List of Enclosures for Loan License

1	Descriptive covering letter and Application in Form-24E
2	Additional Information sheet
3	D. D. for Rs.2000/- in favour of Director, Directorate of Ayush, Bangalore
4	Letter requesting the manufacturer seeking their concern
5	Consent letter for manufacturing from manufacturing unit.
6	Consent letter from AYUSH Approved lab for testing
7	Commercial proof of premises
8	Aadhar card/ Driving License/ Passport
9	Basis of the possession of the premises- copies of lease or rental agreement /sale deed
10	Master Formula in duplicate, book references, proof of efficacy in case of proprietary medicine, testing protocols & Specifications Safety study reports in case of schedule E1 drugs
11	Proof of Constitution of firm; In case of Proprietor – sole proprietorship declaration If Partnership concern –attested copies of Partnership deed If company – Memorandum of Association, Articles of Association, If Trust : Trust Deed
12	Blue print of Loan license Unit
13	Affidavit regarding Non conviction of Director/partner/proprietor/ firm under Drugs & cosmetics Act 1940 & Drugs & Magic Remedies (Objectionable Advertisement) 1954 on Rs.100/- Stamp Paper
14	Stability study reports in case of P&P as per Ayurvedic Pharmacopeia of India as per Rule 161B of Drugs & Cosmetics Rules.

FORM – 24 E
(See Rule 153-A)

Application for the grant of a Loan license to manufacture for sale of Ayurvedic, Siddha or Unani Drugs

1. I / We_____ of _____hereby apply for the grant of a Loan license to manufacture Ayurvedic, Siddha or Unani Drugs on the premises situated at _____
C/o----------
2. Name of drugs categorized according to Schedule –T to be manufactured (with details)

3. The names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic, Siddha or Unani drugs in the manufacturing premises.

4. I/We enclose

   a) A true copy of the letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.
   b) A true copy of a letter from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.
   c) Specimen of labels, cartons of the drugs proposed to be manufactured.

5. A fee of rupees _____ _____ has been credited to the Government under the head of account _____ and the relevant Treasury challan/ online transaction slip is enclosed herewith.

Date:

Signature _____
(Applicant)

Note:

*Enter here name of the proprietor, partners or Managing Director as the case may be.

! Enter here the name of the applicant firm and the address or the principal place of business.

Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also the license number under which the latter operates.

To manufacture Ayurvedic medicines: to obtain new License/Loan License: Renewal of loan license Form 24-D: Form-24 E along with questionnaire. Submit the application to Drug Licensing Authority, Dept of AYUSH, Karnataka.

1)	1	Name of the Manufacturing company and address	:	
	2.	Company details: single ownership/ co-operative society/ partnership company etc., enclose necessary documents.	:	
	3.	Proprietor / Partner/ Director's full name, age and address	:	
2)		Education qualifications		
	1.	Applicant's qualification	:	
	2.	In-charge person's qualification	:	
3)		Total investment Annual Turnover of Medicine a) In India b) Out side India c) Total	: : : : :	
4)		Are you applying for new license or for renewal	:	
5)		What is the present occupation of applicant?	:	
6)		Details of Licenses granted under Drug and Cosmetic Act 1945	:	
		License No : Date :		
7)		Form 25 – D	:	
8)		Details of License renewal	:	

9)		Details of the granted licenses under the rules of Medicine and Toilet preparation Act 1955	:	
10)		Sales Tax registration No. (CST & KST dates)	:	
11)		Details of other licenses, if any?	:	
12)		Details of company registration under SSI & DGID unit	:	
13)		Details of fee paid for Form 24-D application		
14)	1.	Have you submitted the Blue print of Factory premises having not less than 1200 Sq. feet, along with the document details of building (own/ rental)	:	
	2.	Do you have any other manufacturing unit of the company? If yes, provide the details.	:	
	3.	Details of manufacturing the medicines as per GMP rules provide the details of machineries of the different sections, along with authentic books. Submit separate list for each section.	:	
	4.	Are the proposed medicines mentioned in the referential books as per Drugs & Cosmetics Act 1940, 1st schedule? Enclose the details separately along with photo copies.	:	
15)		Working time and No. of shifts	:	
16)		Manufacturing medicines details Ointment: Cream : Oil : Tablets : Capsules : Choorna : Proprietary Medicines etc., submit a separate list along with details	:	
17)		Is Technical person is employed for full time job? a) Name of the Technical person b) Age c) Qualification d) Working time	:	
18)		Have you analyzed the medicines? Send the analytical methods for 1) Raw materials 2) Manufactured Medicines	:	

19)		Employed workers 1) Technical 2) Non-Technical 3) Other employees – Salesman, Representative etc., Total	:	
20)	1.	Do your Medicines contain any poisonous ingredients? Provide the details.	:	
	2.	Are you adding colors, preservatives, perfume, Excipients, sugar or any other chemical ingredient in the medicines? If yes, provide the details. Submit the declaration of approved colors.	:	
21)		Do you have the following documents?	:	
	1)	Purchase of raw materials	:	
	2)	Details of Manufacturing of medicines	:	
	3)	Details of chemical analysis of the medicines	:	
	4)	Details of sale of Medicines	:	
22)		Have you appointed a chemical analyst to chemically analyze and identify the medicine? If yes, submit the details of his name, qualification, working time, experience etc	:	
23)	1)	Has the applicant submitted the labels of medicines? Provide the Packing cartons of the medicines along with literature / therapeutic index etc	:	
	2)	Do you comply with Drug & Cosmetic Act 1945, Rule 161 for the Medicine's labels?	:	
	3)	Have you mentioned the uses, indications, dosage, directions for use and precautionary measures on medicine's label? Provide the details.	:	
	4)	If you are distributing medicine's samples freely to the doctors, have you mentioned the words 'Physician samples not to be sold' on labels	:	
	5)	If you are manufactured any medicine as per schedule 1E, have you prepared the labels as per label rules? Mention the same.	:	

24)		To test your medicines chemically, if you have used any approved drug testing laboratory, enclose the certificate of the last 6 batches for each medicine's.	:	
25)		If you use Alcohol in your medicine', submit the photocopy of the license taken from excise dept.	:	
26)		If you are using self generating alcohol in your medicines, have you paid excise tax as per M.T.C.C Act? Give details.	:	
27)		Submit an affidavit for not having violated any rules or having any dispute on the manufacturing unit as per M & T.P Act (Excise notice Act 1950).	:	
28)		Submit the documents for proposed medicine's safety and efficacy, if necessary.	:	
29)		List of medicines manufactured at your manufacturing unit	:	

I confirm that all the above mentioned information is true. If any of the above explanation proves to be false, this application could be rejected, license can be cancelled and any suitable action can be taken against the applicant.

Note: Strike out any of the above information which are not applicable, if necessary.

Signature of Applicant

Name of the applicant:
(in block letters)

Designation:

Name of the company with -

Complete address :