

BY REGD. POST WITH ACK. DUE

DEPARTMENT OF DRUGS CONTROL ADMINISTRATION
TAMIL NADU

PROCEEDINGS OF THE DIRECTOR OF DRUGS CONTROL (i/c), CHENNAI-6,
Present: Thiru.S. Abdul Khader, B.Pharm.,

D.Dis.No:2718/IW3/NSQ-268/2013-14

Dated: 16.07.2014

Sub: Drugs – Drugs and Cosmetic Act 1940 and rules thereunder –
Sample of Gentamycin Sulphate Inj IP, B.No. GS-12124, M/D.
08/12, E/D. 07/14, Manufactured by M/s. Tamman Titoe Pharma
Pvt. Ltd., Alathur - 603 110 - Declared as Not of Standard Quantity
- Suspension Order issued – Reg.

Ref: This Office show cause memo even No., Dated: 29.05.2014

M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 are holding valid drug manufacturing licence in Form 28, Bearing No. TN0000 2039, Dated. 25.02.2005 valid upto 24.02.2015 to manufacture drugs as endorsed in their licence.

M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 have manufactured Gentamycin Sulphate Inj IP, B.No.GS-12124, under licence in Form 28.

The Drugs Inspector R. Pirabu, Karaikudi office of the Assistant Director of Drugs Control, Virudhunagar Zone, drew sample of Gentamycin Sulphate Inj IP, B.No.GS-12124, manufactured by the said firm on 27.09.2013 from M/s. Government Primary Health Centre, Karaikudi for analysis.

The Government Analyst, King Institute, Drugs Testing Laboratory, in her report No. 360, Laboratory No. 217/2013-14, dated.17.02.14 has declared the sample does not conform to requirement for pH

M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 have contravened the section 18 (a) (i) of the Drug Cosmetic Act 1940 by having manufactured for sale and sold the subject Drug/Cosmetic which is declared as Not of Standard Quality.

In this office show cause memo dated. 29.05.2014 referred to above M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 were directed to show cause as to why their manufacturing licence in Form 28, bearing No. TN0000 2039, dated.25.02.2005 should not be **suspended** for a period of **Two weeks** in respect of the product i.e., Gentamycin Sulphate Inj IP.

The explanation dated. 26.06.2014 submitted by M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 has been examined and found to be not satisfactory in this regard.

Therefore the Director of Drugs Control and Licensing Authority in exercise of power vested in him under Rule 85 of Drugs and Cosmetic Rules 1945 hereby orders **suspension** of the manufacturing licence in Form 28, bearing No. TN0000 2039, Dated.25.02.2005 of M/s. Tamman Titoe Pharma Pvt. Ltd., Alathur - 603 110 for a period of **Two weeks** in respect of the product i.e., Gentamycin Sulphate Inj IP with immediate effect.

The receipt of this proceeding should be acknowledged immediately.

[Signature]
DIRECTOR OF DRUGS CONTROL (i/c).
AND LICENSING AUTHORITY
21/7/14

To

M/s. Tamman Titoe Pharma Pvt. Ltd.,
No.56 & 57, Sidco Pharmaceuticals Complex,
Alathur - 603 110

✓ Copy to: The Assistant Director of Drugs Control, Virudhunagar Zone. with Ref. to this report No. 970/E3/VNR/2014, dated: 28.04.2014

Copy to: The Assistant Director of Drugs Control, Kancheepuram Zone
[He is directed to watch the manufacturing activities of the firm during the suspension period and to submit his report in the matter.]

Copy to: D1 (1) through the Superintendent - for information.

Copy to: Drugs Inspector / Intelligence Wing

Spare Copy - 1

Ref. No : 970/E3/VNR/14 dt : 11.8.14

Forwarded copy for communication and Necessary action.

[Signature]
A.D.D.C.
11.8.14

To : The D.I. / Intelligence Wing