

F. No. DCG (I)/MISC/2017 (93)
Directorate General of Health Services
Central Drugs Standard Control organisation
(O/o Drugs Controller General of India)

To

18 AUG 2017

All the State/UT Drugs Controllers

Subject: Request to advise the manufacturers to submit stability data of non-patent and proprietary medicines for grant of permission- reg.

Sir,

The Drugs & Cosmetics Act, 1940, is an Act, to regulate import, manufacture, distribution and sale of drugs and cosmetics. The Drugs & Cosmetics Rules, 1945, made under the Act prescribe statutory requirements for grant of license to manufacture for sale and distribution of drugs to ensure safety, efficacy and quality of drugs manufactured and sold in the country.

One of the conditions for grant of license to manufacture for sale and distribution of patent or proprietary medicines is that the applicant shall furnish to the licensing authority evidence and data justifying that the medicines are stable under the condition of storage recommended.

Stability of drug is of paramount importance to ensure quality, safety and efficacy of the drugs throughout its shelf life.

In view of above, you are requested to advise the manufacturer under your jurisdiction to submit the stability data of non-patent and proprietary medicines also at the time of submission of application for grant of permission to manufacture such medicine to ensure quality of products.

Yours Faithfully



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

CC:

1. JS (R), Nirman Bhawan.
2. All Zonal Sub Zonal of CDSCO
3. All drug manufacturers association\
4. CDSCO website