F. No. 7-5/2013/DCGI/WC (EU)
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES
OFFICE OF DRUGS CONTROLLER GENERAL (INDIA)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 22 OCT 2013

CIRCULAR

European Union has mandated through Directives No. 2001/83/EC dated 8th June, 2011 that every consignment of Active Pharmaceutical Ingredient (API) from non-EU/ non-listed countries must be supported by a "Written Confirmation" Certificate issued by the Competent Authority of that country, stating that the consignment conforms to standards of Good Manufacturing Practices (GMP) as laid down in the EU guidelines or equivalent thereof. This is effective from 2nd July, 2013.

This Directorate issues Written Confirmation Certificate on the basis of recommendation from the concerned CDSCO zonal office and the standards shall be applicable for issue of "Written Confirmation Certificate" for active substances exported to the EU for medicinal products for human use, in accordance with Article 46(2)(b) of Directives No. 2001/83/EC and the documents required should be as per: "Good Manufacturing Practices guide for Active Pharmaceutical Ingredients ICH Harmonized Triplicate Guideline stated as per ICH Q7".

This office has been receiving recommendation from CDSCO Zonal offices for the grant of Written Confirmation wherein long term stability data and accelerated stability data submitted by the firm is lesser than the period of 12 months and 6 months respectively. The matter has been examined in detail. While renewing our commitment to the spirit of the GMP and also keeping in regard the International Practices, it has been decided that applications containing 6 months accelerated and 6 months long term stability data on 3 batches and if no major changes from the specifications have been observed, issue of Written Confirmation Certificate to such API's would be considered subject to the following conditions:

1. The firm shall submit the Stability protocol along with the undertaking or a stability commitment, that an ongoing stability program is in place and they shall submit the data covering the retest period/shelf life of the API within 30 days on completion of the studies to the concerned Zonal Office.

2. The firm should assign retest/expiry date of the API based on available stability data or as per the procedure laid down in the ICH Guidelines. The firm shall provide a commitment regarding the retest period/ shelf life of the API.

In view of the above all the applicants seeking Written Confirmation Certificate with 6 month stability data should submit an undertaking as mentioned above along with their application.

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

To,

1. All Stake Holders
2. All Zonal and sub-Zonal Office, CDSCO.

Copy To:

1. US (Drugs)
2. Guard file.