

DOCUMENTS REQUIRED IN CASE OF APPLICATIONS FOR FORMULATIONS :

1. Consolidated list of formulations applied for with packing particulars.
2. Specimen Labels.
3. Labels of similar products for Non-Pharmacopial drugs.
4. Method of Test/analysis for the finished products and also for the ingredients which are not specified in any Pharmacopiae or any official compendia of Drugs Standards.
5. Photo copies of monograph in respect of those drugs, which are not official in IP
6. In case of Loan Licensee- consent letter of the parent firm along with details available spare capacity and No. of Loan Licences already held by the Unit.
7. Declaration by the applicant stating that the same formulation was not earlier permitted either on the same brand name or under any other brand names.
8. Declaration of Technical Staff for manufacture or for Test/Analysis (Proforma-II) (Format enclosed)