

F.No. I/12/13/Adm/CCF/2021-22
Government of India
Ministry of Finance
Department of Revenue
New Delhi

Request for Qualification by units to be engaged in manufacture of alkaloids/active pharmaceutical ingredients (APIs) from opium gum.

2. India is one of the few countries permitted to cultivate opium poppy and extract gum by lancing the poppy pods. Farmers are licenced to grow Opium and the entire Opium is procured by the Central Bureau of Narcotics (CBN) and transferred to the Govt. Opium and Alkaloid Works (GOAWs) at Ghazipur and Neemuch for further processing to extract various alkaloids for medical use.

3. With a view to augment the existing capacity of production of alkaloids/APIs from opium gum licitly produced in India, the Government of India has resolved to licence Indian company to produce alkaloids and APIs from the opium gum stored at the Government Opium and Alkaloid Works, Neemuch. The licensed company is required to process at least **100 MT of Opium gum** per annum (Minimum Business Guarantee) to extract alkaloids/active pharmaceutical ingredients (APIs) from it. **The contract will be valid for a period of 05 years (Five years).**

4. The Department seeks "Request for Qualification" from Indian companies having capacity to manufacture Alkaloids/APIs from the opium gum to be supplied by the Govt. Opium and Alkaloid Works. The finished drugs alkaloids/active pharmaceutical ingredients (APIs) shall be tendered back to the Govt. Opium and Alkaloid Works for supplying to the Indian Pharmaceutical companies. The Department would arrange for a visit to GOAF factories at Neemuch and Gazipur, for technical discussions and evaluation of the manufacture of Alkaloids/APIs from Opium gum.

5. The licensed company's facility for processing Opium gum and production of alkaloids would be under the supervision of nominated GOAF personnel at the Company's factory and who will supervise record keeping and other provisions, with respect to the NDPS Act / Rules, 1985 as the same, done in Govt. Opium and Alkaloid Works.

6. To enable Indian companies to submit a bid, the following data points are herewith attached –

a) Detailed, step-wise process of Opium gum processing with input and output norms at each step.

b) All solvents used for processing including quantum per Kg of Opium gum.

c) Input-Output norms of per Kg of Opium gum and Alkaloids

d) Yield of Alkaloids per kg of Opium

e) List of equipments used for processing with sizing of each equipment

f) Capacity per month using the above list of equipments, as per e) above

g) Utility norms per Kg of Opium processed

h) ETP scheme of treating the effluents

7. Taking into consideration the importance and sensitive nature of the Opium, it is very essential that the bidder firms have sufficient experience processing of production of bulk drugs, APIs, finished dosage forms and other pharmaceutical products . The applicants, or contracted company shall fulfill the following criteria:

- a. It should be an Indian pharmaceutical company in the public sector, private sector or joint sector.
- b. The company should be a reputed manufacturer of drugs/pharmaceutical formulations with average turnover of at least Rs. 100 Crores during the past three years. The turnover limit includes their entire range of production of bulk drugs, APIs, finished dosage forms and other pharmaceutical products.
- c. The applicant company should have a strong record of compliance with law and there should not be any convictions against the company or any of its key management personnel under Customs Act, Central Excise Act, Income Tax Act, Drugs and Cosmetics Act or NDPS Act.

8. The selection of an applicant would be made on the basis of financial bids, qualified bidders will be issued the financial bid documents. The bidding criteria would be minimum processing price per MT of the Opium gum. Minimum Business Guarantee shall be part of financial structuring.

9. The licensee will extract alkaloids only from the Opium to be supplied by the Govt. Opium and Alkaloid Works. In the process of extraction of alkaloids following key performance indicators will be considered for payment to the firm and the Department reserves the right to revise the same:- Extraction Efficiency as % of annual defined content	% of defined Govt. pay-out	Details
50% < x < 55%	85%	Complete Dis-incentivization
55% < x < 60%	92%	Partial Dis-incentivization
60% < x < 65%	As defined	As expected
65% < x < 70%	108%	Partial Incentivization
>70%	115%	Complete Incentivization

10. Interested parties may forward their "Request for Qualification" within 30

days from the date of publication of this notice alongwith the following:

- a. Company profile and its organizational set up.
 - b. Equipment/facilities currently available with them
 - c. Work history for the past 5 years including the company's ability to process the production of bulk drugs, APIs, finished dosage forms and other pharmaceutical products in India.
 - d. Balance sheets, Profit and Loss Accounts and any other financial statements for the past three years including any statement which clearly indicates their turnover for the past three years.
 - e. Brief note on how their experience will be useful in manufacture of alkaloids from opium.
 - f. A brief note on the pollution control, quality assurance and security control systems being followed.
 - h. Declarations, by way of sworn affidavit, that the company or any of its key management personnel were not convicted under:
(i). Customs Act. (ii). Central Excise Act. (iii). Income Tax Act. and. (iv). NDPS Act.
 - i. A demand draft for Rs. 5000/- in favour of PAO, Department of Revenue, Ministry of Finance, as non-refundable processing fee.
11. The envelope shall be superscribed with "Request for Qualification" and sent to the undersigned.

Anil Ramteke
Chief Controller of Factories
Department of Revenue
Ministry of Finance