

Expression of Interest (EoI) for ToT of process for manufacturing of 2-DEOXY-D-GLUCOSE (2-DG)

1. Description

2-Deoxy-d-glucose (2-DG) is a glucose analogue, which has the 2-hydroxyl group replaced by hydrogen. 2-DG is transported in cells by the glucose transporters on the cell membrane but it cannot undergo further glycolysis and act as inhibitor of glycolysis. Therefore, cells with higher glucose uptake, for example tumor cells, virally infected cells, inflammatory cells have also a higher uptake of 2-DG. Since, it accumulates selectively more in such cells with high glucose demand; it offers an attractive approach of inhibiting tumor cell growth, viral infection and inflammation.

Laboratory synthesis process for 2-DG (2-Deoxy-d-glucose) has been developed using D-Glucose as starting material. The synthesis process consists of conversion of D-Glucose to 2-DG through five chemical reaction steps followed by purification. The process has been established at batch scale (100g) and pilot plant scale (500g). Necessary patents have been filled by DRDO in this regard. It is proposed to offer Transfer of Technology (ToT) of 2-DG to Indian Pharmaceutical industries for production. The ToT seeking Indian Pharmaceutical industries shall comply following criteria/ requirements:-

- (a) Drug License to manufacture Active Pharmaceutical Ingredient (API) from Drug Licensing Authorities.
- (b) API production capability.
- (c) WHO GMP (Good manufacturing Practices) certification.
- (d) Drug manufacturing facility consisting of chemical operation like acetylation, bromination, reductions etc over wide temperature range (-5 °C to 100 °C) and unit operations like vacuum filtration, vacuum distillation, extraction and crystallisation.
- (e) Capacity to absorb the technology and have capacity to produce the API with approximately 2000 Kg per month and bring the drug in the market within a shortest possible time.
- (f) Fulfilment of all regulatory requirements for manufacturing, QA/ QC etc for the API.
- (g) Not under any ban by Govt of India/ Any state Govt/ UT or any Govt Agency.
- (h) Not be under insolvency resolution.
- (i) In-house R&D facilities for API.

2. ToT Fees

ToT Fee of Rs 25 Lakhs is payable by industry to DRDO at the time of signing of Licensing Agreement for entering into Licensing Agreement for Transfer of Technology (LAToT).

3. EOI Submission Date

Industry may apply for Eol up to **17th June 2021**. The Eol is to be submitted by email only. The Eol submitted by industries will be scrutinised by a Technical Assessment Committee (TAC). Only up to 15 industries will be given ToT on their capabilities, technical handholding capability of DRDO and on “First Come First Served Basis”.

4. Contact Details

Interested companies are requested to apply against this Eol through email to following:-

To

Director

Defence Research & Development Establishment (DRDE)

Defence Research & Development Organisation

Govt. Of India, Ministry of Defence

Jhansi Road, Gwalior-474002

Email : [director\[at\]drde\[dot\]drdo\[dot\]in](mailto:director[at]drde[dot]drdo[dot]in)

Copy to (for information)

The Director

Directorate of Industry Interface & Technology Management (DIITM)

R No 447, DRDO Bhawan, DRDO HQrs,

Rajaji Marg, New Delhi -110011

Email : [diitm\[at\]hqr\[dot\]drdo\[dot\]in](mailto:diitm[at]hqr[dot]drdo[dot]in)

[tot\[at\]hqr\[dot\]drdo\[dot\]in](mailto:tot[at]hqr[dot]drdo[dot]in)

5. Documents to be submitted with Eol

The company must provide details about company and documents in support of their claim as per **Appendix- A**. Any additional documents as required by DRDO shall be sought based on request received from the interested industries.

6. Other Terms and Conditions

The Other Terms and conditions for industry seeking ToT are the following:-

- (a) DRDO reserves the right to reject any offer or proposal without assigning any reasons.
- (b) Submission of EOI does not guarantee ToT to applicant industry.
- (c) A committee of experts constituted by DRDO may visit the company manufacturing sites and facilities for assessing the strengths and capacity as furnished by the respective company before shortlisting for ToT.
- (d) Industry may obtain necessary permission/ License/ approval from the suitable authority for any application/ usage of 2-DG (2-deoxy-D-Glucose) as per the rules/ processes of Govt of India in vogue after successful ToT.

List of support documents to be attached with EOI

- (a) Memorandum and Articles of Association (Should be incorporated as per Indian Companies Act, as amended time to time)
- (b) Certificates of registration as a manufacturing unit, if any.
- (c) Audited Balance Sheet, turnover and net worth of the company for the preceding three years.
- (d) Income Tax returns for the preceding three year period
- (e) Details of shareholding/ownership pattern especially foreign partners/ shareholders, foreign employees, directors, etc. The company must adhere to the prevailing Govt of India policies and regulations on Foreign Direct Investment (FDI)/DIPP norms as applicable.
- (f) Annual budget (if any) for R&D during last three years.
- (g) Numbers and details of IPR or patents, etc., held by the company.
- (h) Number of technically or professionally qualified personnel.
- (i) Record of past performance (e.g., Supply orders executed against of Ministry of Defence orders, Public Sectors and Paramilitary Forces, if any).
- (j) Availability of adequate infrastructure (List of machines and their production capacities) and technical expertise to manufacture 2-DG.
- (k) List of Testing and Support equipments for 2-DG.
- (l) ISO/ ISI certification or any other certification (if any).
- (m) Relevant clearances form the authorities/ ministries (if any).
- (n) WHO GMP certificates, Drug License for API where it is proposed to manufacture.
- (o) Capacity and capability to undertake developmental work and to accept attendant financial and commercial risks.
- (p) Capacity/capability to market the product through the marketing network, sales and service network, reliability to maintain confidentiality.
- (q) Under taking from company seeking ToT that none of its Directors, Independent Directors, non-executive Directors, and Key management personnel are involved in any corrupt practices, unfair means and illegal activities.
- (r) Under taking from Company seeking ToT in respect of Para 1 (g) and Para 1(h) of EoI.
- (s) Brief description of R&D facilities and certificates recognised by any Govt agencies/ institutions like CSIR.