

File No.4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Central Drugs Standard Control Organization,
FDA Bhawan, Kotla Road, New Delhi
(O/o Drugs Controller General (I))

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 05 SEP 2014

To,
All States / UTs Drugs Controllers

Subject: Database of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country -Regarding.

Sir,
Please refer to this office vide letter of even no. dated: 15.01.2013 regarding fixed dose combinations (FDCs) falling in the category of new drugs defined under rule 122(e) of Drugs and Cosmetics Rules licensed by State Licensing Authority (SLAs) without the prior approval of the licensing authority defined under rule 21(b).

In this regard, concerns have been raised from time to time regarding lack of proper database of FDCs licensed for manufacturing and marketing in the country.

In view of above, it has been considered necessary to have a comprehensive database of all FDCs that have been licensed by various State Licensing Authorities (SLAs) in the country.

You are therefore requested to provide list of all FDCs licensed by you till date in your state, as per the format given below:


S. No.	Name of the FDC with strength	Strength	Details of Licensee	Date of issue
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It is requested to fill above format in the manner as given below as an example.

S. No.	Name of the FDC with strength	Strength	Details of Licensee	Date of issue
eg. 1.	Azithromycin Dihydrate + Levofloxacin Hemihydrate Tablets	250 mg + 250 mg	1. M/s. ABC Ltd. Chennai 2. M/s. XYZ Ltd. Chennai 3. 4.	1. 15.07.2010 2. 05.01.2012 3. 4.
2.	Azithromycin Dihydrate + Levofloxacin Hemihydrate Tablets	500mg + 500 mg	1. M/s. ABC Ltd. Chennai 2. M/s. XYZ Ltd. Chennai 3. 4.	1. 25.05.2010 2. 03.08.2011 3. 4.

You are requested to forward the above details at the earliest in a hard copy as well as through an e-mail at fdcdvision@gmail.com. The matter may be given priority.

Yours faithfully,


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

Copy forwarded to:

1. Under Secretary, Drugs, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All Zonal / Sub-Zonal Offices of CDSCO ——— With the request to follow up with the concerned State Licensing Authority.

File No.4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o Drugs Controller General (I))

FDA Bhawan, Kotla Road
•New Delhi-110002
Dated: 17 SEP 2014

To,
All States / UTs Drugs Controllers

Subject: Database of Fixed Dose Combinations (FDCs) permitted for
manufacture for sale in the country -Regarding.

Sir,

This is in continuation to this office letter no. 4-01/2013-DC (Misc. 13-PSC) dated: 05.09.2014 regarding furnishing of list of all FDCs licensed by you till date in your State for creation of a comprehensive database.

In this regard, it is clarified that 'Date of issue' as mentioned in the format shall be considered as the date on which permission was granted for the first time for that particular product for that manufacturer (Licensee).

Yours faithfully,



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

Copy forwarded to:-

All Zonal/Sub-Zonal Offices of CDSCO-With the request to follow up with the concerned State Licensing Authority