

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN, TILAK MARG,
JAIPUR

No.DC/D-1/Amend-41/2011/336

Date/6/06/2011

- 1- Mission Director, NRHM, Medical and Health Services, Hqr. Jaipur
- 2- Project Director, RHSDP, Medical & Health Services, Hqr. Jaipur
- 3- Director, Medical & Health Services (PH/FW/MSU/ESI/AIDS) Raj. Jaipur
- 4- All Principals, Medical Colleges, Rajasthan
- 5- All Superintendent, Associated Group of Hospitals, Rajasthan
- 6- Secretary, Store Purchase Organisation, Hqrs
- 7- All Asstt. Drugs Controllers, Rajasthan
- (Regd) 8- All Drug Control Officers, Rajasthan
- 9- All Manufacturers of Rajasthan State (formulations & bulk drugs)

Copy of letter No. 12-01-11-DC(Pt.27) Dated:- 03.06.2011 received from Drugs
Controller General (In-20), New Delhi is reproduced below:-

Sub:- Clarification regarding continued availability of Gatifloxacin
ophthalmic formulations- regarding.

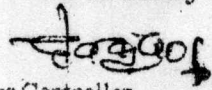
" Gatifloxacin formulation for systemic use in human by any route
including oral and injectable" was prohibited for manufacture, sale and distribution in
the country vide Gazette notification no. GSR 218 (E) dated 16.03.2011 issued by
Ministry of Health & Family welfare, Govt of India.

This Directorate has received representations from State Drug
Control Authorities, IDMA and other stake holders regarding clarification whether
topical formulations (eye drops and eye ointments) of Gatifloxacin are covered
under the said Gazette notification or not.

In view above it is clarified that Gatifloxacin ophthalmic
formulations like eye drops and ointments which are topical formulations and are not
for systemic use, are not covered under the Gazette notification no. GSR 218 (E)
dated 16.03.2011

Above clarification is being issued with concurrence of the Ministry of
Health & Family Welfare."

sdl/-
Drugs Controller General (India)

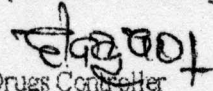

Drugs Controller
Rajasthan, Jaipur

No.DC/D-1/Amend-41/2011/336

Dated: 16/06/2011

Copy forwarded to following for information & needful action to :-

- 1- Drugs Controller General (India) F.D.A. Bhawan, Kotla Road, New Delhi
- 2- Dy. Secretary to Govt., Medical & Health (Gr.II) Deptt. Raj. Jaipur.
- 3- Dy. Drugs Controller(I), CDSCO (NZ), Kamla Nehru Nagar, Hapur Road,
Ghaziabad. (U.P.)
- 4- Director, Public Relations, Sachivalaya, Jaipur for publicity of ban order.
- 5- All P.M.O's/ C.M.&H.O's, Rajasthan State
- 6- Public Relation Officer, Swasthya Bhawan, Tilak Marg, Jaipur to please get it
published in all leading news papers.
- Regd. 7- President, RPMA, SP-2, 22-Godam, Jaipur to inform all manufacturers for
compliance.
- Regd: 8-President, Rajasthan Chemist Association, Dawa Bazar, Film Colony, Chaura
Rasta, Jaipur to please ask all the Chemists to restrain from distribution & sale of
above banned formulations with immediate effect.
- 9- Secretary, Jaipur Medical Association, S.M.S. Hospital Campus, Jaipur
- 10-Computer Desk/Concerning files
- 11-Incharge, Server Room to please put this order on departmental Website under
Gazette India and pls to please mail to all Principals (Medical Colleges),
P.M.O.'s and C.M.&H.O's.


Drugs Controller
Rajasthan, Jaipur

16/6/11

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