

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

1	Name and Complete postal address of the manufacturing Unit with Tel.No. and Fax Nos.	
2	The name of Directors and Managing Director of the firm with their full address and Tel.no./Fax nos.:	
3	Brief description (with boundaries) of the premises:-	
	i. Description of each main division/sub division of the manufactory	
	ii. Stores of the raw material	
	iii. Laboratory/Finished store	
	iv. Size and schematic diagram of the store for narcotic drug raw material	
	v. Whether separate store for string finished goods (formulations of narcotic drugs) is available. If so, indicate the size and schematic diagram of the said store	
4	The number and full description of the permanent apparatus and machinery installed in the manufactory	
5	The name and address of Jurisdictional Commissionerate of Central Excise	
6	Company's PAN (Copy of PAN may be enclosed)	
7	Whether formulation sought to be manufactured is already included in Indian Pharmacopeia	
8	Whether the narcotic drug formulations for which the application is made falls within the definition of new drugs as provided under Rule122(E) of Drugs and Cosmetics Rules,1945. If yes the NOC No. and date from DCG(I) as prescribed under said Rule.(Attested copy of the same be annexed)	
9	Name, strength and pack size of formulations of narcotic drug for which the licence is applied for (Mention the standard IP/BP/USP/Eur.P)	i. ii. iii.
9A	Purpose of manufacture of each formulations of narcotic drug for which the license is applied for (for export only/domestic purpose only/for both export & domestic)	
10	Source from where the Synthetic narcotic bulk drug proposed to be procured for manufacture of formulations	
11	Whether necessary quota allocation has been granted in your favour from CBN, Gwalior for lifting of the bulk drug. If so, the no. and date of quota allocation letters (attested copy to be attached)	

12	Details of procurement of synthetic narcotic bulk drug viz., name of source, quantity procured and date of procurement be provided	
13	Whether manufacturing licence from State Drug Control authorities under the Drugs and Cosmetics act,1940 and rules made thereunder has been obtained for the manufacture of formulations for which licence under Rule 37 of NDPS Rules,1985 is sought for:	
	i) License No.	
	ii) Name of issuing authority	
	iii) Validity period (a copy of valid State license to be enclosed)	
14	Whether possession license for use of the drug is available (a copy of valid license from state authorities to be enclosed)	
	i) License No.	
	ii) Name of issuing authority	
	iii) Validity period (a copy of valid license may be enclosed)	
	iv) Possession limit	
15	Name and address of the concerned State Drug Controller	
16	Name and address of the jurisdictional State Excise authorities in case the possession license is issued by them	
17	The Demand Draft No. and date for Rs.5000/- submitted towards the fee under Rule 37(2) of NDPS Rules,1985	
18	Details of Security deposit of Rs.5000/- submitted under Rule 39(ii) of NDPS Rules,1985	

The undersigned hereby declares that the above information submitted is complete and correct. Further certified that the ----- (name of formulations of synthetic narcotic drug) proposed to be manufactured is required solely for medical and scientific purposes.

Date:

Place:

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. However single application is only required for different formulations of same Synthetic Narcotic Drug. The applicant should enclose Demand Draft for Rs.5000/- (Five thousand only) as processing fee drawn in favour of Drawing & Disbursing Officer, Central Bureau of Narcotics, Gwalior. The applicant should also enclose a National Savings Certificate for Rs.5000/- towards security deposit. Self attested copies of the following documents should also 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 Authorised signatories with their specimen signature duly attested by Managing Director of the Company.
3. Copy of Valid Drug Manufacturing Licence alongwith approved product list issued by the concerned State Government authority under Drugs and Cosmetics Act,1940.
4. Copy of valid possession licence (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. Copy of quota allotment order(s) of previous year, if any.
6. Copy of Central Excise Registration, if registered.
7. Details of Narcotic Drugs procured in the previous year and in the current year in the following proforma

S.No.	Name of synthetic narcotic drug	Name and address of supplier	Quota allocation letter no. and date	Quantity procured along with invoice no. and date

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.
