

No.31015/58/2023-Pricing (E-23864)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Piramal Pharma Limited (hereinafter called the “Applicant”) filed a Review Application dated 27.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, *inter alia*, fixed the ceiling price of Calamine Lotion per ml. M/s Piramal Pharma Ltd is engaged in marketing of Caladryl Lotion containing Calamine IP 8% w/v and Diphenhydramine Hydrochloride IP 1% w/v and cosmetic product Lacto Calamine Face Lotion.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 06.11.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 NPPA issued a notification S.O. No. 1577 (E) dated 31st March, 2023 fixing ceiling prices of 127 Scheduled formulations, *inter-alia* including price of Scheduled formulation “Calamine Lotion as per IP” on per ml basis at Sr. No. 21. The working sheet of S.O. 1577(E) with respect to the Schedule formulation “Calamine Lotion as per IP” is incorrect since it includes the non-scheduled formulation “Caladryl Lotion” and the cosmetic product “Lacto Calamine Face Lotion” in its calculation of ceiling price.

3.2 The company’s product “Lacto Calamine Face Lotion” is a cosmetic product and cannot even be considered formulations and does not fall under the ambit of DPCO, 2013. The formulation “Caladryl Lotion” is not included in Schedule-I of the DPCO with effect from 11.11.2022 and hence the formulation “Caladryl Lotion” must not be included in the calculation of ceiling price for any other scheduled formulation.

3.3 Sr. No. 11.3.2 of Schedule-I of DPCO, 2013 includes “Calamine Lotion as per IP”. It is pertinent to note that Calamine IP 8% w/v + Diphenhydramine Hydrochloride IP 1% w/v is not explicitly included in Schedule-I of DPCO, 2013 and hence, must be construed as non-scheduled formulation. NPPA has erred by including the formulation “Caladryl Lotion” and the cosmetic product “Lacto Calamine Face Lotion” in its calculation of ceiling price for “Calamine Lotion as per IP”.

3.4 Calculation of price of Calamine Lotion as per IP is incorrect and must be rectified after removing the company's brand "Caladryl 8% Lotion 100 ml", "Caladryl 8% Lotion 60 ml", "Lacto Calamine Hydration Lotion 120ml" and "Lacto Calamine Hydration Lotion 60ml".

4. Gist of clarifications made by NPPA:

4.1 Under NLEM, 2022 Calamine Lotion (as per IP) is a scheduled formulation. Calamine Lotion was a Scheduled formulation under NLEM, 2015 also. Caladryl 8% lotion was included while fixation of ceiling price under NLEM, 2015 also. However, at that time the brand was owned by Johnson & Johnson. The brand was sold to Valeant Pharmaceuticals International, Inc. and Piramal Pharma Ltd. acquired the brand from Valeant Pharmaceuticals International, Inc. The above facts have been intimated by M/s JNTL Consumer Health (India) Pvt. Ltd. vide letter dated 17.03.2023 in relation to uploading of draft working sheet of Calamine Lotion.

4.2 No representation was made either from M/s JNTL or from M/s Valeant or from M/s Piramal for not including Caladryl Lotion while fixing the ceiling price of Calamine Lotion. Further, as mentioned above, the product was included while fixing the ceiling price under NLEM, 2015. Hence, the contention of the company that their product Caladryl Lotion is non-scheduled and hence should not be included while fixing the ceiling price is not tenable.

4.3 Similarly, no representation was received from the company in 10 working days with respect to Lacto Calamine Hydration Lotion also, when the draft working sheet was uploaded on NPPA website on 03.03.2023. Further, it is also pertinent to mention herein that all the line items appearing in Pharmatrac database as Calamine Lotion have been considered for draft worksheet and no representation were received from any other company.

4.4 Further, the major component in Lacto Calamine Hydration Lotion is Calamine. Pharmatrac also vide their email dated 13.06.2023 confirmed that Lacto Calamine Lotion contains CALAMINE +KAOLIN + ALOE VERA and in this Kaolin and Aloe Vera may only be considered as excipients in the lotion.

5. Examination:

5.1 It is noted that all the line items appearing in Pharmatrac database as Calamine Lotion have been considered for draft worksheet and no representation was received from any other company.

5.2 Caladryl Lotion was included while fixing the ceiling price of Calamine Lotion under NLEM, 2015 also. It is also noted that neither M/s JNTL nor M/s Valeant or M/s Piramal represented against inclusion of Caladryl Lotion in fixing the ceiling price of Calamine Lotion.

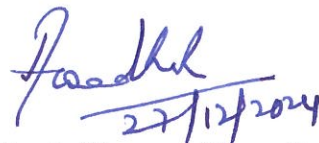
5.3 Also, Calamine is major component in Lacto Calamine Hydration Lotion and Kaolin and Aloe Vera may only be considered as excipients. The other line items/brands considered in draft worksheet also have additional ingredients along with Calamine.

These brands claim 'Calamine' as key ingredient and others as 'Other Ingredients'. These other ingredients include Zinc Oxide IP, Bentonite IP, Glycerin IP, Sodium Citrate IP, Liquid Phenol IP, Methyl Paraben, Butylated Hydroxy Anisole etc.

6. Decision:

The action of NPPA fixing the ceiling prices of the subject formulation suffers no infirmity. Accordingly, the present review application is rejected.

Issued on this, the 27th day of December, 2024.



(Awadhesh Kumar Choudhary)

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

To,

M/s Piramal Pharma Ltd.,
Ground Floor, Piramal Ananta,
Agastya Corporate park,
Opposite Fire Brigade,
Kamani Junction, LBS Marg,
Kurla (West), Mumbai 400070

Copy to:

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

