

## Uttar Pradesh Medical Supplies Corporation Limited

Registered Office: SUDA Bhawan, 7/23, Sector-7, Gomti Nagar Extension, Lucknow-226010 E-Mail: <a href="mailto:quality@upmsc.in">quality@upmsc.in</a> Website: <a href="mailto:www.upmsc.in">www.upmsc.in</a> Contact Number: 0522-2838102

Letter No.: UPMSCL/MD/2020/8888

## OFFICE ORDER

Date: 17/10/2020

Firm, M/s Himalaya Meditek Private Limited Plot No.35 & 36,Pharmacity, Selaqui Industrial Area, Dehradun-248197 was declared L-1 in tender No.-UPMSCL/Drugs-002/26 dated 29/05/2018 for 17 drugs including drug code no. D06017 Dobutamine HCL 50mg/ml in 5ml ampoule & vide this office letter No.(1288/UPMSCL/Drugs/LOI/2018 dated 15/10/2018), the letter of intent was issued to the firm Himalaya Meditek Private Limited Plot No.35 & 36,Pharmacity, Selaqui Industrial Area, Dehradun-248197.

The firm had supplied batches HLI883F and HLI124C, against purchase order no. UP/UP/HQ/19/616/1 (10281910555), dated.30.05.2019 & UP/UP/HQ/19/840/1(10281912797), dated. 19.07.2019 of drug Dobutamine HCL 50mg /ml in 5ml ampoule to different health facilities of Uttar Pradesh.

Drug sample of said drug batch HLI883F was sent to M/s ITL Labs Pvt. Ltd., B-283-284, Mangolpuri Industrial Area, Phase-I, DELHI-110083 which has been declared as "Not of Standard Quality" vide test report no. D2020072300240 dated-09.08.2020 for the reason that "the sample does not conform to claim as per I.P. 2018 in respect to Description, sterility, particulate matter and assay test. Report received to UPMSCL on 01.09.2020.

The second portion of the sample of said drug batch HLI883F was further sent to two empanelled Laboratory of UPMSCL M/s Sophisticated Industrial Materials Analytic Labs. P. Ltd and Interstellar Testing Centre Pvt. Ltd and test report was found "Not Of Standard Quality" from both the laboratories .M/s Sophisticated Industrial Materials Analytic Labs. P. Ltd has declared above said drug batch as "Not of Standard Quality" Vide test report no FT0908000220 dated 26.09.2020 for the reason that "sample referred is Not Of Standard Quality as defined in the Act & the Rules thereunder as per IP, wrt Particulate matter & Assay". Report received to UPMSCL on 01.10.2020. Interstellar Testing Centre Pvt Ltd has declared the said drug batch as "Not of Standard Quality" Vide test report no ICP-2009230105 dated 23.09.2020 for the reason "sample referred is Not Of Standard Quality as defined in the Drug & Cosmetic Act 1940 & the Rules made thereunder wrt Particulate Matter & Assay". Report received to UPMSCL on 01.10.2020.

Another batch of Dobutamine HCL 50mg/ml in 5ml ampoule Batch No –HLI124C from firm was also declared "Not of standard Quality" from M/s Manisha Analytical Lab Pvt Ltd. Vide test report no F/19/0309/045 dated 19.09.2019, M/s ITL Labs Pvt.Ltd. Vide test report no D201910150037 dated 02.11.2019 and M/s Interstellar Testing Centre Pvt. Ltd. Vide test report no ICP-1911190094 dated 19.11.2019.

Notice for NSQ batch No-HLI124C (ref no:-UPMSCL/QC/2019/14925, dated 22.11.2019) was sent to firm on date 22:11.2019. The response of the firm was obtained on 28.11.2019 (ref no HIMALAYA/UPMSCL/L-3). The response given by firm was duly considered and found not satisfactory. However as per request of the firm all the test reports were provided by UPMSCL to firm on dated 29.11.2019.

Notice for NSQ batch No- HLI883F (ref no: UPMSCL/MD/2020/8730, dated 07.10.2020) was sent to firm on date 07.10.2020 and response was obtained on 14.10.2020 (ref no HMPL/2020-21/UP Reply). In response firm has requested to allow the process of testing of said medicines by the Government Laboratories as per Drug & Cosmetic Act as the Government Laboratories is the final authority before taking any action against the company.

All the bidder including the firm in question is well versed with the Terms and conditions of Tender document which provides that the drug samples shall be sent to the NABL accredited Laboratory empanelled by UPMSCL and if the drug is reported to be "Not of Standard Quality" the retained sample shall be sent to other two NABL accredited Laboratories empanelled by UPMSCL. In case any one of two empanelled Laboratory declares



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the drug as "Not of Standard Quality" in the test report then it shall be concluded that the drug is " Not of Standard Quality" .It is worth mentioning here that all the three NABL accredited Laboratories empanelled by UPMSCL have reported the drug to be "Not of standard quality". In case if there is only one or two empanelled laboratories for concluding the test on a specified drug then in that case the confirmatory test shall be done at Government Analysis laboratory, In the instant case, there are more than two NABL accredited laboratories which indicate that the drug supplied by the Firm is "Not of standard Quality" and therefore, the request for re-analysis of the sample from Government testing Laboratories is unsustainable.

In above case final report is "Not of standard quality" on the basis of three analytical laboratory test report. Thus firm Himalaya Meditek Pvt. Ltd has violated the tender clause No. 13(i) " if two batches of any drug supplied by the supplier is found not of standard quality, then the supplier shall be blacklisted for that particular drug for the period of 3 (Three ) Yrs. " and violated Agreement clause No- 4 (a), " If two batches of any drug supplied by the suppliers is found not of standard quality, then the supplier shall be blacklisted for that particular drug for a period of 3 year, " by supplying Not of Standard Quality two batches HLI883F and HLI124C of drug Dobutamine HCL 50mg/ml in 5ml ampoule to different health facilities of Uttar Pradesh. Hence, the firm Himalaya Meditek Private Limited is, hereby, blacklisted for the drug Dobutamine HCL 50mg/ml in 5ml ampoule for three years from the date of issue of this order.

Date:

17 /10/2020

Endorsement No: UPMSCL/MD/2020/ 8888

Attachment: As above

Copy: To following for information & necessary action.

- (1) The Principal Secretary, Department of Health and family welfare, Uttar Pradesh.
  - (2) Mission Director, National Health Mission, Uttar Pradesh.
  - (3) Director General, Medical and Health Services , Swasthay Bhawan, Uttar Pradesh.
  - (4) Director General, family welfare, Uttar Pradesh.
  - (5) Additional Managing Director, UPMSCL Lucknow.
  - (6) M/s Himalaya Meditek Private Limited Plot No.35 & 36, Pharmacity, Selaqui Industrial Area, Dehradun-248197.

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