APPLICATION FORM FOR ALLOTMENT OF QUOTA OF NARCOTIC DRUG FOR THE CALENDAR YEAR 2023

[OTHER THAN UNDER PROVISO TO RULE 54 OF NDPS RULES, 1985]

NOTE: All the Columns are to be filled mandatorily with appropriate response. Inappropriate/ Noresponse 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 I	Company: -
----	---------	--------	-------------	------------

	<u>.</u>						
	Name & complete address (with						
(a)	pin code) of the company						
Tel No., Fax No.							
	The name and complete						
ax	address of jurisdictional/						
(b)	Commissionerate, Division &						
	Range of GST						
	Name and complete address of						
(0)	concerned State Drug Controller						
(c)	(Complete postal address with						
	PIN code)						
	The name of the place and the						
	complete address on which the						
(d)	factory is situated / where the						
, ,	Narcotic drug is intended to be						
	used along with Pin Code						
(e)	The PAN number						
(f)	GST Registration No.						
		Year	Opening	Qty. allotted	Qty. lifted	Qty.	Closing
			Balance			consumed	balance
		2018					
	Details of allotment, lifting &						
(g)	consumption in the Years 2018,	2019					
(0)	2019, 2020, 2021 & 2022 (in kg.)	2020					
	ky.)	2021					
		2022					
		2022					

II. Details of Narcotics Drugs and its procurement: -

(a)	Name of the Narcotic Drug required	
(b)	Quantity of drug required for 2023	
(c)	Name and percentage of Base content in the required Drug	
(d)	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, 1985	
(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 submit separate application by giving figures only for exports consumption in Column I(g).

IV. Details of quota allotted and its utilization during 2022: -

(a)	Total quantity allocated	
(b)	Opening balance as on 1.1.2022	
(c)	Quantity procured and received during the year	Procurement from Opium factories i.e. GOAWs Procurement from other
` ′	2022 (by 31.12.2022)	domestic manufacturers
		TOTAL
(d)	Total quantity (b + c)	
(e)	Quantity utilized - a) Quantity consumed for manufacture of formulations/ preparations covered under NDPS Act b) Quantity utilized for manufacture of formulation/ preparation not covered under NDPS Act	
	c) Quantity utilized for test & analysis d) Manufacturing losses e) Total Utilization E(a)+E(b)+E(c)+E(d)	
(f)	Balance quantity in stock as on 31.12.2022 [d - e(e)]	

V. Manufacturing Pattern: -

 manaraotanny rattorn				
(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			

VI. Manufacturing details of multiple manufacturing Units: -

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

Note: - (i) If Principal company is manufacturing the goods and 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 company 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.

VII. Availability of Requisite Documents

	Details of Drug Manufacturing Licence for	
	use of the Drug Preparation:	
(a)	i. License No:	
	ii. Name of the Issuing Authority	
	iii. Validity Period	
	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: License to Import	
(b)	drug for the purpose of Examination, Test or	
	Analysis (Form-11) issued by the State	
	FDA/DCGI and its validity	
	iii. If Form 11/ Form CT-17 utilized earlier,	
	quantity remaining to be utilized in the said	
	Form11/ Form CT-17	
	Details of the possession licence of the	
(0)	factory of manufacture for the Drug applied	
(c)	for:	
	i. License No.	

Ī		ii. Name of Issuing	g Authority				
		iii. Validity period					
Ì		iv. Possession limit	t of the requested Dr	ug		(in Kg)	
1		v. Type of possess	sion limit - i.e. Annua	ıl/at a		` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `	
		time/ quarterly/ a	as allotted by compet	tent			
		authority (Please	e specify)				
Ī		In the case where	the Possession lim	it is fixed	specifying	a particular quantity	in the case of annual
			annual consumption				
Ì		Opening Stock on 1st			ired on or	Qty. consumed after	
		day of possession				1st day of possession	
		limit (if possession				limit (till last date of	
		limit is for 2022-23 i.e			ed on or after		application
	(d)	possession limit is	after 1 st April, 2022)	1st April, 20)22)	to applying month) (If	
		valid from				applied during Feb,	
		01.04.2022 to				2023 i.e. qty	
		31.03.2023, then as				consumed till	
1		on 01.04.2022)				31.01.2023)	
		1.	2.		3.	4.	5.

VIII. Details of fee paid-

(a)	Demand Draft No. & Date/Self attested copy of Challan generated for online payment made in www.bharatkosh.gov.in	
(b)	Name of Issuing Bank (in case of Demand Draft):	

IX. Details of Narcotic drug procured in the previous year (1st January to 31st December 2022): -

Quarter	Opening	Qty.	Total consumption		Closing
	Stock	procured	Qty. consumed for manufacture of formulations	Processing Loss	stock
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:

(A) LIST OF DOCUMENTS REQUIRED: -

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 <u>valid Possession Licence</u> (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 alongwith 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) Copy of Annual Return for Manufacture, Consumption/ Utilization and Sale of Narcotic Drugs of 2022 duly attested/ countersigned by State FDA/ State Excise Department. (Format uploaded on www.cbn.nic.in)
- f) <u>Copies of Annual Returns for Manufacture, Consumption/ Utilization and Sale of Narcotic Drugs of 2019, 2020 and 2021 duly authenticated</u> by the authorized signatory of the applicant company.
- **g)** In the cases of quota allocation for export purposes only, **valid Purchase Orders duly authenticated by the importer** is necessarily required with the application.
- **h) An Undertaking** with regard to pending case/investigation against the firm/Director/Partner/Proprietor by any agency under NDPS Act or Drug and Cosmetic Act.

(B) LIST OF ADDITIONAL DOCUMENTS REQUIRED FROM NEW APPLICANTS: -

Self-attested copies of additional documents which are to be submitted by new applicants only and if there is changes in the below documents, all applicants are invariably required to submit amended/changed documents

- **a)** Complete postal address and telephone, fax no. of the company indicating Jurisdictional GST division and GST Commissionerate.
- **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 of 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.

(C) <u>OTHER INSTRUCTIONS</u>: -

- a) Application can also be sent through e-mail, but hard copy of the same along with all requisite documents should also be sent mandatorily. For the purpose of cutoff date, application through e-mail on the official of this office suptd-narco@cbn.nic.in within stipulated date will be considered as having been received within time limit.
- **b)** 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.
- c) Correspondence will be made to the e-mail ID of the company only. 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, all the correspondences shall be made through the speed post only and the respective companies themselves will be responsible for the delay, if any.
- 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)** Separate application (with complete set of documents) has to be made for each Narcotic Drug.
- g) The applicant should enclose either Demand Draft for Rs.50/- drawn in favour of Drawing & Disbursing Officer, Central Bureau of Narcotics, Gwalior or Self attested copy of Challan generated for online payment of Rs. 50/- made in www.bharatkosh.gov.in as processing fee.
- **h)** The company shall submit Quarterly Returns along with Sale and Distribution Details on regular basis.