APPLICATION FORM FOR ALLOTMENT OF QUOTA OF CODEINE PHOSPHATE & MEDICINAL OPIUM FOR THE CALENDAR YEAR 2016.

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)	E-mail ID of the company for making correspondence.				
(c)	Whether the company is registered with Central Excise? If yes, ECC No. may be mentioned. (A copy of Registration certificate may be enclosed).				
(d)	The name and address of jurisdictional / Commissionerate, Division & Range of Central Excise				
(e)	Company's PAN (A copy of PAN may be enclosed).				
(f)	If the company is having Importer Exporter Code (IEC), attach a copy thereof.				
(g)	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				
(h)	Whether the company has been allotted any such quota of Narcotic drug earlier? If so, indicate the details and enclose a copy thereof.				
(i)	Details of allotment, lifting & consumption in the years 2011, 2012, 2013, 2014 and 2015 (in kg.)	Year	Qty. allotted	Qty. lifted	Qty. consumed
		2011			
		2012			
		2013			
		2014			
		2015			

II Details of Narcotic Drug and its procurement:-

(a)	Name of the Narcotic Drug required	
(b)	Quantity of drug required for 2016	(in Kg.)
(c)	In case of Medicinal Opium, please intimate your preference whether cake or powder form.	

III Details of quota allotted and its utilization during 2015:-

(a)	Total quantity allocated (copies to be enclosed)	
(b)	Opening balance as on 1.1.2015	
(c)	(i) Quantity procured indigenously **(invoiced in 2015)**	
	(ii) Quantity imported	
(d)	Quantity utilized	
	(i) Quantity consumed for medical and scientific purposes	
	(ii) Quantity utilized for manufacture of formulation / preparation mentioned in Schedule III to the 1961 convention	
	(iii) Quantity utilized for purpose other than (i) & (ii) above if any, along with the details thereof	
(e)	Manufacturing losses, if any (Should be shown separately from Col.(d) above)	
(f)	Balance quantity in stock as on 31.12.2015	

IV Proposed use of Narcotic Drug:-

(a)	Manufacture of formulation / preparation for domestic consumption	
(b)	Manufacture of formulation / preparation for export (copies of purchase orders along with calculation sheet justifying the requirement should be submitted)	
(c)	Manufacture of other drugs	
(d)	For Test & Analysis Purpose	
(e)	Other purpose viz. Research, BA/BE Studies, etc. (please specify)	

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.	

Sl. No.	Name & 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 licences 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 Contract Manufacturer should make the application.

VI. Availability of Requisite Documents for allocation:-

(a)	Details of Drug Manufacturing Licence for use of the drug in preparation:	
	(i) Licence No.	
	(ii) Name of Issuing Authority	
	(iii) Validity Period	
(b)	If the Quota allocation is for Test & Analysis purpose:	
	(i) Recognition of In-House R&D Unit given by Dept. of Scientific & Industrial Research or Central Standard Drug Control Organization or State 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 State FDA / DCGI	
	(iii) Validity of Test Licence	
(c)	Details of Possession licence 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	

Note: Please indicate whether the possession limit is annual production limit / annual consumption limit or maximum quantity of stock which a company can hold at a time during currency of licence in Column (c) (v).

VII. Others:-

(a)	Name and address of concerned State Drug Controller (complete postal address with **pin code**).	

Details of Narcotic drug procured in the previous year (1st January to 31st December **2015**) in the following proforma:-

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

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. **Self attested** copies of the following documents should also be submitted:-

a) List of Directors with office and residential address along with telephone number.

b) List of Authorised signatories with their specimen signature duly attested by Managing Director of the company.

c) Copy of valid Drug Manufacturing Licence (Form 25 & 26) along with approved product list issued by the concerned State Government authority.

d) 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).

e) 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.

f) Copy of quota allotment order(s) of previous year if any

g) Copy of Central Excise Registration, if registered

h) Copy of company's PAN

i) 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.

j) Copies of all the four quarterly returns along with sale details with complete postal address of consignees.

INSTRUCTIONS:

a) Application for Codeine Phosphate & Medicinal Opium by the existing companies should be submitted by 31.1.2016, if they are interested for immediate provisional quota. Existing companies applying after 31.1.2016 will not be granted quota on provisional basis but will be eligible for final quota allocation as per policy. No application received after 10.11.2016 shall be considered for allocation of quota.

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 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.

d) 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.

e) It is stipulated that company should lift atleast 90% of allocated quota by 31st December of relevant year. If a company expects that they will not be able to lift 90% of quota by 31st December, then they should surrender the excess quota by 10th August, failing which they would be liable to be penalized while allocating the quota during next year.

f) A company failing to lift 90% of allocated quota by 31st December and not surrendering it by 10th August shall be visited with a quota reduction to the extent of 10% of quota eligibility in next year.

g) For the purpose of calculating 90% of allocated quota in clause (f) above, total quota allocation shall be considered as quota initially allocated minus quota surrendered by 10th of August.

h) 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.

i) 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.

j) For all the cut off dates, the date of receipt of mail at suptd-narco@cbn.nic.in or narcommr@cbn.nic.in shall be relevant.

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.

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