

Registered

**GOVERNMENT OF RAJASTHAN
DRUG CONTROL ORGANISATION, SWASTHYA BHAWAN,
TILAK MARG, JAIPUR**

No. DC-2/2011/

Dated:

The Licensing Authority
Cum Controlling Authority,
CMO's Office Complex,
Solan Div., Distt. Solan-173212
(Himachal Pradesh)

Subject:- Change of colour in injection Leclav (1.2 gm), Batch No. LEE-1111, Mfg date:-
Aug. 2011, Exp. Date:-Jan 2013, Mfgd by M/s Park Pharmaceuticals, Village
Kalijhanda, near Nanakpura, Teh. Kasauli, Distt. Solan (H.P.)


Sir,

It has been reported that subject drug, when was reconstituted with water for injection, supplied by the manufacturer in the packing, changed the colour and solution became brown, whereas it should have been transparent. The matter was reported to this department by the Superintendent, Sawai Man Singh Hospital, Jaipur.

The drug has been supplied by the manufacturer to M/s Lee Chem. Biotech Pvt. Ltd., First floor, Plot No. 36, Sharma Colony, 22 Godam Industrial Area, Jaipur vide invoice no. 01169 dated 30.08.11 & No.01143 dt. 26.08.11 in quantity 4990 x 1.2 gm Inj., which was further distributed to M/s Medi Life Sciences, 22 Godam, Jaipur vide invoice no. 97 dt. 29.08.11 and 102 dt. 31.08.11 in quantity 3885 x 1.2 gm, M/s Medi life Science, Jaipur supplied it to M/s. Ganesh Distributer, Jaipur and M/s. Ganesh Distributer supplied the drug to M/s. Life Line Fluid Store, S.M.S. Hospital, Jaipur. Thus the case has been linked with manufacturer, Rajasthan based distributors have been asked to withdrawn the already sold drug in the trade.

Sample of the drug in question has been drawn under the provision of Drugs & Cosmetics Act 1940 & Rules made there under by Drugs Control Officer, Jaipur, which has been sent for analysis to Government analyst.

The purpose of writing this letter to you is, that the manufacturer being located under your Jurisdiction in H.P. You are requested to get the matter investigated at manufacturing site through your officers and to take appropriate action as deemed fit so that the drug in question is not used further till the report is received.

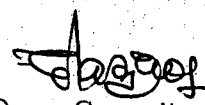

Drugs Controller
Rajasthan, Jaipur

Dated: 4-11-11

No. DC-2/2011/ (Gen-6) 668

Copy to:-

1. Superintendent, SMS Hospital, Jaipur.
2. Drugs Controller, Licensing Authority Cum Controlling Authority, Sai Road, Baddi (H.P.)
3. All Assistant Drug Controller's.
4. All Drug Control Officers to stop sale and distribution of said drug and to recall the said stock to take appropriate action under the provision of Drugs & Cosmetics Act & Rules made there under.
5. Incharge, Server Hq: Room to please put the letter on Departmental website..


Drugs Controller
Rajasthan, Jaipur