11/01.01.2013

File No. 4-173/2006-DC (Pt. GMH LAB)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

Tele. No. : 011-23236965
Fax No. : 011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 11 NOV 2013

To
M/s. GMH Laboratories,
Plot No. 13, Bhatoli-Kalan, Baddi,
Dist-Solan, H. P.

Subject: Grant of permission to manufacture and market FDC of Cefixime IP (as trihydrate) Eq. to Anhydrous Cefixime 100mg/200mg + Ofloxacin IP 100mg/200mg tablet-Regarding.

Sir,

You applied to this office for grant of permission to manufacture FDC of Cefixime + Ofloxacin tablets. After examining the documents, various deficiencies were observed which were communicated to you vide this office letter dated: 17.04.2012. Accordingly, you submitted your reply to this office vide letter dated: 12.11.2012. After scrutiny of the reply, it was observed that the data submitted by you may not be authentic. The detailed observations made after scrutiny of the reply is as under:-

1. Dissolution test and disintegration timer were not conducted during stability studies neither at initial stage nor during stability studies at different interval of timer. You have stated that due to oversight, you have not mentioned the results of dissolutions test as well as D.T. which is not acceptable.
2. COA of the product mentioned date of testing, however as per records, compression was also not carried out on that date. You have stated that it was a typographical mistake which is not acceptable.
3. It appears from the present data submitted by you that process validation report is just generated to satisfy the query raised as it is not in line with the process validation report submitted earlier.
4. You have not submitted any details with regard to dissolution media used, RM, time etc. while conducting comparative in-vitro dissolution studies.
5. Now you have submitted the revised BMRs with changes values/results just to satisfy the query and is not inline with the results/values reflected during previously submitted BMRs.
6. Reply/clarification submitted by you in respect of average weight of tablet before and after coating is also contradictory when compared to the average weight submitted earlier.

Accordingly vide this office letter dated: 06.06.2013 you were requested to come for technical discussion on 10.06.2013 alongwith certain data in respect of the application filed by you in this office as same appeared to be of doubtful integrity. However, you did not turn up.

In view of submission of non authentic data, it is to inform you that your application is hereby rejected.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy for necessary action to:-

1. Deputy Drugs Controller (I), CDSCO, North Zone, CGO 1, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad. U.P.
2. The State Drugs Controller Authority, Nagar Panchayat Bhawan, Sai Road Baddi, Distt. Himachal Pradesh.