

**No. 31015/13/2018-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,  
New Delhi 110 001**

**Order**

1. This is an order on an application dated 20.01.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Ltd. (hereinafter called the applicant) against notification S.O. No.02(E), dated 01.01.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Tigatel CH 80.

2. The applicant has contended as under:-

2.1 In retail price notification of above formulations, market based data were not considered; rather previously notified prices were extended. As per para 9(4) of DPCO 2013 – “Market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug.” Therefore, the price notified for captioned formulations appear to be contrary to DPCO provisions.

2.2 It is pertinent to note that the price notified to captioned formulation is actually the extending the previously notified price of similar drug by NPPA. In the minutes of the 184<sup>th</sup> (overall) and 52<sup>nd</sup> meeting of the Authority under DPCO, 2013 held on 15.01.2018, NPPA clarified that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to subsequent applicants also without any annual indexation. Such extension of previously notified price to current date is not as per DPCO 2013 provision. Further, no reference of such notifications has been given by NPPA. Company highlighted the previously notified price vis-a vis recently notified price product wise –

<b>Products</b>	<b>Composition</b>	<b>Price per unit notified on 18.12.2017 (Rs.)</b>	<b>Previous Price per unit (Rs.)</b>	<b>NPPA S.O. /Date</b>
<b>Tigatel CH80</b>	Telmisartan 80 mg + Chlorthalidone 12.5 mg Tablet	6.713	7.00	SO 1689(E)/ 24.05.2017

2.3 Working sheet of these price notifications was not uploaded on the NPPA official website. It is pertinent to note that working sheet helps in understanding the price methodology & calculation and brings transparency in procedure.

2.4 Company also referred the DoP Review Order No. 31015/73/2016-PI.I dated 10.01.2017 and reproduce extract of “Examination” and “Government Decision” :-

**“Examination:**

As per provision of para 5(1) read with para 9(4) of DPCO 2013 NPPA is required to consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the new drug price as per the simple average formula contained in para 4(1) of DPCO 2013. NPPA has fixed the retail price of Rs. 14.30/ml based on the Form-I application submitted by M/s Nitin Lifesciences (Ltd.) (manufacturer) and M/s Galpha lab Ltd. (marketing company) for the same composition vide S.O. 1562(E) dated 27/04/2016, based on the decision taken in 14th meeting of Authority held on 23/04/2014 that the price for formulations having same composition and strength shall be valid for one year. This decision is not in accordance with the provisions of DPCO, 2013.

**Government Decision:**

Based on the above, the Government has decided as under:

“Review application of the company is accepted and NPPA is directed to re-fix the price as per the provisions of DPCO 2013 within one month of this Order, rather than deciding the prices on its own derived principles which are beyond the provisions of DPCO 2013. The calculation sheets should also be put up in the public domain.”

2.5 Company further submitted that the captioned formulation is not a Scheduled formulation, and hence applicability of Form – III, Form IV does not stand appropriate in this case. Therefore, term Scheduled formulation and footnote (f) should be removed for transparent instruction and compliance.

2.6 In view of above, company requested to issue necessary directive to NPPA to revise the retail price of captioned formulation.

**3. Comments of NPPA:**

3.1 Retail price of formulation fixed by NPPA, vide S.O. No. 02(E) dated 01.01.2018 as detailed below:-

Sl. No.	Name of the Formulation	Company's Composition	Product	Brand Name	Notified Price (Rs)
1	Telmisartan 80 mg + Chlorthalidone 12.5 mg Tablet	Each film coated tablet contains: Telmisartan 80 mg + Chlorthalidone 12.5 mg		Tigatel CH 80 Tablet	6.713

3.2 The Grievances of the company and NPPA's reply is as follow:

**i) Company's Grievance:**

Company stated that in retail price notification of above formulations, market based data were not considered; rather previously notified prices were extended. As per para 9(4) of DPCO 2013 – Market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug.” Therefore, the

price notified for captioned formulation is not as per provision of DPCO 2013. Company has also stated that it is pertinent to note that the price notified to captioned formulation is actually extending the previously notified price of similar drug by NPPA. In the minutes of the 184<sup>th</sup> (overall) and 52<sup>nd</sup> meeting of the Authority under DPCO 2013 held on 15.01.2018 NPPA clarified that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to subsequent applicants also without any annual indexation.

**NPPA's Comments:**

NPPA fixed the retail price of Tigatel CH 80 Tablet (Telmisartan 80 mg + Chlorthalidone 12.5 mg) manufactured/ marketed by M/s Sun Pharma Laboratories Limited as Rs 6.713 per tablet, vide S.O. 02 (E) dated 01.01.2018 (copy enclosed) under the provision of Para 5,11 and 15 of DPCO, 2013, as per the decision taken in 51<sup>st</sup> Authority meeting, wherein it was decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. This decision has been endorsed at a high level meeting which has been communicated to all concerned. Accordingly, the price was fixed as per the above decision.

**ii) Company's Grievance:**

Company further stated that working sheet of price notification was not uploaded on the NPPA office website which helps in understanding the price methodology and calculation and brings transparency in procedure.

**NPPA's Comments:**

As the retail price has been extended on the price notified earlier for other companies therefore, working sheet was not uploaded on NPPA website.

**iii) Company's Grievance:**

Company also referred DoP order No. 31015/73/2016-PI-I dated 10.01.2017 wherein it was decided as follows:

“Review application of the company is accepted and NPPA is directed to re-fix the price as per the provisions of DPCO 2013 within one month of this Order, rather than deciding the prices on its own derived principles which are beyond the provisions of DPCO 2013. The calculation sheets should also be put up in the public domain.”

**NPPA's Comments:**

Regarding DoP review order No. 31015/73/2016-PI-I dated 10.01.2017 against S.O. No. 1562 (E) dated 27.04.2016, it is to mentioned that the same was closed based on the decision taken in 53<sup>rd</sup> meeting of Authority held on 22.01.2018 where it was decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to subsequent applicants

also without any annual indexation since that has been nullified by Govt. New applications without any precedence to be dealt under para 5 of DPCO, 2013.

**iv) Company's Grievance:**

Company also pointed out about the table title column no. 2, and footnote (f) regarding submission of Form III in the caption notification and stated since it is not a schedule formulation the applicability for form – III and IV is not appropriate considering the formulation as new drug. Therefore, term scheduled formulation and footnote (f) should be removed for transparent instruction and compliance.

**NPPA's Comments:**

As regard to removable of the word schedule formulation in column (2) of the table and note of this notification, NPPA in principle agree to remove the same.

**v) Company's Grievance:**

Company pointed out about DoP review order 31015/09/2017-Pricing dated 27.08.2017 regarding retail price fixation of Volitra Enzo Tablet wherein DoP directed to remove the word 'schedule formulation' in column of (2) of table and Note (f) of the notification for this product, since the subject product is 'new drug.'

**NPPA's Comments:**

As regard to removable of the word schedule formulation in column (2) of the table and note of this notification, NPPA in principle agree to remove the same. However, M/s Sun Pharmaceuticals Industries Limited once again gone for review in this case, when decision of Govt. is awaited.

**4. Examination:**

4.1 NPPA cannot decide to adopt a different methodology for fixing of retail price of a new drug when the DPCO, 2013 clearly lays down the procedure for fixing such a price. The decision taken by NPPA in its 51<sup>st</sup> Authority Meeting held on 15.12.2017 was against the provisions of DPCO and hence it cannot be a basis for fixing the retail price of a new drug.

4.2 Review application of the applicant is accepted.

**5. Government Decision:**

**“NPPA is hereby directed to refix the retail price of new drug Tigatel CH 80 Tablet (Telmisartan 80 mg + Chlorthalidone 12.5 mg) strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.”**

**“NPPA is further directed to take similar action in all similar cases within a period of one month from the date of issue of the order.”**

Issued on this date, the 29<sup>th</sup> day of May, 2018.

**(M.K. Bhardwaj)**  
**Deputy Secretary**  
**For and on behalf of the President of India**

Copy to :-

1. M/s Sun Pharma Laboratories Ltd., 8-C, 8<sup>th</sup> Floor, Hansalaya Building, 15-Barakhamba Road, Connaught Place, New Delhi-110 001.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS (C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website