

**No. 31015/49/2017-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 J.B. Chemicals & Pharmaceuticals Ltd. against price fixation of “Nifedipine Soft Gelatin Capsules 10 mg.” vide NPPA order No. S.O. 1039(E), dated 01.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:** 1) Review application dated 20.04.2017  
2) NPPA notification under review S.O. 1039(E), dated 01.04.2017  
3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.1039(E), dated 01.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Nifedipine Capsule 10 mg.

2. The petitioner has contended as under:-

- I. National Pharmaceutical Pricing Authority (NPPA) issued notification no S.O. 4128(E) dated 22<sup>ND</sup> December, 2016 fixing prices of Nifedipine Capsule at Sr. No. 01 under the provisions of Para 4 and explanatory note 1 of the first schedule of Drugs (Prices Control) Order (DPCO), 2013.
- II. AND WHEREAS, the worksheet for calculation of ceiling price of formulation Nifedipine 10 Mg- Conventional Capsule notified vide S.O. 4128 (E) dated 22<sup>ND</sup> December, 2016, NPPA has erred by considering their formulation “NICARDIA 10 MG CAPSULE 10” which is a **Soft Gelatin Capsule** and not covered in the First Schedule of DPCO, 2013.
- III. AND WHEREAS, Explanation 1 to First Schedule of DPCO, 2013 reads as under: **“if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included”**. The Report of the Core Committee for Revision of National List of Medicines published in November 2015 explained dosages form covered in NLEM, 2015 as under: “Oral solid dosage forms include tablet, capsule, sachet, etc. Tablets include film coated, uncoated, sugar coated etc. Capsules include hard gelatin capsule, soft gelatin capsules etc. **(Unless specified, capsules mentioned in the NLEM are considered as hard gelatin capsules).**”
- IV. AND WHEREAS, the company submits control sample and drug license clearly stating the specialized dosage type as Soft gelatin capsule. Thus, their

formulation is a Non Scheduled formulation and ceiling price cannot be made applicable to their formulation.

- V. AND WHEREAS, Department of Pharmaceuticals had allowed the company a personal hearing on 7<sup>th</sup> March, 2017 against their protest on calculation of ceiling price of formulation Nifedipine 10 Mg- Conventional Capsule vide S.O. 4128 (E) dated 22<sup>nd</sup> December, 2016. The company still awaits the Review Order.

**Under the circumstances:**

- (a) Soft Gelatin Capsules continues to be excluded from the First Schedule of DPCO, 2013 as they are not '**conventional capsules**' as clearly specified in the Report of the Core Committee for Revision of National List of Medicines published in November 2015 on Page 31, Soft Gelatin Capsules are non scheduled unless specifically mentioned in the National List of Essential Medicines, 2015.
- (b) Their formulations namely; "NICARDIA 10 MG CAPSULE 10" must not be considered in the calculation of ceiling price for aforesaid formulation for conventional Hard gelatin capsules.
- (c) NPPA should notify the ceiling price under the provisions of Para 4 of DPCO, 2013 for NIFEDIPINE CAPSULE 10 MG after removal of their Non Scheduled formulation for conventional hard gelatin capsules only.

VI. In view of above, applicant prayed as under:-

- a. To consider and conclude that NPPA had erred in pricing of their formulation Nifedipine Capsule 10 MG under Notification no. S.O 4128 (E) dated 22<sup>nd</sup> December, 2016.
- b. To consider and conclude that Nifedipine soft gelatin capsules are not conventional capsules as covered under the First schedule of DPCO, 2013.
- c. NPPA should wait for the Review Order to be notified by Department of Pharmaceuticals and consider compliance with S.O. 1039 dated 01<sup>st</sup> April, 2017 as under protest.
- d. Pass a speaking order in respect hereof.
- e. Any other order in interest of this manufacturer.

**Comments of NPPA:**

- I. Ceiling price of **Nifedipine 10mg Capsule** was notified as Rs. 0.79 per capsule vide S.O. 4128(E) dated 22.12.2016 and revised to Rs. 0.81/capsule vide S.O. 1039(E) dated 01.04.2017 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- II. The company stated that correct methodology was not followed in arriving at the ceiling price for **Nifedipine 10mg Capsule**. The points raised by the

company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 27<sup>th</sup> Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	NPPA has considered the PTR and MAT value of their formulation Nicardia 10mg Soft Gelatin Capsule while arriving the ceiling price for <b>Nifedipine 10mg Capsule</b> which is not as per the provisions of DPCO, 2013.	S.O. 1039(E) dated 01.04.2017 was issued to give the effect of WPI applicable from 01.04.2017 only. Nifedipine 10mg Capsule is included under section 12.3 of NLEM 2015. NPPA has considered the PTR and MAT value of their formulation Nicardia 10mg Soft Gelatin Capsule for working out the ceiling price of this formulation, which is in conformity with the provisions of explanation to note (1) of DPCO S.O. 701 (E) dated 10.3.2016 and as per 27 <sup>th</sup> Authority meeting decision held on 29.3.2016.
2.	Company has pointed out that their product Nicardia 10mg Soft Gelatin Capsule is a non-schedule formulation as it is not specified capsule mentioned in NLEM 2015.	NPPA fixed the ceiling price for <b>Nifedipine 10mg Capsule</b> as per the decision of 27 <sup>th</sup> Authority Meeting held on 29.3.2016, which is a scheduled formulation and there is no merit in company representation. NPPA has fixed the ceiling price for this pack strictly within the provisions of DPCO, 2013.
3.	Company has stated that they have filed a review petition against S.O. 4128(E) dated 22.12.2016 under para 31 of DPCO, 2013 for non-compliance with the provisions of para 4 of DPCO, 2013 and the review order is still awaited.	
		<p><b>Detail of trade margin based on AIOCD-AWACS data as on August 2015:-</b></p> <p>Trade Margin from PTS level of the product of J.B. Chemicals:-            Nicardia 10mg capsule 10's – 36.72%</p>

III. Company has not challenged any notification in respect of **Nifedipine 10mg Capsule** in the Court.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that –

- NPPA issued notification no. S.O. 1039(E) dated 1<sup>st</sup> April'2017 in respect of Nifedipine Capsule – 10mg, under Para 4 for Price Revision as per Annual Wholesale Price Index (WPI) @ 1.97186% increase.
- The ceiling price w.e.f (01.04.2017 with WPI @1.97186%) was erroneously fixed as Rs.0.79/-. This was due to the fact that the base price was incorrectly taken.
- The incorrect base price was notified by SO 4128(E) dated 22/12/2016. The error was due to the fact that the following product prices were wrongly considered.

Composition	Pack	Brand	Company	Strength	Pack size	Units	PTR	Mat %	Price per units
Nifedipine	Calcigard 10mg capsule 20	Calcigard	Torrent	10mg	20	Capsules	2.01	0.87 %	0.10
Nifedipine	Depin 10mg capsule 100	Depin	Zydus cadila	10mg	100	Capsules	30.83	0.3%	0.31

- In support to above Statement Company had provided the AWACS certificate dated 16/01/2017 which clearly indicates that above mentioned brand are inactive as on MAT Aug'15. So correct calculations based on the revised data is shown below.
- Personal hearing granted by DOP on 07.03.2017 in respect of the review application against SO. 4128(E) dated 22.12.2016. The order of the said hearing is awaited.
- Without prejudice, the company humbly submits that the data considered for calculation of ceiling price under Para 4 as notified while SO 4128 (E) dt. 22<sup>nd</sup> Dec'2016 is incorrect to the extent of the price per unit of certain formulations.
- For ready reference, company provided the correct calculations based on the corrected AWACS data.

Composition	Pack description	Brand	Company	Strength	pack size	units	PTR	MAT (RS)	SKU wise MAT	Qualify (Y/N)	Price per unit	Price per unit considered
Nifedipine	Cardules Retard 10mg capsule	Cardules	Abbott	10mg	10	capsule	12.24	55,765	0.22	N	1.224	
Nifedipine	Nifelat 10mg capsule	Nifelat	cipla	10mg	10	capsule	8.02	11,445	0.05	N	0.802	
Nifedipine	Nicardia 10mg capsule	Nicardia	JB Chemicals	10mg	10	capsule	10.49	37,33,120	14.88	Y	1.049	1.05
Nifedipine	Depicor 10mg capsule	Depicor	Merck	10gm	10	capsule	10.14	1,54,623	0.62	N	1.014	
Nifedipine	calcigard 10mg capsule 20	calcigard	torrent	10gm	20	capsule	2.01	2,17,256	0.87	N	0.1005	
Nifedipine	calcigard 10mg capsule 10	calcigard	torrent	10gm	10	capsule	10.11	89,08,656	35.50	Y	1.011	1.01
Nifedipine	Depin 10mg capsule	Depin	Zydus	10mg	100	capsule	30.83	6,413	0.03	N	0.3083	
Nifedipine	Depin 10mg capsule 30	Depin	Zydus	10mg	30	capsule	31.48	1,20,05,280	47.84	Y	1.049333	1.05
								Total Mat Value	2,50,92,558			3.11
										Average price		1.04
								Add		16% margin		0.17
										Average PTR		1.20
								Less		WPI Reduction 2.7105%		0.03
										Derived Ceiling price		1.17
								Add		WPI increase of 1.975%		0.02
										Final Derived Ceiling price per capsule		1.19

- As can be seen, the correct price of the product works out to Rs 1.19 per capsule instead of Rs. 0.79 as notified by the SO 4128 dated 22.12.2016.
- Thus the company requested to order revision in calculations of ceiling price and subsequently provide the effect of WPI for the calendar year 2017.

4. NPPA representative submitted the following as detailed below:

- a. With respect to the issue of soft gelatin capsule, NPPA has no further comments in addition to given above.
- b. With respect to inclusion of the products of Torrent Pharmaceuticals (calcigard) and Zydus Cadila (depin) while fixing the ceiling price, NPPA representative submitted that the same has been included based on the data provided by AIOCD-AWACS/Pharmatrac for the month of August, 2015 and as per the policy taken by the Authority in its 27<sup>th</sup> meeting dated 29.3.2016 regarding consideration of the least of the three alternatives while fixing the ceiling price.

## 5. Examination:

The stand taken by NPPA in the instant case is in order as **Nifedipine 10mg Capsule** is included under section 26.2.2 of NLEM 2015. NPPA has considered the PTR and MAT value of their formulation **Nicardia 10mg Soft Gelatin Capsule** for working out the ceiling price of this formulation, which is in conformity with the provisions of explanation to note(1) of DPCO S.O. 701(E) dated 10.3.2016. Therefore, the soft gelatin capsules are considered to be included in Schedule I on the following grounds:-

- (i) Nifedipine tablet 10 mg are specifically included vide Section 26.2.2 in NLEM 2015 without indicating any specific type of gelatin.
- (ii) Soft gelatin capsules are considered included in the light of the Explanation (1) in Schedule I of NLEM 2015, which says that if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included.

5.2 Moreover, there is no provision in DPCO to consider gelatin coating differently.

5.3 During the personal hearing, the representative of the company also raised the issue that PTR of two formulations, namely, '**Calcigard 10mg Capsule 20**' and '**Depin**

**10mg Capsule 100'** have been incorrectly considered as the aforesaid two packs are having market share at less than 1% of MAT for August, 2015 and must not be considered in the calculation of ceiling pricing under the provisions of Para 4 of DPCO, 2013. Since this review application against SO 1039(E), dated 1.4.2017 and not against SO 4128(E), dated 22.12.2016, this issue is irrelevant here and cannot be considered.

6. Government Decision:

**“The petition of M/s J.B. Chemicals & Pharmaceuticals Ltd. that the price of formulation “NICARDIA 10 MG CAPSULE 10” should not be considered, being Soft Gelatin Capsule and not covered in Schedule I of DPCO, 2013, cannot be accepted to as Nifedipine 10mg is included under section 26.2.2 of NLEM 2015.”**

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

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

To

1. M/s. J.B. Chemicals & Pharmaceuticals Ltd.  
“NEELAM CENTRE”, ‘B’ Wing, 4<sup>th</sup> Floor,  
Hind Cycle Road, Worli,  
Mumbai-400 030.
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