

File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Dated:

12 0 MAR 2019

To,
All State/UT Drugs Controllers

Subject: Procedure to be followed for subsequent applicant in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I) -regarding.

Sir,

This is with reference to this office letter dated 12.12.2018 whereby you were requested to ask the concerned manufacturers/stakeholders to follow the procedure as laid down by this Directorate for obtaining the product license w.r.t. FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I).

As per the said letter; 3 months accelerated Stability studies data was required to be submitted by the applicants for obtaining the product license from your office. However the matter was discussed in the 55th DCC meeting held on 31-01-2019 & 01.02.2019 and it was decided that applicant should submit 6 Months accelerated stability study data in place of 3 months accelerated data so that there is no disparity.

It is further clarified that the manufacturer who are not holding product licence prior to 01.10.2012 should generate and submit stability study data after obtaining From-29 from the concerned SLA.

Yours Faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy to:-

1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All Zonal/Sub Zonal offices of CDSCO
3. Indian Drug/Pharmaceuticals Association Forum
4. Website of CDSCO