

**No. 31015/7/2018-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 16.01.2018, 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.3915(E), dated 18.12.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Tigatel AM 40, Tigatel H 40, Tigatel H 80, Tigatel AMH 40 and Tigatel AMH 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 Through OM F. No. 19(78)/2014/DP/NPPA/Div. II dated 19.12.2017; NPPA clarified that retail price for such formulations were notified on 18.12.2017 where the price of the similar drug was already approved by NPPA, by extending the same price already notified by NPPA. Such extension of previously notified price (in few case almost 4 years old price) to current date is arbitrary and unfair. Company highlighted the previously notified price vis-a vis recently notified price product wise –

Products	Composition	Price per unit notified on 18.12.2017 (Rs.)	Previous Price per unit (Rs.)	NPPA S.O. /Date
<b>Tigatel AM 40</b>	Telmisartan 40 mg + Amlodipine 5 mg Tablet	6.90	7.19	SO 2308(E)/ 24.08.2015
<b>Tigatel H 40</b>	Telmisartan 40 mg + Hydrochlorothiazide 12.5 mg Tablet	7.16	7.47	SO3780(E)/ 20.12.2013
<b>Tigatel H 80</b>	Telmisartan 80 mg + Hydrochlorothiazide 12.5 mg Tablet	11.12	11.60	SO843(E)/ 25.03.2015
<b>Tigatel AMH 40</b>	Telmisartan 40 mg + Amlodipine 5 mg + Hydrochlorothiazide 12.5 mg Tablet	7.48	7.80	SO 3145(E)/ 10.12.2014
<b>Tigatel</b>	Telmisartan 80 mg +	11.783	12.286	SO 845(E)/

<b>AMH 80</b>	Amlodipine 5 mg + Hydrochlorothiazide 12.5 mg Tablet			25.03.2015
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2.3 Company also referred the DoP Review Order No. 31015/73/2016-Pl.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.”*

2.4 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.

2.5 In view of above, company requested to issue necessary directive to NPPA to revise the retail price of captioned 5 formulations.

**3. Comments of NPPA:**

3.1 Retail prices of Tigatel AM 40, Tigatel H 40, Tigatel H 80, Tigatel AMH 40, and Tigatel AMH 80 notified as Rs 6.90, Rs 7.16, Rs 11.12, Rs 7.48, and Rs 11.783 respectively vide S.O. 3915 (E) dated 18.12.2017 as per Para 5, 11 and 15 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the retail price of Tigatel AM 40, Tigatel H 40, Tigatel H 80, Tigatel AMH 40, and Tigatel AMH 80. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Company's Grievances	NPPA's comments
<p>Company stated that In retail price calculation of above formulation, market based data were not considered; rather previously notified prices were extended. As per Para 9(4) of DPCO, 2013 the prices notified for captioned formulation appear to be contrary to DPCO, 2013 provisions. Through OM 19(78)/2014/DP/NPPA/Div II date 19.12.2017, NPPA clarified retail price for such formulations were notified on 18.12.2017 where the price of the similar drug was already approved by NPPA, by extending the same price already notified by NPPA. Such extension of previously notified price to current data is arbitrary unfair.</p> <p>Company further stated that the earlier notified price of of Tigatel AM 40, Rs 7.19 per tablet vide SO 2308 (E) dated 24.08.2015, Tigatel H 40, Rs 7.47 per tablet vide SO 3780 (E) dated 28.12.2013, Tigatel H 80, RS 11.60 per tablet vide SO 843 (E) dated 25.03.2015, Tigatel AMH 40, Rs 7.80 per tablet vide SO 3145(E) dated 10.12.2014 and Tigatel AMH 80 were Rs 12.286 per tablet vide SO 845 (E) dated 25.03.2015 whereas, NPPA vide SO 2915 (E) dated 18.12.2017 fix the prices as Rs 6.90, Rs 7.16, Rs 11.12, 7.48, and Rs 11.783 per tablet respectively.</p> <p>Company also stated that working sheet of this price notification was not uploaded on NPPA,s official website. Company is of the opinion that working sheet helps in understanding the price methodology &amp; calculation and bring transparency in procedure.</p>	<p>The Authority examined the Form I applications and decided in 51<sup>st</sup> Authority meeting that wherever the application has been received by NPPA for any new drug for which NPPA has already notified the price, the same would be extended to the subsequent applicant also. This decision has been endorsed at a high level meeting the minutes of which have been issued.</p> <p>Accordingly NPPA fixed the retail prices of Tigatel AM 40, Tigatel H 40, Tigatel H 80, Tigatel AMH 40, and Tigatel AMH 80 as Rs 6.90, Rs 7.16, Rs 11.12, Rs 7.48, and Rs 11.783 respectively vide S.O. 3915 (E) dated 18.12.2017 as per Para 5, 11 and 15 of DPCO, 2013.</p> <p>Earlier notification was issued when excise duty was applicable,. While fixing the subject formulation vide SO 3915 (E) dated 18.12.2017 the excise component was removed by multiplication factor of 0.095905 on account of GST implementation.</p>

#### 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. Decision:**

**“NPPA is hereby directed to refix the retail prices of new drugs Tigatel AM 40 (Telmisartan + Amlodipine tablet); Tigatel H 40 (Telmisartan + Hydrochlorothiazide); Tigatel H 80 (Telmisartan + Hydrochlorothiazide); Tigatel AMH 40 ((Telmisartan + Amlodipine tablet) and Tigatel AMH 80 ((Telmisartan + Amlodipine tablet) as per provision of para 5(1) read with para 9(4) of DPCO, 2013.”**

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