INFORMATION DATA TO BE SUBMITTED ALONG WITH THE APPLICATION FORM FOR MANUFACTURE OF DRUG FORMULATIONS

1. Name and address of the firm:

i)Licence No: ii)Date of issue: iii)Valid upto:

2. If under loan licence

i)Name of the loanee firm:

ii)Licence No.: iii)Valid upto:

3. Fees paid Rs._____ Challan No._____ Dated _____

4. i)Generic name of the drug : Whether RM/FP official in any Pharmacopoeia (Pharmacopoeial edition & page No.) Yes/No

ii)Brand Name : Whether brand name undertaking submitted Yes/No

5. In case of :
a) New drug : i. Attested true copy of approval In Form 46 issued by D CG (I) Submitted/ not submitted
ii. Drug Profile Submitted/ not submitted
b)Other Drugs :

i. Date when cleared as new drug by DCG(India) :

ii. Date of clearance of FDC by DC G (India) :
iii. Submit sample of identical product being marketed

6. Therapeutic rationality of FDC :
7. Shelf life of the product :

8. Particulars of stability studies Conducted on product with unstable and thermo labile Drug substances : Submitted/not submitted

9. Fascimile of label/carton/Foil/Package (Please tick for submitted)

10. Detailed particulars of packing

A) Tablets & Capsules (Bulk/strip)
Type of container/foil

ii. Volume filled	:	
iii. Number of doses filled in (Multi dose container)	:	
E)Other dosage forms (Give all particulars)	:	
11. Proposed daily dosage of the product.	:	
12. Testing	:	
a. Whether in house facilities provided for complete analysis of R M/FP	:	Yes/No
b. Details of test to be carried out at approved testing laboratory.	:	

i)Raw material	Test	Name of laboratory	Approval No.
ii)Finished product	Test	Name of laboratory	Approval No.

(iii)Patent & Proprietory drug Submit specification & Consolidated method of analysis)	:	Yes/No
13 Whether approved facilities for manufacturing of the product provided	:	available/will be provided
14. Complete formula with list of excipients and specifications	:	submitted/not submitted.
15. Any other information	:	

Production In-charge

Quality analysis In-charge