

NO.H.244/SD/100/Sub.Std. Drugs

Dt 22/09/2010

M.D. BY.

CMS : KYN BSL NGP SUR PA

Sub : Non-standard quality of Tab. Pioglitazone Hcl 15 mg.
Batch No.05901747 Mfg. Dt. 01-09-2009 Exp. Dt. 28-02-2011
By M/s. Glenmark Pharmaceuticals Ltd..

Ref : CMS SUR's letter No.U/MD/100/Drugs Analytical report dt.11-09-2010.

As per analytical report from Government Analyst Drug Control Laboratory, Maharashtra State, Aurangabad vide report No.NPS/NSQ/679/2010/2 dt. 31-8-2010 & Report No.M/975/2010 dt. 18-8-2010 Tab. Pioglitazone Hcl 15 mg. Batch No.0591747 Mfg. Dt. 1-9-2009 Exp. Dt. 28-02-2011 is **NOT OF STANDARD QUALITY.**

If the above Batch has been supplied to you the use of the same may please be discontinued immediately and full quantity of the supply order be got if replaced from the firm at their cost, payment should not be realized till the whole stock is replaced.

A copy of the replaced stock supplied should also be obtained from the firm and also sample sent for analysis.

DA/as above



(M. H. LIKHAR)
-/Chief Medical Director

Copy forwarded for information and necessary action to:
C/- DG(RHS), Railway Board, New Delhi.

C/- M/s. Glenmark Pharmaceuticals Ltd.,
Village Kishanpura, Baddi-Solan (H.P.)
Dist. Solan (H.P.) 174
Replace the whole order quantity immediately.

C/- **Chief Medical Director,**

Northern Railway, Baroda House, New Delhi.	N.W.Rly. Jaipur
Southern Railway, Park Town, Chennai-3.	EC Rly. Hajipur
SE Rly. Garden Reach, Kolkatta-13	W.C.Rly. Jabalpur
E.Rly, 12 th floor 14 Stand Road, Kolkatta-01	SE C Rly. Bilaspur
W.Rly. Churchgate, Mumbai - 20	E Coast Rly. Bhubaneswar
S.C.Rly. Raxil Nilayan Secunderabad-31	S.W.Rly. Hubli
N.E. Rly. Gorkhapur (UP)	NF Rly. Guhatti (Assam)

30/8/10

177

13/13

11/10/10
DDM/11
15/11

C. RLY

No.U/MD/100/1702 AURANGABAD

TO,
CMD CST MB


Office of the
Chief medical Superintendent,
Solapur.
Date: -11/09/2010

Sub: - Non Standard quality of Tab Piroglitazone Hcl 15mg having
Batch No 05901747 Mfg Date 1st/10/09 Exp Date Feb/2011

Ref: -Your S.Order No CMDR R/NO MED/263/333 Dated 31/08/2009.

With Reference to above subject matter, this is to inform that local Food & Drug administration Maharashtra State SOLAPUR has taken a sample of medicine Tab Piroglitazone Hcl 15mg OF above batch Number & found to be of **Non Standard quality** for the related substance & the drug is **Misbranded vide rule 96, section 17(b) of the Drug & Cosmetic Act, 1940 and rule there under.**

This is for your information & for necessary action please.


Chief Medical Superintendent
SOLAPUR

DA 1 Form 17 Dated 26/04/2010

- 2 Your Supply Order No CMDR R/NO MED/263/333 Dated 21/08/2009.
- 3 Letter from Local Food & Drug administration Maharashtra State SOLAPUR Dated 31/08/2010
- 4 Analysis Report No M/975/2010 Dated 18/08/2010
- 5 Enclosure of AR/M-975/2010, of DC Lab (MS) AURANGABAD

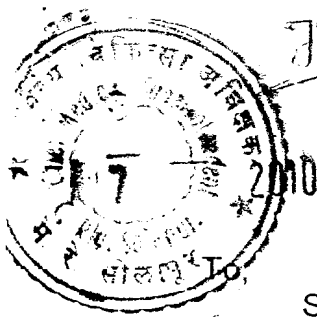
CC to

Office of the Assistant Commissioner
Food & Drug administration Maharashtra State SOLAPUR for
information please.

APMC
Share
Circulate all MD, CMSD
CMD & all indres RLY.
PR

Shyamshir A
16/9/10

3. Pa. 7. 8. 9. 10. 11. 12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22. 23. 24. 25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35. 36. 37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47. 48. 49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 59. 60. 61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71. 72. 73. 74. 75. 76. 77. 78. 79. 80. 81. 82. 83. 84. 85. 86. 87. 88. 89. 90. 91. 92. 93. 94. 95. 96. 97. 98. 99. 100. 101. 102. 103. 104. 105. 106. 107. 108. 109. 110. 111. 112. 113. 114. 115. 116. 117. 118. 119. 120. 121. 122. 123. 124. 125. 126. 127. 128. 129. 130. 131. 132. 133. 134. 135. 136. 137. 138. 139. 140. 141. 142. 143. 144. 145. 146. 147. 148. 149. 150. 151. 152. 153. 154. 155. 156. 157. 158. 159. 160. 161. 162. 163. 164. 165. 166. 167. 168. 169. 170. 171. 172. 173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199. 200. 201. 202. 203. 204. 205. 206. 207. 208. 209. 210. 211. 212. 213. 214. 215. 216. 217. 218. 219. 220. 221. 222. 223. 224. 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2017. 2018. 2019. 2020. 2021. 2022. 2023. 2024. 2025. 2026. 2027. 2028. 2029. 2030. 2031. 2032. 2033. 2034. 2035. 2036. 2037. 2038. 2039. 2040. 2041. 2042. 2043. 2044. 2045. 2046. 2047. 2048. 2049. 2050. 2051. 2052. 2053. 2054. 2055. 2056. 2057. 2058. 2059. 2060. 2061. 2062. 2063. 2064. 2065. 2066. 2067. 2068. 2069. 207



No. NPS/NSQ/679/2010/2
Office of Assistant Commissioner
Food & Drug Administration,
Central Administrative Building,
'A' Wing, Solapur.
Date : 31-8-2010

Shri Siddayya Shivrudrayya Mathpati
Pharmacist, Medical Store,
Dr. K.M. Railway Hospital,
Bhayya Chowk, Solapur. (M.S.)

Subject :- Drugs and Cosmetic Act, 1940 and Rules thereunder
Not of standard quality drug : Pepar-15, Mfg. Lic
No. MNB/05/182, B. No.- 05901747, Mfg date-Sep. 09,
Exp. Date- Feb. 11

Ref. : 1) Form-17 Dated 26-4-2010.

Sir,

This is to inform you that the above sample of drug was drawn by the undersigned for purpose of test/analysis vide Form-17.

The Government Analyst, Drugs Control Laboratory, M.S., Aurangabad reported the said drug to be **not of standard quality** vide report in form 13 No. M/975/2010 dated 18-08-2010.

Therefore as per provision of section 25 (2) of the said act, the copy of report in form 13 No. M/975/2010, dated 18-8-2010 along with its protocol is enclosed herewith. You are hereby intimated to stop sale/distribution of said drug & recall the sold/distributed stock and submit the details thereof within 4 days.

also you are hereby intimated to submit information & certified copies of document to the undersigned as required under section 18-B & section 18-A of the said act.

1. Name, address & other particulars of the person from whom you had purchased the said drug.
2. Certified copies of purchase invoice, transport receipt payment made.
3. Purchase & sale/distribution record.
4. Your drug licence and its renewal

Kindly submit the certified copies of above documents and information immediately.

Kindly acknowledge receipt of this letter.

Dr. Chandra Prasad
27/8/10

Informing MO

Yours

S.B. Patil

(S.B. Patil)

Drug Inspector,
Food & Drugs Administration, M.S.,
Solapur.

Encl. Form 13 M-975/2010, dated 18-8-2010 alongwith protocol & method of analysis.

FORM 13

[See Rule 46]

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST
(Under Section 25 (1) of the Drugs and Cosmetics Act, 1940.)

Page : 1 of 2

Report # : M/975/2010

Name of the Inspector from whom received :

SHRI. N. P. SUPE
FOOD & DRUGS ADMINISTRATION, (M.S.)
ADMINISTRATION BLDG.-A, 2 ND FLOOR, DIST.
COLLEC. COMP, SOLAPUR-, MAHARASHTRA

Serial number and date of Inspector's memorandum :

NPS/3/4/SOLAPUR-DEPU/10 Dt : 26/04/2010

Number of Sample :

10 x 10 TAB

Date of receipt :

06/05/2010

Name of drug purporting to be contained in the sample :

PEPAR- 15 TABLETS

Condition of seals on the package :

Intact and Tallies with the specimen impression of the
seal received separately.

Results of tests or analysis with protocol of test applied :

Batch No. : 05901747

Mfg. Date : 01/09/2009

Mfg. Lic No. : MNB/05/182

Exp. Date : 28/02/2011

Anomalies :

Observation on labelling :-

Content And Container Label : PEPAR- 15 TABLETS

PIOGLITAZONE HYDROCHLORIDE TABLETS
COMPOSITION
EACH UNCOATED TABLET CONTAINS
PIOGLITAZONE HYDROCHLORIDE
EQUIVALENT TO PIOGLITAZONE.....15MG
EXCIPIENTS.....QS
STORE IN A COOL DRY PLACE
RAILWAY HOSPITAL SUPPLY NOT FOR SALE

Manufactured by :

GLENMARK PHARMACEUTICALS LTD
VILLAGE KISHANPURA, BADDI - NALAGARH ROAD, DIST. SOLAN (H.P.) - 174
101.

Description :

WHITE CIRCULAR FLAT, BEVEL EDGED UNCOATED TABLETS.

Report # : M/975/2010

(Tested as per I.P.)

entification : The sample gives I.P. identification tests for the presence of Pioglitazone hydrochloride.

he sample complies with LP. requirements for the following tests :-

UNIFORMITY OF WEIGHT

DISSOLUTION

ie sample does not comply for the following tests :-

RELATED SUBSTANCES

Assay :

INGREDIENT	FOUND	% OF LABELLED AMT.	LIMIT
PIOGLITAZONE	15.05MG/ TABLET	100.33	90 - 110

ditional Text : (For details of the test Related substances please refer enclosure with this report.)


the opinion of the undersigned the sample referred to above is of NOT OF STANDARD QUALITY as defined the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below :-

pinion

he sample does not comply with LP. requirements for the test Related substances.

V.B.: Pioglitazone tablets are official monograph (drug) in Addendum 2008 of LP.2007. But the manufacturer does not state LP. on the label of drug, hence the drug is misbranded vide Rule 96, Section 7(b) of the Drugs and Cosmetics Act, 1940 and Rules there under.)

∴ 18/08/2010


Dayanand P. Awashank

GOVERNMENT ANALYST (M.S)

[See Rules 56 and 145A]

Intimation to person from whom sample is taken.

From,
Shri. N.P. Supe
Drugs Inspector,
Food and Drug Administration, M.S.
Solapur.

To
Shri. Siddayya Shivrudrayya Mathpati
Pharmacist, Medical Store
Dr. K. M. Railway Hospital
Bhayya Chawalk
Solapur (M.S.)

I have this day taken from the premises of M/s. Medical Store
situated at Dr. K. M. Railway Hospital, Bhayya
Chawalk, Solapur, M.S.
samples of drugs/cosmetics as specified below for the purpose of test or analysis.
Date: 26/4/2010

Details of samples taken

Inspector

- ① 4 x 1 x 10 x 14 Tablets LOMOL-SD, Lot No: U9008, Mfg. Mar. 2010
Exp. Nov. 2012, Manufactured in India by: Khan Telwal
Laboratories Pvt. Ltd. Plot No. 20, Sec: 6, IIE, SIDCUL, Patna Nagar
U.S. Nagar-263153, Uttarakhand.
- ② 4 x 1 x 10 x 10 Tablets. CARVAS-6.25, Mfg. Lot No: 10/220 Batch
No: D90758, Mfg. Date: Oct/2009, Exp. Date: Sep/2011, Manufactured
by: Medley Pharmaceuticals Ltd, Factory: ZARI Causeway Rd.
Kachigam, Daman.
- ③ 4 x 1 x 10 strips of 10 Tablets each Pepar-15, Mfg. Lot No: MKB/05/182
Batch No: 05901747, Mfg. Date: Sep. 09, Expiry date: Feb. 11
Manufactured in India by: Glenmark Pharmaceuticals Ltd.
Village: Kishanpura, Baddi, Nalagarh Road Dist Solan (H.P.)
- ④ 4 x 1 x 10 x 10 Tablets LOMADOL-50 DT, Mfg. Lot No: MKB/06/
396, Batch No: LOD-9101, Mfg. Date: OCT-09, Exp. Date: MAY-11
Manufactured & marketed by: Parvateer Drugs (India) Limited
Village: Bhud, Post: Baddi, Tehsil: Nalagarh Dist Solan (H.P.)
- ⑤ Date: 26/4/2010
4 x 1 x 100mg Citel, Mfg. Lot No: -
Batch No: CCC09A04, Mfg. Date: 01/2010 Exp. Date: 12/2012
Mfg. in India by: Indoco Remedies Ltd, Village: Kacha
Baddi, Tehsil: Nalagarh, Dist: Solan (H.P.) 173205.
Date: 26/4/2010

(N.P. Supe)
(Drugs Inspector)

Inspector
(N.P. Supe)

27/4/10