

**No. 31015/31/2017-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 IPCA Laboratories Limited against price fixation of "Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10's)" vide NPPA order No. S.O. 443(E), dated 14.02.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 03.03.2017  
2) NPPA notification under review S.O. No. 443(E), dated 14.02.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 31.10.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s IPCA Laboratories Limited (hereinafter called the petitioner) against notification S.O. No. 443(E), dated 14.02.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10's).

2. The petitioner has contended as under:

I. Company referred their representation letter dated **24<sup>th</sup> October, 2016** against draft worksheet dated **21<sup>st</sup> October, 2016** of Isosorbide-5 Mononitrate 20mg Tablets displayed on the NPPA website. NPPA has failed to carry out the rectification of company's observation in draft worksheet against **Sr. No. 21**. The PTR shown against this Sr. No. was Rs. 22.50 per 40 Tablets for **Solotrate 20mg Tablets** marketed by M/s. Zydus Cadila.

II. Following are their points for review under para 31 of DPCO - 2013:-

- (i) There is no pack of **Solotrate 20mg Tablets marketed by M/s Zydus Cadila in 40's**. This product pack is discontinued by Pharmatrac in their database and the same is made inactive. Hence NPPA need to delete **Sr. No. 21** of worksheet i.e. Solotrate 20mg Tablets in pack of 40's shown with PTR **Rs 0.56/Tablet**. Further IMS Health does not show Solotrate 20mg Tablets in 40's. It shows only pack of 10's.
- (ii) Under Sr. No.10, PTR of Isonorm 20mg Tablets 10's marketed by M/s Lupin is shown as **Rs. 1.62/Tablet**. The IMS Health Aug-2015 data shown PTR as **Rs.**

**22.71/10 Tables or Rs. 2.27/Tablet.** They understand that M/s. Abbott Healthcare has also challenged this point.

- III. In view of the above anomalies in the worksheet, they provided the correct calculation of ceiling price of Isosorbide-5 Mononitrate 20mg Tablets as under:

Particular	PTR Rs./unit
Sum of PTR per unit considered for price calculation as per worksheet published on 14.02.2017	30.26
<b>Less:</b> Sr. No.21 Solotrate 20mg Tablets 40's Rs.(0.56) Sr. No. 10 Isonorm 20mg Tablets 10's Rs.(1.62)	(2.18)
<b>Add:</b> Correct PTR of Isonorm 20 Tablets in 10's as per IMS Health August-2015.	2.27
Sum of PTR per unit after due correction	30.35
Number of packs now considered <b>(From earlier 12)</b>	11
Average PTR (30.35 /11)	2.76
<b>Add:</b> @16% Retailer Margin to Average PTR	0.44
<b>Ceiling price before WPI</b>	3.20
<b>Less:</b> WPI @ -2.7105%	(0.09)
<b>Correct Ceiling price per Isosorbide-5 Mononitrate 20mg Tablets</b>	<b>3.11</b>

- IV. They also enclosed extract copy of IMS Health for August-2015 and requested this Department for corrective action in the matter.

3. **Comments of NPPA:**

- I. In this regard, it is mentioned that ceiling price of Isosorbide 5 Mononitrate 20mg tablet was notified as Rs. 2.84/tablet vide S.O. 443(E) dated 14.02.2017 and revised to Rs. 2.90/tablet vide S.O. 1039(E) dated 01.04.2017 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 **Isosorbide 5 Mononitrate 20mg tablet**. 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 pointed out that there is no pack of Solotrate 20mg tablet of M/s Zydus Cadila in Pharma market as considered by NPPA in their calculation sheet for fixing the ceiling price of Isosorbide 5 Mononitrate 20mg tablet. Company has also pointed out that NPPA has considered PTR Rs. 1.62 per tablet	NPPA considered the data provided by AIOCD-AWACS for month of August 2015. The Authority notified the ceiling price of Isosorbide 5 Mononitrate 20mg tablet in terms of the decision taken in its 41st meeting held on 13.02.2017 vide S.O. No. 443(E) dated 14.02.2017 (copy enclosed). Company has not provided

	against the actual PTR Rs. 2.27 per tablet for Isonorm 20mg tablet of M/s Lupin Limited.	supporting documents in respect of products of other companies.
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III. Company has not challenged any notification in respect of **Isosorbide 5 Mononitrate 20mg tablet** in the Court.

## 5. Examination:

The company contended that there is no pack of Solotrate 20mg tablets marketed by M/s Zydus Cadila in 40's pack. On going through the calculation sheet, it is seen that the market share of Solotrate 20mg tablets (Sr.No.21) is only 0.01%, which otherwise should not have been considered while calculating the CP of the subject formulation. It is also observed that market share of Monit 20mg tablet 10 of Intas Pharmaceuticals Ltd. (Sr.No.5) is only 0.98%, i.e. less than 1%. NPPA has considered the PTR of 2 packs of Intas Pharmaceuticals, based on company wise 1% market share of MAT value, whereas DPCO does not recognize a company for average PTR but only medicines/formulations. It is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below :-

Formulation Name	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded having less than 1% market share</u>
Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10's)	10	2

5.2 In view of the above, NPPA may be directed to re-fix and re-notify the ceiling price of formulation Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10's) by considering the PTR of those formulations having MAT value of more than 1% market share.

5.3 The company also raised the issue of correct PTR of Isonorm 20mg tablets 10's, marketed by M/s Lupin, not being considered by NPPA. Company stated that, as per IMS Health Data, the correct PTR of Isonorm 20mg tablets is Rs.2.27/tablet as on August, 2015, whereas the NPPA has considered as Rs.1.62/tablet. In support of its claim, the company has submitted documentary proof. The company submitted the data of IMS Health, whereas NPPA consider Pharmatrac data. However, company claimed that the correct PTR of Isonorm 20mg tablets 10's marketed by M/s Lupin is Rs.2.27/tablet and not Rs.1.62/tablet, as considered by NPPA. In view of this, the Hearing Authority is of the opinion that NPPA may be directed to examine the information/documentary evidence submitted by the petitioner company, and after verification, re-fix and re-notify the ceiling price of formulation Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10's), on merit.

**6. Government Decision:**

**“NPPA is hereby directed to re-fix and re-notify the ceiling price of formulation Isosorbide 5 Mononitrate 20mg Tablets (Mono Isordil 20mg Tablets 10’s) by considering the PTR of those formulations having MAT value of more than 1% market share.”**

**“NPPA is further directed to examine the information/documentary evidence submitted by the petitioner company, and after verification, re-fix and re-notify the ceiling price of subject formulation, on merit.”**

Issued on this date, the 28<sup>th</sup> day of November, 2017.

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

**To**

- 1. M/s. IPCA Laboratories Limited,  
125, Kandivli Industrial Estate,  
CTS No.328, Kandivli (West),  
Mumbai-400 067.**
- 2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, 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**