



# CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SSI) (Regd.)

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## Constituent Members

All India Small Scale Pharmaceutical Mfrs. Association, New Delhi-110054

All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

Himachal Drug Mfrs. Association, Baddi -173205

J&K Small Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

Organisation of Pharmaceutical Mfrs., Hyderabad - 500038 (A.P.)

Ludhiana Drug Mfrs. Association, Ludhiana - 141001

Rajasthan Pharmaceutical Mfrs. Association, Jaipur - 302006

The Pharmaceutical Mfrs. Association of Tamilnadu, Chennai - 600015

Pharmaceutical Mfrs. Association (Kanpur), Kanpur, U.P.

West Bengal Small Scale Pharmaceutical Mfrs. Association, Kolkata - 700033

Baghat Pharmaceutical Mfrs. Association, Solan - 173212

BBN Industries Association, Baddi - 173205

Federation of Pharma Entrepreneurs, Gurgaon - 122015

Association of Pharmaceutical Mfrs., Haridwar - 249403

Devbhoomi Association of Pharmaceutical Mfrs., Dehradun - 248002

Karnataka Drugs & Pharmaceutical Mfrs. Association, Bangalore - 560001

Sirmour Pharma Mfrs. Association, Paonta Sahib - 173025

Ambala Pharmaceutical Mfrs. Association, Ambala City - 134003

Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No.: CIPI/2017/229  
17<sup>th</sup> May, 2017

Sh. K.L. Sharma  
Joint Secretary, Ministry of Health & Family Welfare  
Department of Health & Family Welfare

**Sub: Gazette Notification No. 327(E) dated 03.04.2017-  
Biopharmaceutical Classification System**

Dear Sir,

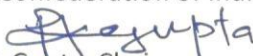
Sir, it is very much unfortunate that Ministry of Health (MoH) vide Notification No. 327(E) dated 03.04.2017 under your signature has notified many drugs for which Bioequivalence report is mandatory. We have gone through the products which have been notified for BE studies. We noted that 99% drugs are 50 years old and many pharmaceutical manufacturers are manufacturing these drugs since long. It has never come to notice that these drugs have not given response when compared to the large company's drugs.

It has become difficult to find out which company's product is to be treated as reference sample because many Large Medium Small companies are manufacturing these drugs. It is also to be noted that any drug which is in the market for the last more than 4 years, there is no requirement to follow Schedule Y of the Drugs and Cosmetics Act. On the other hand, institutions/CROs which perform these tests/studies are not adequate, as a result such studies may take a very long period and a huge amount is to be spent by the Pharmaceutical industry to these CROs. Ultimately no purpose will be solved and the amount spent by Pharmaceutical industry shall go into the drain.

Pharmaceutical industry especially in export business is also passing a very tough time because even small countries where there is no Pharmaceutical industry and strong Pharmacy background, have started to ask Indian manufacturers that as per the notification of Indian government, bioequivalence is needed in future for registration of products.

We are confident that registration in other countries will become difficult and costly and ultimately will affect the export business. It is our humble request that this notification be revoked. In this regard, a letter may kindly be issued so that exporters can inform that this clause has been deleted.

For Confederation of Indian Pharmaceutical Industry

  
P. K. Gupta, Chairman