Application for the manufacture of Synthetic Narcotic Drugs (Rule 37 or 38 of the Narcotic Drugs and Psychotropic Substances Rules,1985)

Part-A		
1	Name or names & address or addresses of the person or applicant is a firm and if, a company, the registered name and address thereof, the name of Directors and Manager and Managing Agents, Servants etc. and if there is a Managing Director, the name of each Director.	
2	The amount of Capital proposed to be invested in the venture.	
3	The name of the place and the site on which the building or building housing the factory is/are situated or to be constructed in case or renewal of license, the following particulars with distinguishing letter or number of letter and number of each to be furnished.	
	i. Brief Description (with boundaries) of the premises	
	ii. Description of each main division of sub-division of the manufactory.	
	iii. Stores for the Raw Material	
	iv. Laboratory / Finished Store.	
	v. Approximate date for which the applicant desires to commence the manufactory.	
3	The number and full description of the permanent apparatus and machinery which the applicant wished to set up.	
4	The name and address of jurisdictional/ Divisional Commissionerate of Central Excise.	
5	Whether accommodation for the Supervisory staff will be provided within the manufactory or its vicinity.	
6	The amount in cash or Govt. promissory notes which the applicant is proposed to furnish for the due performance of the conditions on which the license may be granted.	
7	Whether the company has been issued any Mfg. License for manufacture of Narcotic Drug earlier? If so, indicate the details and enclose a copy thereof.	
Part-B		
8	(i) Name and Quantity of the drugs for which the license is required.	
	(ii) Manufacture of drug for domestic	

	Consumption.	
	(iii) Manufacture of drug for export.	
9	Whether valid **Drug Manufacturing Licence** issued under D & C Act by State authority for manufacture of subject drug is available. If so	
	(i) Licence No.	
	(ii) Name of Issuing Authority	
	(iii) Validity Period	
	(iv) Name and approximate quantities of dangerous drugs other than in a year by the manufacturer in the premisese.	
10	Whether **Possession licence** issued under D & C Act by State authority for the drug applied is available? If so,	
	(i) Licence No.	
	(ii) Name of Issuing Authority	
	(iii) Validity period	
	(iv) Possession Limit of the requested Drug	
	(v) The Maximum quantity of finished drug likely to remain in the manufactory at one time.	
	(vi) The kind and number of each license under Drug and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945 and State NDPS Act/Rules, 1985 held by the applicant.	
11	Name and address of concerned State Drug Controller (complete postal address with pin code)	

Certified that ……. (name of drug) proposed to be manufactured is required solely for medical and scientific purpose. Further certified that the details given are true and correct.

Seal of Company

Signature:
Full Name:
Position in the company:
Date:

NOTE

Separate application (with complete set of documents) has to be made for each Synthetic Narcotic Drug complete in all respect alongwith the requisite documents. Self attested copies of the following documents should be submitted:

1. Name, address, telephone Nos and Fax no. of the chairman, Managing Director and other Directors, proprietor/Partners, Incharge of production and finance.
2. List of the authorized signatories with their specimen signature duly attested by Managing Director of the Company.
3. Copy of Valid Drug manufacturing License alongwith approved product list issued by the concerned State Govt. authority under Drugs and Cosmetics Act, 1940.
4. Copy of valid possession license ((NDPS I/MD VI.L-I/L-II or any other licence as the case may be mentioning the name of the Narcotic Drugs applied for alongwith the possession limit.
5. Demand Draft for Rs. 5000/- in favour of Drawing & Disbursing Officer, Central Bureau of Narcotics, Gwalior.
6. National Savings Certificate for Rs. 5000/- towards security deposit (Not required for renewal of license)
7. Copy of Central Excise Registration, if registered.
8. Copy of site plan of the manufacturing unit approved by Drug control Administration of the concerned state.
9. List of approved technical persons in the production and Quality control.
10. List of Laboratory equipments and raw materials.
11. Profile of your company.
12. Balance Sheet of Company for the last 3 years.
13. Flow Chart of manufacturing process and per annum capacity.
14. Statement of annual production & consumption of drug in prescribed format (for renewal).

**** It may be noted that incomplete application received in this office shall not be entertained.**