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FORM - I
PART C8

(See Rule 69, Form 24)

**Application for Grant or Renewal of a Licence to Manufacture for sale
[or distribute of Drugs other than those Specified in Schedule X, C and C(1)]**

1. I/We ofhereby apply for grant / renewal of Licence to manufacture on the premises situated at
.....
the following drugs being drugs other than those specified in (Schedules C, C(1) and X) to the Drugs and Cosmetics Rules 1945.
2. Name of the Drugs categorized according to Schedule M.
3. Names, Qualifications and experience of technical staff employed for manufacture and testing.
4. A fee of Rupees has been credited to Government under the Head of account

Place :

Date :

Signature of the Applicant

Note : The application should be accompanied by a plan of the premises.

FORM - I
PART C8

(See Rule 69-A, Form 24-F)

**Application for the Grant or Renewal of a Licence to Manufacture for sale
[or distribute of Drugs Specified in Schedule X and not specified in Schedule C and C(1)]**

1. I/We of hereby apply for the grant / renewal of a licence to manufacture on the premises situated at
.....
the following drugs being drugs other than those specified in Schedules X to the Drugs and Cosmetics Rules, 1945.
2. Names of drugs
5. A fee of Rupees has been credited to Government under the head of account

Place :

Date :

Signature of the Applicant

FORM - I
PART - C8
(Form 27)

Application for Grant / Renewal of a Licence to Manufacture for sale (or for distribution of) drugs specified in Schedule-C and C(1) [excluding those specified in (part-XB and) Schedule X]

1. I/We ofhereby apply for grant / renewal of a manufacture on the premises situated atthethe under mentioned drugs being drugs specified in schedule - C and C1 [excluding those specified in (part - XB and) Names of Drugs (each item to be separately specified)
2. The names, qualifications and experience of expert staff responsible for manufacture and testing of the above mentioned drugs.
 - a) Name(s) of staff responsible for test.....
 - b) Name(s) of staff responsible for manufacture
3. The Premises and plan are ready for inspection will be ready for inspection on
4. A fee of Rupees and an inspection fee of Rs..... has been credited to Government under the Head of account

Place :

Date :

Signature of the Applicant

Passport size Photograph

AFFIDAVIT - I

DECLARATION ABOUT RESIDENTIAL ADDRESS OF M/s

I/We the under mentioned to hereby declared our permanent residential address as follows :

Name with Father's Name / Husband's Name and Age.	Position held in the Company and Address	Permanent Residential Address	Signature
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I/We whose Name(s) is/are given below will be responsible for the affairs of the Company to which the Company is held liable for any offences punishable under the Drugs and Cosmetics Act. 1940 and for contravention of other enactments enforced by Licensing Authority, Director, Drugs Control Administration, Andhra Pradesh, Hyderabad.

Name with Father's Name / Husband's Name and Age.	Position held in the Company	Permanent Residential Address	Signature
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AFFIDAVIT - II

I S/o
aged about years Resident of do hereby affirm on oath as under.

1. That I am Managing Director / Director / Partner / Proprietor of M/s on whose behalf an application for grant of Licence to manufacture Drugs / Cosmetics has been made to the Licensing Authority, Director, Drugs Control Administration, Andhra Pradesh, Hyderabad.
2. That I am responsible for the day to day affairs and conduct of business of M/s..... for the purpose of Section 34 of the Drugs and Cosmetics Act, 1940 to which M/s and us Director / Partners etc., are held liable for any act of omission punishable under the Drugs and Cosmetics Act, 1940 and other enactment enforced by the Officers of Drugs Control Administration.
3. That in the event of any change in the constitution of the Company, I will inform the Director, Drugs Control Administration, Andhra Pradesh, Hyderabad.

The following are the Directors / Partners of the Company whose Names and permanent address are given below :

Name	S/o	Age	Residential Addresses
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1

2

3

WITNESSES WITH FULL ADDRESS :

1

2

I, Sri..... do hereby declare on oath that the above contents are true to the best of my knowledge and belief and nothing has been hidden.

DEPONENT

No.

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FORM - I
PART - C8

APPLICATION FOR GRANT OF LICENCE TO MANUFACTURE BULK DRUGS

Fee Structure

Amount to be paid	:	Form	24	-	Rs. 7,500/-
			24 F	-	Rs. 7,500/-
			27	-	Rs. 7,500/-
Mode of Payment	:	D.D. drawn in favour of Commissioner of Industries or General Manager/DIC			

Check Slip

All documents in duplicate

- | | | |
|--|-----------------------------------|--------------------------|
| 1) Part C8 of Form-I | 2 copies + 1 copy to Nodal Agency | <input type="checkbox"/> |
| 2) Plan and Layout of the premises showing the installation of Machinery and Equipment | | <input type="checkbox"/> |
| 3) Attested copies of documents relating to the ownership/rent/lease | | <input type="checkbox"/> |
| 4) Declaration of the Proprietor/Partners/Directors etc., in Affidavit I, (Format enclosed)
attested copies of partnership Deed/Memorandum and Articles of Association | | <input type="checkbox"/> |
| 5) Affidavit-II (Format enclosed) attested by Notary regarding the name, address and other details of the person responsible to the day to day affairs of the company and for the conduct of business along with his photograph duly attested. | | <input type="checkbox"/> |
| 6) Attested copy of Ration Card or passport or Electoral Card in support of proof of residential address of the responsible person. | | <input type="checkbox"/> |
| 7) Detailed list of Manufacturing and Analytical Equipment with copies of purchase bills. | | <input type="checkbox"/> |
| 8) Attested copies of certificates of academic qualification, experience certificates, Bio-data and declarations of Technical Staff in the prescribed proforma with attested photos | | <input type="checkbox"/> |
| 9) Permission from the Municipality or Municipal Corporation or Panchayat authorities for construction and starting the Unit. | | <input type="checkbox"/> |
| 10) Clearance from Drugs Controller General (India), New Delhi in case of new drugs (Either Bulk drug or formulation) - New drugs are defined under Rule 122 E of Drugs and Cosmetics Rules 1945 | | <input type="checkbox"/> |
| 11) Permission from the Health Authorities of the area for setting up the manufacturing facility. | | <input type="checkbox"/> |
| 12) Permission from A.P. Pollution Control Board | | <input type="checkbox"/> |
| 13) Brief manufacturing procedure and flow chart along with consumption Co-efficient effluents generated and their treatment for the drugs applied for along with the methods procedure of Test/Analysis | | <input type="checkbox"/> |
| 14) Details of Fee paid | | <input type="checkbox"/> |

D.D. No. Amount Date

SIGNATURE OF THE APPLICANT