

**APPLICATION FORM FOR ALLOTMENT OF QUOTA OF NARCOTIC DRUG FOR THE CALENDAR YEAR 2021
[OTHER THAN UNDER PROVISIO TO RULE 54 OF NDPS RULES, 1985 (IMPORT FOR THE PURPOSE OF EXPORT)]**

NOTE: All the Columns are to be filled mandatorily with appropriate response. Inappropriate / No-response will cause delay in processing of application. All the documents listed below are to be submitted invariably along with the application.

I. Details of the Applicant / Company:-

(a)	Name & address (with pin code) of the company Tel No., Fax No.						
(b)	The name and address of jurisdictional/ Commissionerate, Division & Range of GST						
(c)	The name of the place and the address on which the factory is situated / where the Narcotic drug is intended to be used along with Pin Code						
(d)	The PAN number						
(e)	Details of allotment, lifting & consumption in the Years 2016, 2017, 2018, 2019 & 2020 (in kg.)	Year	Opening Balance	Qty. allotted	Qty. lifted	Qty. consumed	Closing balance
		2016					
		2017					
		2018					
		2019					
		2020					

II. Details of Narcotics Drugs and its procurement:-

(a)	Name of the Narcotic Drug required	
(b)	Quantity of drug required for 2021	
(c)	Sources of procurement of Drug (Name and address of the supplier)	

III. Proposed use of Narcotic Drug:-

(a)	Manufacture of formulation/ preparation for domestic consumption covered under NDPS Act	
(b)*	Manufacture of formulation/preparation for export (copies of the purchase orders along with calculation sheet justifying the requirement should be submitted)	
(c)	Manufacture of other drugs not covered under NDPS Act, 1985	
(d)	Other purpose viz. Test and analysis, Research, BA/BE Studies, etc (please specify)	

*If proposed use is for exports, then file separate application by giving figures only for exports consumption in Column I (d)

IV. Details of quota allotted and its utilization during 2020:-

(a)	Total quantity allocated	
(b)	Opening balance as on 1.1.2020	
(c)	Quantity procured and received in factory by 31.12.2020	
(d)	Total quantity (b+c)	
(e)	Quantity utilized	
(i)(A)*	Quantity consumed for manufacture of formulations covered under NDPS Act	

(i)(B)	Quantity utilized for manufacture of formulation / preparation not covered under NDPS Act	
(ii)	Quantity utilized for test & analysis	
(iii)	Manufacturing losses	
(f)	Total Utilization e(i)(A)+i(B)+iii+iv)	
(g)	Balance quantity in stock as on 31.12.2020 (d-f)	

*Separate quantities to be mentioned in e(i)A and e(i)B only, if applying for quota allocation for exports otherwise mention total quantity in Column e(i)(B)

V. Manufacturing Pattern:-

(a)	Whether manufacturing in own factory for own brand. If yes, give name & address of factory (Self)	
(b)	Whether manufacturing in own factory for others brand (contract manufacturing), then give name of brand name, owner along with address of factory	
(c)	Whether own brand, being manufactured in others factory (Loan Licence) then, name & address of factory	

S.No	Name and address of units	Whether manufacturing for self/ loan or through Contract	Percentage of allocation to be made	Brand name

Note:- (i) If Principal is manufacturing the goods also getting manufactured by others, then he should make single application for all factories, whether it is own or loan licenses or through contract manufacturing. In such a case, percentage of allocation should be indicated factory wise.

(ii) In a case Principal is not manufacturing in his own factory or as a loan licence but only through contract manufacturer, then in such a case Principal Company should make the application.

VI. Availability of Requisite Documents for allocation:-

(a)	Details of Drug Manufacturing Licence for use of the Drug Preparation:	
(i)	Licence No:	
(ii)	Name of the Issuing Authority	
(iii)	Validity Period	
(b)	If the Quota allocation is for Test & Analysis:	
(i)	Recognition of In-House R&D Unit given by Dept. of Scientific & Industrial Research or CDSCO/FDA (enclose valid copy)	
(ii)	If the Drug is to be imported: Licence to Import drug for the purpose of Examination, Test or Analysis (Form-11) issued by the State FDA/DCGI and its validity	
	(iii) If Form 11 utilized earlier, quantity remaining to be utilized in the said Form11	
(c)	Details of the possession licence of the factory of manufacture for the Drug applied for:	
(i)	Licence No.	
(ii)	Name of Issuing Authority	
(iii)	Validity period	
(iv)	Possession limit of the requested Drug	(in Kg)
(v)	Type of possession limit - i.e. Annual/at a time/ quarterly/ as allotted by competent authority (Please specify)	

(d)	In the case where the Possession limit is fixed specifying a particular quantity in the case of annual production limit / annual consumption limit, the following additional information should be provided				
	Opening Stock on 1 st day of possession limit (if possession limit is for 2020-21 i.e. possession limit is valid from 01.04.2020 to 31.03.2021, then as on 01.04.2020)	Qty. allocated on or after 1 st day of possession limit (i.e. qty allocated on or after 1 st April, 2020)	Qty. procured on or after 1 st day of the possession limit (i.e. qty. procured on or after 1 st April, 2020)	Qty. consumed after 1 st day of possession limit (till last date of the preceding month to applying month) (If applied during Feb, 2021 i.e. qty consumed till 31.01.2021)	Closing stock on the last day of the month preceding the date of filing application
	1.	2.	3.	4.	5.

VII. Others

(a)	Name and address of concerned State Drug Controller (Complete postal address with PIN code)	
(b)	Details of fee paid	
(i)	Demand Draft No. & Date/Self attested copy of Challan generated for online payment made in www.bharatkosh.gov.in	
(ii)	Name of Issuing Bank (in case of Demand Draft):	

Details of Narcotic drug procured in the previous year (1st January to 31st December **2020**) in the following proforma:-

Quarter	Opening Stock	Qty. procured	Total consumption		Closing stock
			Qty. consumed for manufacture of formulations	Processing Loss	
1 st Quarter					
2 nd Quarter					
3 rd Quarter					
4 th Quarter					
Total:					

The undersigned hereby declare that the above information submitted is complete and correct. It is also certified that I have gone through the aforesaid instructions.

Seal of the Company

Signature of Authorized signatory
 Name:.....
 Date.....
 Place.....
Mobile No.....
 E-mail ID:.....

Self attested copies of the documents which are to be submitted by all applicants. To be submitted once in a year along with their first application and whenever there is any change in their details:-

- a) Copy of valid Drug Manufacturing Licence (Form 25 & 26) along with approved product list issued by the concerned State Government authority and Form 20 B/ 21 B, if other than manufacturer
- b) Recognition of In-House R&D Unit given by Dept. of Scientific & Industrial Research or Central Standard Drug Control Organization or State FDA and Licence to Import drug for the purpose of Examination, Test or Analysis (Form-11) issued by State FDA / DCGI (where applicable).
- c) Copy of valid Possession Licence (NDPS 1 / MD VI / M.D. IV / L-I / L-II / N.D.L.D. / N.D.R.C. or any other licence for possession of narcotic drug(s) as the case may be) mentioning the name of the narcotic drug applied for along with the possession limit.
- d) Copy of 3rd party manufacturing agreements clearly indicating name and composition of products agreed to be manufactured and duly signed by the parties to such agreement along with Joint undertaking by the parties to the effect that both the parties will remain responsible for any misuse/diversion/illicit trade of Codeine based formulations.
- e) Copies of the quarterly returns of 2020 along with sale details with complete postal address of the consignee. In case of the manufacturers of medicinal opium preparations, they shall submit buyer's licence to sale preparations of medicinal opium, if applicable as per State NDPS Rules.

Self attested copies of additional documents which are to be submitted by new applicants only and whenever there is change in the details as specified below

- a) Complete postal address and telephone, fax no. of the company including Jurisdictional GST division and GST Commissionerate and Zonal office of Narcotics Control Bureau.
- b) Name, address, telephone Nos. and Fax No. of the Chairman, Managing Director and other Directors, proprietor/ partners and / PAN of directors/proprietors/partners & DIN (For companies only)
- c) GST Registration No., Company's PAN No. , IEC (for exports) and CIN Number (for companies only)(Attested copies of these documents shall be submitted.)
- d) Turnover of the company for last three years in crores.(to be submitted in first application of the calendar year by all existing companies for previous financial year ending 31st March)
- e) List of Authorized signatories with their specimen signature duly attested by Managing Director/ Partner/proprietor of the company/ firm

INSTRUCTIONS:

- a) If the language of any document is other than Hindi or English, translated copy of the same to either Hindi or English is to be submitted.
- b) Correspondence will be made to the e-mail ID of the company as well as through Speed Post. Therefore, all the companies should provide proper e-mail id of the company as well as the Authorized Signatory. For the all purpose, date of receipt of e-mail by CBN / date of sending e-mail shall be applicable. In case, e-mail ID is not filled up or wrong e-mail ID given, then respective companies themselves will be responsible for the delay.
- c) If no reply is received from a company against query letter within one month of sending the mail, the application will be treated as closed and if the company desires, it can re-apply for quota allocation afresh with all the requisite documents along with Demand Draft.
- d) The company should ensure that they do not cross the possession limit and manufacturing limit fixed by the concerned State Authority, irrespective of the quantity of drug allocated by this Bureau in a year.
- e) If any company submits wrong information with regard to lifting, consumption, etc. action may be taken against such company under the provisions of concerned rules if it so warrants.
- f) For all the cut off dates, the date of receipt of mail at supdt-quota@cbn.nic.in shall be relevant.
- g) Separate application (with complete set of documents) has to be made for each Narcotic Drug. The applicant should enclose Demand Draft for Rs.50/- as processing fee drawn in favour of Drawing & Disbursing Officer, Central Bureau of Narcotics, Gwalior.