



JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD.

(Public Sector Undertaking of Govt of Jammu & Kashmir)

Corporate Head Office: Plot N-58 Friends Colony, Satyam Road-Marble Market, Trikuta Nagar Jammu.
Corporate Office Kashmir: Opposite, State Motor Garage Deptt. Baramulla National Highway, Bemina
Telephone: 0191-2478842, 0191-2476548 (Jammu).

Subject:- Blacklisting/Debarring of product manufacture by M/s ANG Life Sciences India Ltd.

Order No: **35 JKMSCL of 2020**
Dated : **22 -12-2020**

Whereas, the Medicines i.e Pantoprazole Sodium Tablets IP 40 mg, bearing batch No. ATPP-2003, ATPP-2006 and ATPP-2009 manufacture by M/s ANG Life Sciences India Ltd., Khasra No; 139/2, village Jodhapur Barotiwai, District Solan, Himachal Pardesh have been supplied to Jammu and Kashmir Medical Supplies Corporation Ltd. against the Rate Contract approved by J&K Medical Supplies Corporation Ltd. for the tender No: **JKMSCL/Med/2019/361**, dated **19-09-2019**.

Whereas, the Tab. Pantoprazole Sodium Tablets IP 40 mg, bearing batch No. **ATPP-2003** was sent by Quality Control Cell JKMSCL for quality control check to Empanelled Laboratory of JKMSCL and the report of the drug in discussion was received vide Analytical report No. SKF-290620010 dated 29-6-2020, wherein the concerned batch of the drug in discussion was declared as "STANDARD QUALITY".

Whereas, the said batch i.e. ATPP-2003 was lifted by Drugs Control Officer DFCO, J&K for test/analysis and was declared "**NOT OF STANDARD QUALITY**" by the Government Analyst, Drug Testing Laboratory, Dalgate Srinagar vide test report No: L/DA/2020-21/630 dated 07-09-2020 for the reasons that the sample fails in "**Disintegration Test**".

Whereas vide this office letter No. JKMSCL/QC/SGR/2020-21/420-26 dated 08-09-2020, your company was asked to explain your position with regard to the declaration of said batch of medicine as "**NOT OF STANDARD QUALITY**" within three days.

Whereas, an explanation was served to the empanelled laboratory of JKMSCL for declaring the said batch "Standard Quality" vide letter No: JKMSCL/QC/Sgr/2020-21/463-65, dated 09-09-2020 and the reply was received on dated 12-9-2020 but was not satisfactory.

Whereas in the mean time state Drug Controller J&K advised Drug Analyst DTL, Dalgate Srinagar vide No; DFO/D-T/1793/23 dated 12-9-2020 to conduct "Dissolution" profile of the sample in question.

Whereas, reminder was sent to your company vide No: JKMSCL/QC/SGR/2020-21/526-32, dated 06-10-2020.

Whereas a fresh opinion was received from Government Analyst, Drug Testing Laboratory Dalgate Srinagar regarding the subject batch of drug, wherein the said batch was declared as "**NOT OF STANDARD QUALITY**" vide test report No: L/DA/2020-21/789 dated 09-10-2020 with the reason that the sample does not comply to the IP requirements with respect to "Dissolution Test" and your company was intimated vide No: JKMSCL/QC/SGR/2020-21/614-20 dated 10-10-2020 with regard to the fresh opinion.

Whereas the said batch was sent by the Quality Control Cell, JKMSCL Jammu for quality check to the another Empanelled laboratory of JKMSCL and the Analytical report of the said batch was received on 13-10-2020 vide test report No; DF2020091872 dated 30-9-2020 and the batch was declared as "**NOT OF STANDARD QUALITY**" for the reasons that the sample fails in "**Disintegration Test**".

Whereas the reply from your company was received, however was not satisfactory.

Batch No. ATPP-2006

Whereas, the batch Pantoprazole Sodium Tablets IP 40 mg, bearing batch No. ATPP-2006 was sent by Quality Control Cell JKMSCL for quality control check to Empanelled Laboratory of JKMSCL and the report of the drug in

discussion was received on 08-09-2020 vide Analytical report No. DF2020080868 dated 28-08-2020 wherein the concerned batch of the drug in discussion was declared as "**Not of Standard Quality**" for the reasons that the sample fails in "Dissolution Test".

Whereas, the said batch was lifted by Drugs Control Officer, DFCO, J&K for test/analysis and was declared as "**Not of Standard Quality**" by the Government Analyst, Drug Testing Laboratory, Dalgate Srinagar vide test report No; L/DA/2020-21/632, dated 07-9-2020 for the reason that the sample fails in '**Disintegration Test**'.

Whereas your company was asked to explain your position within three days vide letter No: JKMSCL/QC/SGR/2020-21/451-58, dated 08-9-2020 regarding declaring of said batch "Not of Standard Quality".

In the mean time State Drug Controller, J&K advised Drug Analyst DTL, Dalgate Srinagar vide No; DFO/D-T/1793/23, dated 12-9-2020 to conduct "Dissolution" profile of the samples in question and the fresh opinion was received from Government Analyst, Drug Testing Laboratory, Dalgate Srinagar regarding the subject batch of the drug wherein the said batch was declared as "**Not of Standard Quality**" vide test report No; L/DA/2020-21/790 dated 09-10-2020 with the reason that the sample does not comply to the IP requirements with respect to "Dissolution Test".

Whereas reminder was sent to your company vide No: JKMSCL/QC/SGR/2020-21/533-39, dated 06-10-2020.

Accordingly, your firm was intimated vide this office No: JKMSCL/QC/SGR/2020-21/621-27 dated 10-10-2020 with regard to the fresh opinion of the subject drug.

Whereas vide this office No: JKMSCL/QC/SGR/2020-21/724-30 dated 21-10-20 final reminder was served to your company and consequent upon reply was received but was not satisfactory.

BATCH NO-ATPP-2009

Whereas the analytical report of drug for Batch No: ATPP-2009 received on 03-10-2020 from the empanelled laboratory of the JKMSCL vide report No; SKF-040820046, dated 08-08-2020 and was declared as '**STANDARD QUALITY**'.

However, the same batch No: ATPP-2009 of drug was send to another empanel lab for testing and was declared as "**NOT OF STANDARD QUALITY**" vide Analytical report No: DF2020080869, dated 28-8-2020.

Whereas the said batch of drug was send to another empanelled laboratory of JKMSCL and was declared as "**STANDARD QUALITY** " vide analytical report No; SF0918002220/O dated 26-9-2020.

Whereas your company was asked to explain your position with in three days vide letter No: JKMSCL/QC/SGR/2020-21/439-46, dated 08-9-2020 regarding declaring of "**NOT OF STANDARD QUALITY**" of said batch.

Whereas reminder was sent to your company vide No: JKMSCL/QC/SGR/2020-21/512-18, dated 06-10-2020.

Whereas the said batch ATPP-2009 was lifted by Drugs Control Officer, DFCO J&K for test/analysis and was declared as "**Not of Standard Quality**" by the Government Analyst, Drug Testing Laboratory Dalgate Srinagar vide there test report No: L/DA/2020-21/850, dated 19-10-2020 for the reason that the sample fails in "**DISSOLUTION TEST**" and the said report of the Government analyst was sent to your company vide No: JKMSCL/QC/SGR/2020-21/689-95, dated 19-10-2020.

Whereas reminder was sent to your company vide No; JKMSCL/QC/SGR/2020-21/717-23, 21-10-2020 and the reply was received which was not satisfactory.

Whereas, vide this officer order No. 108-JKMSCL of 2020 Dated 02-09-2020 a team comprising of following officers was constituted to inquire into the quality failure of three (03) batches of the drugs Pantoprazole(ATPP-2003, ATPP-2006, ATPP-2009).

1. General Manager (Adm), JKMSCL.
2. General Manager (K), JKMSCL.
3. Sr. Law Officer, JKMSCL
4. Incharge Quality Control, JKMSCL.
5. Medical Officer, Quality Control, JKMSCL.

Whereas, the enquiry team submitted its report/opinion with the following recommendation:-

As per the policy for Blacklisting/ Debarring of Product or Company under clause-4 read with sub-clause-4.6

“If three batches of a particular item supplied under a tender tenure by the supplier are declared as Not of Standard Quality during its entire shelf life by an empanelled lab or Govt. Lab in test for assay and /or in any other parameter(s) and if such failures are further confirmed by another empanelled lab or Govt. Lab during its entire shelf life, the particular item of the drug shall be liable for blacklisting for a period of not less than 2(Two) years.”

The action as per “Policy for Blacklisting/Debarring of Product or Company” under clause-4, on account of Quality failure of Drugs and Medicines” read with sub-clause 4.6 may be taken against the manufacturer i.e. M/s ANG Life Sciences India Ltd. Khasra No. 139/2, village Jodhapur Barotiwal District Solan HP-174101.

Whereas, the matter was examined in light of above quality testing report and recommendation of the enquiry team, the competent authority has decided to take necessary action in the matter in terms of para 4.8 of Procedures

and policies/Guidelines (book) regarding Policy for blacklisting/debarring of product of company.

Now, therefore, it is hereby ordered that the **Product Tablet Pantoprazole Sodium IP 40mg** manufactured by M/s ANG Life Sciences India Ltd, at Khasra No. 139/2, Village Jodhapur, Barotiwal, District Solan, Himachal Pradesh-174101 is hereby debarred/blacklisted from JKMSCL for 02(Two) years with immediate effect.


Sd/-
Managing Director
J&K Medical Supplies Corporation Ltd.

No. JKMSCL/Adm/ANG LIFE/BL/52/2020/5876-82

Dated: 22-12-2020

Copy to the:

1. Financial Commissioner to Government, Health and Medical Education Department, Civil Secretariat, Jammu.
2. Financial Advisor/Chief Account Officer, JK, Medical Supplies Corporation Ltd.
3. General Manager-K, J&K Medical Supplies Corporation Ltd.
4. In-charge Quality Control Cell, J&K Medical Supplies Corporation Ltd.
5. Incharge Medical Officers Drug Ware Houses _____
6. PA to Managing Director, J&K Medical Supplies Corporation Ltd.
7. M/s ANG Life Sciences India Ltd, Khasra No: 139/2, Village Jodhapur Barotiwal, District Solan, HP-174101.


22.12.20
(Saleem Beigh), KAS
General Manager (Adm)
J&K Medical Supplies Corp. Ltd
Jammu