

No. 31015/87/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

Subject: Review application of M/s Sun Pharmaceutical Industries Limited against price fixation of “Nitrofurantoin Capsule 100mg” vide NPPA order No. S.O. 2401(E), dated 28.07.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 25.08.2017
2) NPPA notification under review S.O. 2401(E), dated 28.07.2017
3) Record Note of discussions held in the personal hearing held in the matter on 07.11.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited (hereinafter called the petitioner) against notification S.O. No.2401(E), dated 28.07.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Nitrofurantoin Capsule 100mg.

2. The petitioner has contended as under:-

I. The price notification (i.e. S.O. No. 2401(E) dated 28/07/2017) issued in respect of Review Order No. 31015/91/2016-PI.I (dated 06.03.2017); however the Review Order implementation is partial, and not in totality. Thus, Company is aggrieved by the said notification and sought a review of the price notification of Nitrofurantoin Capsule 100 mg under paragraph 31 of DPCO 2013 on following grounds:

(i) The Review Order No. 31015/91/2016-PI.I dated 06.03.2017 reads as:-

*“NPPA is hereby directed to re-fix and re-notify the price of the products of the petitioner company under Para 4, taking into account Para 9(5) of DPCO 2013 and without applying WPI change in ascertaining the ceiling price. The same principle should be applied to all other such cases also by NPPA. NPPA is further directed to exclude the product pack of U FREE 100 mg capsule 14X10 of M/S Zydus Cadila in the price calculation of Nitrofurantoin 100 mg, verify the data of **URIFIST CP 100 MG** Capsule of M/s Cipla and to re-fix the ceiling price of Nitrofurantoin 100 mg Capsule, on merit.”*

(ii) Company submitted that despite having explicitly mentioned in review order:-

(a) WPI factor of Calendar year 2015, i.e. -2.7105% was applied in ceiling price application. It is against the Review Order.

(b) Pack of URIFAST CP 100 MG Capsule of M/s Cipla was not included in ceiling price calculation despite the product having composition as Nitrofurantoin 100 mg. We would like to highlight that the actual product name should read as URIFAST, and not URIFIST. We had also submitted the pack of URIFAST CP 100 MG Capsule of M/s Cipla along with our review application dated 20.10.2016 for perusal, and shown the pack during personal hearing dated 15.11.2016.

(iii) Company had submitted the price list in Form V of DPCO 2013 of the captioned ceiling price of Nitrofurantoin Capsule 100 mg.

II. In view of above, Company requested this Department to issue necessary directive to NPPA to include the pack of URIFAST CP 100 MG Capsule of M/s Cipla, and without applying WPI factor of Calendar year 2015, i.e. -2.7105% of captioned formulation.

3. Comments of NPPA:

I. Ceiling price of ceiling price of **Nitrofurantoin Capsule 100mg** was notified as Rs. 7.13/capsule vide S.O. 2401(E) dated 28.07.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Nitrofurantoin Capsule 100mg**. 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:-

Sl. No.	Company's Grievances	NPPA's comments
1	Company has stated that the said price notification came in effect of review order no. 31015/91/2016-PI-I dated 06.03.2017. Company has also stated that review order implementation is partial and not in totality. As per review order no. 31015/91/2016-PI-I dated 06.03.2017:- "NPPA was directed to re-fix and re-notify the prices of product of the company under para 4, taking into account para 9(5) of DPCO, 2013 and without applying WPI change in ascertaining the ceiling price. The same principle should be applied to all other such cases also by NPPA. NPPA was further directed to exclude the product pack of U FREE 100mg capsule 14X10 of M/s Zydus Cadila in the price calculation of Nitrofurantoin Capsule 100mg ,	NPPA fixed ceiling price of Nitrofurantoin Capsule 100mg as Rs. 7.13/Capsule as per direction given by DOP vide review order no. 31015/91/2016-PI-I dated 06.03.2016 against S.O. 3180(E) dated 07.10.2016 filed by M/s Sun Pharmaceuticals Industries Ltd. in respect of Nitrofurantoin Capsule 100mg . As per as the applicability of WPI is concerned, the same was done based on the policy being consistently followed by the Authority. The competent Authority discussed the matter with Department of Pharmaceutical and decided that the same cannot be changed retrospectively. Accordingly, WPI effect was given in CP calculation. As directed in the stated review order the data related to the product Urifist

<p>verify the data of URIFIST CP 100 MG CAPSULE of M/s Cipla and to re-fix the ceiling price of Nitrofurantoin Capsule 100mg, on merit.”</p> <p>Company has also pointed out:-</p> <p>a. WPI factor of calendar year 2015, i.e., -2.7105% was applied in ceiling price application. It is against the review order.</p> <p>b. Pack of URIFAST CP 100mg CAPSULE of M/s Cipla was not included in ceiling price calculation despite the product having composition as Nitrofurantoin Capsule 100mg. Company highlighted that actual product name should read as URIFAST, and not URIFIST. Company has stated they had submitted the pack of URIFAST CP 100MG CAPSULE of M/s Cipla along with their review application dated 20.10.2016.</p> <p>c. Company claimed that they had submitted the price list in form-V of DPCO, 2013 in respect of Nitrofurantoin Capsule 100mg.</p>	<p>CP 100mg capsule was sent to Pharmatrac for verification. Pharmatrac in its reply stated that there is no product in their data base as URIFIST CP 100mg capsule. Accordingly, Urifist CP 100mg capsule was not included in calculation sheet.</p>
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III. Company has not challenged S.O. No. 2401(E) dated 28.07.2017 in any Court.

4. Examination:

The petitioner company has challenged the NPPA Order S.O. 2401(E), dated 28.07.2017 for price fixation of their formulation **Nitrofurantoin capsule 100mg** on the ground that NPPA has not fully implemented the DoP's Review Order No. 31015/91/2016-PI-I dated 06.03.2017 against S.O. 3180(E) dated 07.10.2016. As regards the issue raised by the petitioner company about applicability of WPI, it has since been decided that WPI impact for 2015 will factor for fixing the ceiling price of the formulations which have first time been included in the scheduled-I of NLEM, 2015, since the data considered for calculating the ceiling price is of August, 2015. A revised Review Order No. 31015/91/2016-PI-I dated 22.01.2018 to this effect has already been issued.

As regards the issue raised by the petitioner company that the pack of URIFAST CP 100mg Capsule of M/s Cipla was not included in ceiling price calculation, it is seen that in the previous Review Order, there was a typographical error in mentioning the name of the formulation, and was written as URIFIST. In support of its claim, the company submitted documentary proof, which is placed at page 8/c. Hence, NPPA may be directed to hear the petitioner and examine the documentary proof submitted by the petitioner company about considering the pack of URIFAST CP

100mg Capsule of M/s Cipla, and after verification, refix the price of formulation **Nitrofurantoin capsule 100mg**, on merit.

5. **Government Decision:**

“The grievance raised by M/s Sun Pharmaceutical Industries Ltd. about not considering negative WPI for 2015 cannot be considered as the base price considered for fixing the ceiling price is of August, 2015.”

“NPPA is, however, directed to consider the petitioner’s representation and examine and verify the documents claimed by the petitioner, i.e. scanned copy of show box of URIFAST CP 100mg Capsule of M/s Cipla, and after verification, refix the price of formulation Nitrofurantoin capsule 100mg, on merit. The petitioner should submit his/her case/representation along with all documents/evidences at the earliest. NPPA would decide the case within a period of thirty days from the date of receipt of representation/evidences from the petitioner and intimate the Government.”

Issued on this date, the 21st day of March, 2018.

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

To

1. M/s. Sun Pharmaceutical Industries Limited,
Sun House, Plot No.201 B/1,
Western Express Highway, Goregaon (E),
Mumbai-400063.
2. Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building,
1, Jai Singh Road,
New Delhi-110001

Copy to :

1. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department’s Website