

**No. 31015/17/2018-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

A- Wing, Shastri Bhawan,  
New Delhi 110 001

**Order**

1. This is an order on an application dated 14.02.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharmaceutical Industries Limited. (hereinafter called the applicant) against notification S.O. No. 270(E), dated 16.01.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Stancef-O Plus Tablet and Volitra Enzo Tablet.

2. The applicant has contended as under:-

2.1 Application in Form -1 for Stancef- O Plus tablet & Ranixime Plus tablets (both having the same composition - Cefixime 200 mg + Ofloxacin 200 mg) was submitted to the Office of NPPA on 24.07.2017. The price of the Ranixime Plus was notified as Rs.9.46 per tablet on 18.12.2017. The said price is the price fixed by NPPA for the similar formulation in September 2016 and the same was extended to the company. Company requested for the review of this price extended to Ranixime Plus Tablets as well.

2.2 On 16.01.2018, NPPA notified the price of Stancef-0 Plus tablets as well as Rs.9.46 per tablet, which is a price fixed for the similar formulation in September 2016. It seems the process for fixation of the prices followed by the NPPA is contrary to the provisions made in DPCO, 2013.

Para 5(1) of the DPCO 2013 runs as "The retail price of the new drug available in the domestic market shall be calculated as provided in sub paragraph(1) of paragraph 4.

Para 4(1) runs as " The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step 1. First the average price to Retailer of the scheduled formulation i.e P(s) shall be calculated as below:

Average Price to Retailer.

2.3 Further provisions are made in Para 9 for the Reference data and source of market based data. Para 9(4) runs as "*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.*" Here in this case, the data available with the company reveals that the applicable MAT of for the month ending immediately before six months of receipt of application, and the average price of the available qualified formulations on the date have not been considered for price fixation.

2.4 Similarly the price of Volitra Enzo was notified as Rs.13.85 per tablet, which is a price fixed by NPPA in December 2016 for the similar composition and the same is extended to company.

2.5 In retail price notification of these two formulations, market based data were not considered; rather previously notified prices were extended. Therefore, the price notified for captioned formulations appear to be contrary to DPCO provisions.

2.6 The comparative of product wise already notified prices in 2016 and the price extended to us is depicted in the table below.

Products	Composition	Price per unit notified on 16.01.2018 (Rs.)	Previous Price per unit (Rs.)	NPPA S.O. /Date
Stancef-O Plus	Cefixime 200 mg + Ofloxacin 200 mg Tablet	9.46	9.86	S.O,2965 (E)/15.09.2016
Volitra Enzo	Trypsin BP 48mg, Bromelain 90mg, Rutoside Trihydrate BP 100mg & Diclofenac Sodium IP 50mg tablet	13.85	14.44	S.O.4131 (E)/22.12.2016

2.7 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.

2.8 In one of the earlier review orders, this authority was kind enough to decide in its Order No. 31015/73/2016-PI.I dated 10.01.2017 that *"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 complete review order with Examination is reproduced below:-

**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/m based on the Form-1 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.”

2.9 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 The retail price of above mention formulation fixed by NPPA, vide S.O. No. 270(E) dated 16.01.2018 is detailed below:-

S. No	Name of the Formulation	Company's Product Composition	Notified Price (Rs)
1	<b>Stancef-O Plus Tablet</b>	Each tablet contains : Cefixime 200mg + Ofloxacin 200 mg	9.46
2	<b>Volitra Enzo Tablet</b>	Each tablet contains : Trypin BP 48mg + Bromelain 90 mg + Rutoside Trihydrated BP 100 mg + Diclofenec Sodium IP 50mg	13.85

3.2 NPPA fixed the retail price of the above formulations marketed by M/s Sun Pharma Industries as Rs. 9.46 per tablet & Rs.13.85per tablet respectively vide S.O. 270 (E) dated 16.01.2018 on the basis of decision taken in the 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.

### 4. **Examination:**

4.1 The decision taken in 51<sup>st</sup> Authority meeting of NPPA, held on 15.12.2017 was erroneous as it was beyond the powers of NPPA to take such a decision which was contrary to the clear provisions provided in DPCO, 2013 for fixing retail price of a new drug. In the result that the ground on which NPPA fixed the price of subject formulation is wrong and against provisions provided in DPCO, 2013.

4.2 In view of the position explained above, the NPPA needs to be directed to fix the retail price of new drug strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.

**5. Decision:**

**“NPPA is hereby directed to refix the retail price of new drug Stancef-O Plus Tablet and Volitra Enzo Tablet 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 22<sup>nd</sup> day of June, 2018.

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

Copy to:-

1. M/s Sun Pharmaceuticals Industries Limited, 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.