

**No.31015/22/2023-Pricing (E-23303)**  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

Room No. 207, D Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s Dales Laboratories Private Limited (hereinafter called the "Applicant") filed a Review Application dated 20.01.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 193(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the retail price of Paracetamol 500 mg + Phenylephrine Hydrochloride 5 mg +Diphenhydramine 25 mg + Caffeine (Anhydrous) 30 mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 02.06.2023 and present their respective logics.

**3. Major contentions raised by the Applicant:**

It was contended, on behalf of the applicant, that NPPA has erred in determining retail price of the above drug and hence may be directed to revise the retail price of their formulation by considering the actual PTR on the following grounds:

**3.1.** In the computation sheet (97965/2022/NPPA), NPPA considered P.T.R. Rs. 1.84/tablet for the company's product Sinus 77 Advanced tablet which is not correct.

**3.2.** NPPA fixed retail price for Sinus 77 Advanced tablet Rs. 2.57/tablet vide S.O. 02(E) dated 01.1.2018. Later on company availed 10% annual increase for this pack under para 20 of DPCO, 2013. Accordingly, PTR of company product Sinus 77 Advanced Tablet was Rs. 2.68 per tablet against the considered PTR 1.84 /tablet. Table of MRP revision is mentioned in table below:

1st Batch	1st	2nd	3rd	4th
B.No. 18058	Revision B.No.	Revision	Revision B.No.	Revision
Date	19053	B.No. 20037	21046	B.No.
27.09.2018	Date	Date	Date	22082
Mfg. Sep,	28.09.2019	29.09.2020	23.10.2021	Date
2018	Mfg. Sep,	Mfg. Sep,	Mfg. Oct, 2021	7.11.2022

Exp. Feb, 2020 MRP RS. 25.70	2019 Exp. Feb, 2021 MRP RS. 28.24	2020 Exp. Feb, 2022 MRP RS. 31.04	Exp. Mar, 2023 MRP RS. 34.11	Mfg. Nov, 2022 Exp. Apr, 2024 MRP RS. 37.49
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**3.3.** In addition, the cost of Paracetamol and others active ingredients used in the formulation have increased substantially. Moreover, NPPA has also allowed more than 10% increase in the WPI applicable for schedule formulations on 01.04.2022.

#### **4. Gist of clarifications made by NPPA:**

NPPA on the other side urged that the instant review is not tenable on the following grounds:

4.1. Under para 9(4) of DPCO, 2013, the data considered for fixation of retail price is data available for the month ending immediately before six months of the application date. Accordingly, data for April 2022 as appearing in Pharmatrac data base of October 2022 has been considered for the calculation of retail price. The PTR of brand Sinus 77 as appearing in the data was Rs. 1.84 per tablet. Accordingly, the same was considered for retail price fixation.

4.2. Thereafter, the draft worksheet was uploaded on NPPA's website on 20.12.2022 for 10 working days to invite comments from affected pharmaceutical firms in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals. No representation was received from M/S Dales or any other person in this respect.

4.3. Further, M/S Dales has never filed Form- V for the Sinus 77 claiming the annual increase of 10% as per provisions of Para 20 of DPCO, 2013. Therefore, the claim that correct PTR of the said tablet is Rs. 2.68 per tablet cannot be verified. Therefore, NPPA has taken correct data for retail price calculation of the above mentioned formulation as available in market based data i.e. Pharmatrac database.

#### **5. Examination:**

5.1. It is noted that Para 9 (4) of DPCO 2013 states that, *"The 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".*

5.2. In terms of extant provisions in para 20 of DPCO 2013, annual increase of up to 10% in the prices of Non-Scheduled Drugs are to be reported in Form-V under Schedule-II. It is noted that M/S Dales has never filed Form- V for the Sinus 77 claiming the annual increase of 10% as per provisions of Para 20 of DPCO, 2013. As a consequence, the contention advanced on behalf of the applicant that correct PTR of the said tablet is Rs. 2.68 per tablet cannot be verified.

5.3. Therefore, in the present case, NPPA had to depend upon the market based data as displayed in Pharmatrac for retail price calculation of the drugs being considered in the present case.

## **6. Decision:**

In the backdrop of these facts, the department is of opinion that the action of NPPA fixing the Retail prices of the formulation Paracetamol 500 mg + Phenylephrine Hydrochloride 5 mg +Diphenhydramine 25 mg + Caffeine (Anhydrous) 30 mg of M/s Dales Laboratories Private Limited vide S.O. No. 193(E) dated 11.01.2023 suffers no infirmity. Accordingly, the present review is rejected.

Issued on this, the 20th day of June, 2023.

  
(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India  
[For and on behalf of the President of India]

### **To:**

M/s Dales Laboratories Private Limited,  
101, Abhishek, C5, Dalia Industrial Estate  
Off Link Road, Andheri (West),  
Mumbai-400058, Maharashtra, India

### **Copy to:**

1. Chairperson, NPPA, New Delhi
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi
3. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
4. Technical Director, NIC for uploading the order on DoP's Website.
5. Guard File