non-pharmacopoeial methods.

Selection of a optimized formulation out of F1-F9, as Pilot scale for further study.

Selection of 3 Pilot scale batches for stability studies according to stability guidelines for different countries

Selection of manufacturing Batches for different validation studies (i.e Process & method validation etc.)

Preparation of manufacturing Batches according to the marketing requirements.

1.4.6 Dissolution studies at different time points

1.4.7 Preparation of dossier in C.T.D. Format for taking marketing approval of Tianeptine sodium in US

1.4.8 Preparation of dossier in C.T.D. Format for taking marketing authorization of Tianeptine sodium in U.K.

1.4.9 Preparation and submission of dossier in EU-C.T.D. format for taking marketing authorization of Tianeptine sodium in CIS Countries (Russia)
1.4.10 Preparation of non infringing strategy

Prior art search

Evaluation of patent identified as relevant
Ideas against claims, objectives, strategies and resources

Patented and develop product concepts
proposed plan for an appropriate strategy

Analysis of profitability
(Market, competition, costs etc)

Technical and commercial product development

Implementation of Proposed product

Commercialization