DETAILS TO BE SUBMITTED BY THE MANUFACTURER ALONG WITH THE APPLICATION FOR THE ADDITIONAL PRODUCT.

01. Licence in FORM NO. __ bearing manufacturing Licence No. __ under which following products are proposed to be manufactured by M/s. _____ Daman.
02. If the proposed product is intended to be manufactured on the loan licence, name of the manufactory where it is proposed to be manufactured.
03. if the reply to '1' is affirmative, application should be accompanied by a letter from the manufacturer to the effect those similar products are being manufactured by them. The manufacturer should also incorporate details of the products viz. shelf life, date since manufactured etc.
04. Name of Additional Product with undertaking and duly signed, in 3 copies and 4 in case of Loan Licence.
05. Generic name if any
06. Category of Drug
07. Pharmacopoeial Claim
08. Strength to be Manufactured
09. Period of Shelf-life
10. Standards for Release
11. Name and Qualification of Technical Person for manufacturing section.
12. Whether similar products are manufactured by other manufacturers. If so, give name of the manufacturers and their product.
13. If the Product is a pharmacopoeia preparation, reference to pharmacopoeia should be stated in abbreviation.
14. Name and percentages of the preservatives in other dosage forms
15. In case of Tablets whether any diluents are added. If so, details thereof
16. In case of hard Gelatin capsules whether diluents are added? If so give details thereof
17. Dosage of the product.
18. Size of the packaging in which the proposed products is to be intended to be manufactured
19. Details of analysis
20. Details of analysis of all active ingredients present in the product, if it is Patent and Proprietary one
21. Details of Pharmaceutical aids

22. Stability study data in case of thermo labile ingredients present in product and proposed life period intended to be assigned to the product.
23. Data to show that proposed product contains constituent ingredients in therapeutic / prophylactic quantities as determined in relation to claims or conditions for which medicines are recommended for uses or claimed to be useful
24. Data to show that proposed product is safe for use in the context of vehicles, excipients, additives and pharmaceuticals aids used in formulation for administration and uses are recommended
25. In case of fine chemicals, flow-sheet of the unit processes involved in the manufacture of such chemicals should be attached. Information about the annual production and production per shift should also be attached
26. In case of products containing a new drug, true copy of letters from the DRUG CONTROLLER OF INDIA granting permission to manufacture the product should invariably be attached
27. Whether the product will be tested at own manufactory or at an approved laboratory, if the same is to be tested at an approved laboratory to consent letter from the approved laboratory to undertake testing should invariably be attached

Name of Approved Technical persons(s)

28. Whether any special type of machinery is provided for manufacture of this products
29. If the product is a combination formulation, data on the rational and efficacy for the ingredients present in the product, in-single & in-combination
30. Therapeutic indications or claims to be made on the labels or cartons of the product
31. Draft labels for PS & SALES

Category of Drugs

Trade Name

Generic Name

Label Claim

Name of the Colour

Storage Condition

Dosage

Any other information required

32. Whether this product was permitted earlier and withdrawn by Department if yes, please give details

33. Whether already permitted to manufacture this category or this is an application for addition category?

In addition to the above a Loan Licencee should furnish the following information also

Total no. of products permitted to the parent firm to manufacture on behalf of loan licencee.

Consent letter of the parent firm

No. of products permitted to the applicant

34. Any other information related with Drug (if any)

DECLARATION

I declare that the information stated above is true and in case if it is proved otherwise, my application would be liable for rejection without any notice.

I declare that to the best of my knowledge no other firm is determined to manufacture this product under the said brand name in case if any firm is found permitted to manufacture the produced under the same brand name, my permission is liable for cancellation without any notice.

AUTHORISED SIGNATORY.