

File No. X11026/67/15-BD
Directorate General of Health Services
O/o Drugs Controller General (I)
(Biological Division)

Top Priority
Alert Notice

FDA Bhawan, Kotla Road,
New Delhi

Dated: 19 MAY 2015


Office Memorandum

Sub: Sub-standard quality of Human Albumin IP/EP (Albiomin 20%) 200 g/l, solution for infusion, Batch No. B236434, Mfd. Dt. 30/07/2014 and Exp. Dt. 30/06/2017 and Batch No. B236444, Mfd. Dt. 16/08/2014 and Exp. Dt. 31/07/2017, imported by Paviour Pharmaceuticals (P) Ltd., New Delhi - regarding.

Ref: Letter No. ADC/Delhi/Imp/NSQD-Paviour/14-15/119 dated 28/04/2015 from ADC(I), IGI Cargo Complex, New Delhi Vide FTS No. 22578/2015 dated 29/04/2015.

This is with reference to the Human Albumin IP/EP (Albiomin 20%) 200 g/l, solution for infusion, Batch No. B236434, Mfd. Dt. 30/07/2014 and Exp. Dt. 30/06/2017 and Batch No. B236444, Mfd. Dt. 16/08/2014 and Exp. Dt. 31/07/2017, manufactured by Biotest Pharma GmbH, Germany, imported by Paviour Pharmaceuticals (P) Ltd., New Delhi and declared as sub-standard by NIB, Noida.

In view of above, you are requested to recall the subject batches and keep vigil over quality of next batches imported by the firm and inform this Directorate in case of any non-compliance reported.


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

Enclosure: A test reports received from NIB, Noida.

To,

Asst. Drugs Controller (I),
Customs House, Indira Gandhi International Airport,
New Delhi)

Copy to:

1. All Zonal/ Sub-Zonal/ Port Offices of CDSCO - with the Direction to submit the action taken report to this office
2. M/s Paviour Pharmaceutical (P) Ltd., 311-312, Suneja Tower-I, District Centre, Janak Puri, New Delhi-110058- with the direction to submit the details of these batches in the market.