Regulatory Affairs Division

To offer our Customers a complete range of services, we have a separate Regulatory Affairs Division who provide all technical documentation and support with regard to API's, intermediates and fine chemicals. This mainly includes the following :

- Drug Master File is available - Open Part of the DMF as per the EEC Format against a Secrecy Agreement directly from the customer. All the documents can be provided to the customer on request.
- Method of Analysis - Besides/ in addition to the official pharmacopoeia.
- Material Safety Data Sheet (MSDS) / BSE - TSE Certificate
- Reference Working Standards and Purity Standards.
- Impurity Profile complying to ICH guidelines (Organic inorganic residual Solvents)
- Toxicity Data
- Stability studies.
- Registration Dossiers for Finished formulations & API's.
- Bio - equivalence and Bio - Availability Studies are available.

Due to the above technical support guaranteed by the Company, the customers opt to purchase several products from the company as the availability of such documents fulfill customers technical and regulatory requirements and hence we are able to develop a long term business relationship with several customers.