

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

Request for Qualification of units to be engaged in manufacture of alkaloids/active pharmaceutical ingredients (APIs) from unlanced poppy capsule along with straw through CPS method.

2. India is one of the few countries permitted to cultivate opium poppy, obtain gum by lancing the poppy pods for extracting alkaloids for medicinal purpose from such opium gum. From the current FY i e 2021-22, the farmers have been licenced to grow unlanced poppy capsule alongwith straw for production of CPS and extraction of alkaloid therefrom. The entire unlanced poppy capsule alongwith straw is procured by the Central Bureau of Narcotics and transferred to the Govt. Opium and Alkaloid Works for further processing to extract alkaloids for medical use.

3. With a view to augment the existing capacity of production of alkaloids/APIs from opium licitly produced in India, the Government of India has resolved to allow Indian company on short term contract to produce alkaloids and APIs from the unlanced poppy capsule alongwith straw. The company is required to process at least **500 MT of (Minimum Business Guarantee)** unlanced poppy capsule alongwith straw per annum to manufacture CPS and extract alkaloids/active pharmaceutical ingredients (APIs) therefrom. **The contract will be valid for a period of 5 (Five) years.**

4. The Department seeks "Request for Qualification" from Indian companies having spare capacity to manufacture Alkaloids/APIs from the unlanced poppy capsule alongwith straw 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.

5. The contracted company's facility for processing CPS and production of alkaloids would be under the supervision of nominated GOAF personnel at the Company's factory who will supervise record keeping and other provisions, with respect to the NDPS Act / Rules, 1985.

6. Taking into consideration the importance and sensitive nature of the Poppy Straw, 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 good 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.

7. The selection of bidder shall be based on financial bids, qualified bidders will be issued financial bid documents. The bidding criteria would be minimum processing fee per MT of the unlanced poppy capsule alongwith straw. Minimum Business Guarantee shall form part of the financial structuring.

8. The licencees will extract alkaloids only from the unlanced poppy capsule alongwith straw 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 licensee:-

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

9. Interested parties may forward their "Expression of Interest" 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 will they manufacture CPS and extracts alkaloids from unlanced poppy capsule alongwith straw.
- f. A brief note on the pollution control, quality assurance and security control systems being followed.
- g. Declarations, in form 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.

10. 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