**CENTRAL MEDICAL SERVICES SOCIETY**
Ministry of Health & Family Welfare
*(Autonomous Body under MoHFW, Govt. of India)*
*2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road,*
*Chanakyapuri, New Delhi-110021* PHONE -:011-21410905/6, Fax -:011-21410849

**Date: - 29/09/2023**

**Minutes of Pre-bid Meeting**
**For Procurement of Sofosbuvir 400mg and Daclatasvir 60mg for NVHCP**
**CPP Tender ID: 2023_CMSS_771268_1, dated 12/09/2023**
**Pre-bid Meeting held on 19/09/2023 at 11:00 AM**

1. Following officials were present during the Pre-bid meeting: -
   (i) Dr. Sandhya Kabra, Deputy Commissioner (NVHCP)
   (ii) Dr. Partha Rakshit, Joint Director (NVHCP)
   (iii) Mr. D Mohapatra, GM (Finance), CMSS
   (iv) Ms. Anjana, GM (Procurement), CMSS
   (v) Mr. Lava Mishra, AGM (Procurement), CMSS
   (vi) Ms. Akanksha Jain, AGM (QA), CMSS

2. Following representatives from prospective bidders were present during the Pre-bid meeting: -

| Sr. No. | Name of Representative | Name of Bidder |
|---|---|---|
| 1. | Mr. Ankush & Mr. Arun Kumar Sharma | M/s Mylan Laboratories Ltd. |
| 2. | Mr. Arun Sharma | M/s Natco Pharma Ltd |

3. Queries from following prospective firms were received via email: -

| Sr. No. | Name of the bidders | | |
|---|---|---|---|
| 1 | M/s Mylan Laboratories Ltd. | M/s Natco Pharma Ltd | M/s Hetero Labs Limited |

4. Points raised by representatives of prospective bidders were discussed. After due consideration of the queries, the response/clarifications are enclosed.

## Annexure-1

**Pre-bid queries raised by the prospective bidders & their Response/Clarifications by CMSS**

| Sr. No. | As per tender | Bidder's Representation | Bidder's Name | Response/Clarifications |
|---|---|---|---|---|
| **1.** | Technical Specification of Sofosbuvir 400mg | We will be participate Sch I Sofosbuvir 400mg with the Pharmacopeia "IP" as applicable in India. | **M/s Mylan Laboratories Limited** | **Clarified as:**<br><br>Acceptable. |
| **2.** | Technical Specification of Daclatasvir 60mg | We will be participate Sch II Daclatasvir 60mg with the Pharmacopeia " IH", as applicable in India. | **M/s Mylan Laboratories Limited** | **Clarified as:**<br><br>Acceptable. |
| | | We intend to participate in this tender, however, we wish to seek clarification as per the attached letter against the following point:<br><br>Point No. 6, Testing Parameters and Methods, Technical Specification of Tab. Daclatasvir 60mg<br><br>We hereby declare that API Daclatasvir Dihydrochloride is official in IP and testing of Daclatasvir Hydrochloride (API) is being done as per IP monograph. Since, finished product Daclatasvir Tablets 60mg is not official in IP, so we are following In-house Finished product specification & standard testing procedure for said product.<br><br>Therefore, requested to consider the In-house method for the product under CMSS tender. | **M/s Hetero Labs Limited** | **Clarified as:**<br><br>Acceptable, However, tablet Daclatasvir 60mg must conform to dissolution test acceptance criteria i.e. the amount of Daclatasvir 60mg released is not less than 75% of the amount declared in the label. |
| | | We wish to bring to your attention towards the point no. 6 of technical specification of Tab. Daclatasvir 60 mg it is mentioned that " Testing parameters for tablets including dissolution, disintegration and assay studies for oral formulations must provided as per methodology prescribed in International Pharmacopoeia"<br><br>Please note that as per our information nobody in India market have product permission for Tab. Daclatasvir 60 mg as per International Pharmacopoeia. This product is continuously being supplied to various procurement agencies in India as per In house specifications only as Tab. Daclatasvir 60 mg is not official in India pharmacopoeia. It is pertinent to mention that API of Daclatasvir is official in Indian Pharmacopoeia. (Page no. 2005 of IP 2022).<br><br>This clause inserted in the technical specification in this tender only. This clause was not part of technical specifications of tender No. CMSS/PROC/2022-23/NVHCP/037 under which the procurement of these two drugs were dropped and a fresh tender for fixed dose combination of Tab. Sofosbuvir 400 mg + Daclatasvir 60 mg were floated. Unfortunately that tender for | **M/s Natco Pharma Ltd** | **Clarified as:**<br><br>Acceptable, However, tablet Daclatasvir 60mg must conform to dissolution test acceptance criteria i.e. the amount of Daclatasvir 60mg released is not less than 75% of the amount declared in the label. |

| | | | | |
|---|---|---|---|---|
| | | fixed dose combination was also scrapped inspite of two companies participating with complete technical docs and now this tender is floated.<br><br>We feel that this clause will restrict the competition as none or one company may qualify the technical specifications for supply of Tab. Daclatasvir 60 mg. It is requested that kindly remove this clause from the tender so that we may participate and supply Tablet Daclatasvir 60 mg as per Inhouse specifications. | | |
| **3.** | | Please allow us 75 days delivery period instead 60 days from LOA . | **M/s Mylan Laboratories Limited** | **Clarified as:**<br><br>Kindly adhere tender terms & conditions. |
| **4.** | | We would like to inform you that Govt/ Institutions across India using Sofosbuvir 400mg with "IP" specification and Daclatasvir 60mg with "IH" Specification. | **M/s Mylan Laboratories Limited** | **Clarified as:**<br><br>Kindly adhere tender terms & conditions. |

**Note: - Above changes will be part of the tender document.**

**Sd/-**
**GM (Procurement)**

**Annexure-2**

## REVISED CRITICAL DATE SHEET ARE AS UNDER:

| Description | Scheduled date |
|---|---|
| Bid Document Download End Date & time | 06/10/2023 till 03:00 PM |
| Bid Submission End Date and Time | 06/10/2023 till 03:00 PM |
| Last date of submission of original documents | 09/10/2023 till 03:00 PM |
| Bid Opening Date and Time | 09/10/2023 at 04:00 PM |

**Note: - Apart from above, all other terms & conditions of tender document will remain unchanged.**

**Sd/-**
**GM (Procurement)**

**Annexure-3**

**The technical specification of Schedule II (Daclatasvir 60mg) is revised and attached herewith.**

irrelevant to the context since the clause pertains to schedule M III for notified medical devices and in vitro diagnostics of the Drugs and Cosmetics Act. Moreover, the said clause stands obsolete now after the release of National Medical Device Policy, 2023.

b) Prospective bidders who attended the prebid meeting expressed their concern that though they conform to the testing parameters like dissolution, disintegration and assay they are not as per the International Pharmacopeia, Eleventh edition 2022 which is a requirement in the revised technical specification. They conform to these testing parameters as per the In-house standards.

Hence, in the view of above fact, the program division convened the meeting, for ratification of technical specification, if required, to promote competition for financial efficiencies ensuring adherence to quality standards of the said drugs. The meeting was convened urgently considering the critical stock of the above-mentioned drugs across the country and in larger public interest.

Agenda 1: To ratify the existing technical specifications of the tablet Daclatasvir 60 mg to be used for NVHCP and other related programs

The committee deliberated on the drug specifications of tablet Daclatasvir 60 mg and ratified few clauses. The committee approved the technical specifications for tablet Daclatasvir 30 mg drug as follows:

**Daclatasvir 60 mg**

**Technical Specifications**

1. Each tablet contains Daclatasvir 60mg.
2. Number of tablets per container:28 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act 1940 and Rules, made there under
4. The product insert must indicate dosage form (tablet) and the drug content, interactions, adverse effect and contraindications.
5. The product should conform to standards of Indian Pharmacopoeia/Official pharmacopoeia of any other country/In-house specification duly approved by licensing authority. Further, Daclatasvir 60mg must conform to dissolution test acceptance criteria i.e. the amount of Daclatasvir 60 mg released is not less than 75% of the amount declared on the label.
6. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act 1940 and Rules, made there under.

**General specifications**

1. Standard Shelf Life: should not be less than 24 months and atleast 5/6th of total shelf life i.e. ≥ 20 months at the time of delivery to the consignee site
2. Primary Container: Suitable, plastic/ glass bottle to contain 28 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.
3. Label: It should be in accordance with the statutory requirements as per Drugs and Cosmetics Act. The standard color of the label as approved by program division should be used. Each label should have clearly marked as "Government of India Supply, Not for Sale" on primary and secondary packaging.
4. Each lot shall be tested in compliance with the above specifications by a designated NABL accredited laboratory before supply as specified above and each batch should be accompanied by manufacturer's in-house testing report.

Agenda 2: To ratify the existing technical specifications of the tablet Daclatasvir 30 mg to be used for NVHCP and other related programs

The committee deliberated on the drug specifications of tablet Daclatasvir 60 mg and ratified few clauses. The committee approved the technical specifications for tablet Daclatasvir 30 mg drug as follows:

**Technical Specifications**

1. Each tablet contains Daclatasvir 30mg.
2. Number of tablets per container:28 tablets
3. Should be licensed under the provisions of Drugs and Cosmetics Act 1940 and Rules, made there under
4. The product insert must indicate dosage form (tablet) and the drug content, interactions, adverse effect and contraindications.
   The product should conform to standards of Indian Pharmacopoeia/Official pharmacopoeia of any other country/In-house specification duly approved by licensing authority. Further, Daclatasvir 30mg must conform to dissolution test acceptance criteria i.e. the amount of Daclatasvir 30 mg released is not less than 75% of the amount declared on the label.
5. The label must indicate clearly the manufacturing and the expiry dates, specific storage requirements, batch number and manufacturer's address and other requirements as per Drugs and Cosmetics Act 1940 and Rules, made there under.

**General specifications**

1. Standard Shelf Life: should not be less than 24 months and at least 5/6th of total shelf life i.e. ≥ 20 months at the time of delivery to the consignee site

2. Primary Container: Suitable, plastic/ glass bottle to contain 28 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap.

3. Label: It should be in accordance with the statutory requirements as per Drugs and Cosmetics Act. The standard color of the label as approved by program division should be used. Each label should have clearly marked as "Government of India Supply, Not for Sale" on primary and secondary packaging.

4. Each lot shall be tested in compliance with the above specifications by a designated NABL accredited laboratory before supply as specified above and each batch should be accompanied by manufacturer's in-house testing report

***The committee approved the modifications of the technical specification of the tablet Daclatasvir 60 mg and Daclatasvir 30mg in supersession to the previous specifications approved on 3.08.2023 vide file no: F.No.M.12052/01/2018-Hep (NCDC)***