

No.31015/48/2023-Pricing (E-23606)
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 Aristo Pharmaceuticals Private Limited (hereinafter called the “Applicant”) filed a Review Application dated 23.03.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 878(E) dated 24.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the retail price of Multivitamin tablets with Mineral and Trace elements (Non Schedule).

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 26.06.2023 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 retail price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The Applicant applied for the price of its Multivitamin Tablets with Mineral and Trace Elements under para 5 of DPCO, 2013 as they are ‘existing manufacturer’ of NLEM Drug “Cholecalciferol Tablets 60000 I.U.” and “Cholecalciferol Capsules 60000 I.U.”. The Applicant submitted the price application in respect of the subject formulation with following composition:

Each sugar coated tablet contains

Vitamin A (As Acetate) 10000 IU + Cholecalciferol 1000 IU (In stabilized form) + Thiamine Mononitrate 10 mg + Riboflavin 10 mg + Pyridoxine Hydrochloride 3mg + Cyanocobalamin 15 mcg + Nicotinamide 100 mg + Calcium Pantothenate 16.30 mg + Ascorbic Acid 150 mg + a Tocopheryl Acetate 25 mg + Biotin 0.25 mg + Tribasic Calcium Phosphate 129 mg + Light Magnesium Oxide 60 mg + Dried Ferrous Sulphate 32.04 mg + Manganese Sulfate Monohydrate 2.03 mg + Total Phosphorus in the preparation 25.80 mg + Copper Sulfate Pentahydrate 3.39 mg + Zinc Sulphate 2.20mg + Sodium Molybdate Dihydrate 0.25 mg + Sodium Borate 0.88 mg.

3.2 NPPA displayed draft version of proposed price calculation sheet for retail price calculation of the said formulation on 4th January, 2023 under Para 5(1) based on the market price of a drug available in the market viz., Supradyn Tablet

manufactured by Piramal Healthcare Limited and marketed by Bayer Pharmaceuticals Private Limited.

The composition of Supradyn tablet is as below:

Vitamin A (As Acetate) 5000 IU + Cholecalciferol (Vitamin D3) 400 IU + Vitamin B1 (as Thiamine Mononitrate) 5mg + Riboflavin (Vitamin B2) 5mg + Vitamin B6 (as Pyridoxine Hydrochloride) 1.5mg + Nicotinamide (Vitamin B3) 50mg + Calcium-D Pantothenate 10mg + Ascorbic Acid 75mg + Tocopheryl Acetate 25mg + D-Biotin 150mcg + Magnesium Oxide Light 10mg + Manganese Sulphate Monohydrate 5mg + Copper Sulphate (as Copper Sulphate Pentahydrate) 2mg + Zinc Sulphate 55mg + Sodium Molybdate (as Sodium Molybdate Dihydrate) 25mcg + Methylcobalamine 500mcg + Folic Acid 1.5mg + Chromium Picolinate 250mcg + Selenium (as Sodium Selenite Pentahydrate) 70 mcg + L- Glutamic Acid 50mg.

3.3 The Applicant made representation on 6th January, 2023 and 16th January, 2023 to NPPA to consider anomaly in the price fixation in the draft sheet uploaded on the NPPA website. However, NPPA did not consider the company's representation in their Authority Meeting held on 21.02.2023 in the right perspective as per provision of DPCO, 2013 and dismissed the representation. Accordingly, NPPA notified price of formulation erroneously and arbitrarily at Rs. 1.88 per tablet which is not correct.

3.4 The Applicant disagrees with NPPA's decision to treat their product with the product Supradyn Tablet which is not a similar drug to their New Drug Multi V Daily Tablets /Multi-V Tablets as is evident from the composition. The Applicant claimed that their product is a New drug in the domestic market and there is no similar drug available in the market. Decision to derive the price of their formulation based on the product Supradyn Tablet is erroneous and arbitrary. Therefore, price fixation of their formulation should have been dealt with under para 5(2) read with 15(3) of DPCO, 2013.

3.5 Further, NPPA has in the past fixed ceiling price of single ingredient Cholecalciferol 1000 I.U. at Rs. 4.16 per tablet vide notification S.O. 1499 (E) dated 30th March, 2022 and also at Rs. 3.84 per tablet vide Notification S.O. 5938 (E) dated 19th November, 2022. However, as against this, the computation of retail price in respect of their product 'Multi V daily tablets/ Multi V-tablets' is recommended at Rs.1.88 per tablet, i.e. much below the ceiling price of a single ingredient.

4. Gist of clarifications made by NPPA:

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

4.1 The Applicant had filed Form-I application to NPPA for retail price fixation of the subject formulation on 22.11.2022. Since, only a single line item, viz., Supradyn Tablet, appeared in November, 2022 Pharmatrac database, the position in this regard was confirmed from Pharmatrac vide email dated 02.12.2022. The draft working sheet was uploaded on NPPA's website on 04.01.2023 considering one-line item confirmed by Pharmatrac.

4.2 Further, the Applicant vide letter dated 06.01.2023 filed a representation stating that:

- a. 'Their new drug, Multi V Daily tablet / Multi-V Tablet', for which Form-I application is submitted is comparable with the existing product in the market Viz. 'Surbex XT Tablet' marketed by Abbot India Ltd. at the MRP of Rs. 144.05 for a pack of 15 tablets. Hence, the MRP of 'Surbex XT Tablet', may be comparable product with 'Multi V daily tablets/ Multi-V Tablets'.
- b. The Applicant further mentioned that the price of per tablet of Surbex XT Tablets comes to Rs. 9.60, whereas the computation of Retail Price in respect of their Product is recommended at Rs 1.62 per tablet.
- c. It is evident that some errors have crept in while calculating/ computing the 'Retail price' in respect of 'Multi V Daily tablet/ Multi-V Tablet'.

4.3 The Applicant's request for either considering Surbex XT for pricing or referring the matter to MDC was examined, and it was observed that:

- i. The composition of Surbex XT and the formulation for which retail price is applied are different. Therefore, Surbex XT can't be compared and taken as basis for price fixation. Further, the Applicant itself has submitted a comparison of Surbex-XT and the applied formulation in its representation dated 06.01.2023 in which it is seen that both the tablets have different composition except few common ingredients.
- ii. Since the data for the exact formulation is available in Pharmatrac database, the matter was not referred to MDC as per provisions of DPCO, 2013. Confirmation regarding the data in the Pharmatrac database was sought. Pharmatrac vide email dated 18.01.2023 confirmed that the line item Supradyn Tablet, provided by them earlier is only available item in database and have the same composition as applied by the applicant.

4.4 From the Pack shot and confirmation as provided by Pharmatrac vide mail dated 18.01.2023, it is seen that the applied formulation and Supradyn have the same composition. Hence, the Authority in its 109th meeting held on 21.02.2023 examined these facts and took a considered decision to approve the retail price of the subject formulation. Further, the contention of the applicant in the representation that ceiling price of single component cholecalciferol 1000 IU is higher than the applied FDC, is not tenable as retail price calculation of the captioned formulation as available in market based data i.e. Pharmatrac database has been considered for price fixation in line with DPCO provisions.

4.5 In response to subsequent query, Pharmatrac re-confirmed vide email on 23.09.2023 that though the brand Supradyn Tablet was discontinued from May 2021, it was being sold in the market during the period May 2021 to April 2022 and the MAT value was 22.39 crores. In view of this, the retail price fixed and notified is correct and

the brand considered for retail price fixation has the same composition and also was in the market during the period as per provisions of DPCO, 2013.

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*”. It nowhere differentiates between continuing and discontinued products.

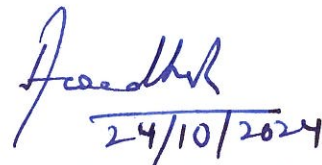
5.2 A comparison of Surbex-XT and the applied formulation submitted by the Applicant in its representation dated 06.01.2023 shows that both the tablets have different composition except few common ingredients. Since the data for the exact formulation is available in Pharmatrac database, the matter was not referred to MDC as per provisions of DPCO, 2013

5.3 Therefore, under the facts cited under above paras of 5.1 and 5.2, arguments and logics given by NPPA are acceptable.

6. Decision:

In the backdrop of these facts, the action of NPPA fixing the Retail prices of the formulation Multivitamin tablets with Mineral & Trace elements (Non Schedule) of Aristo Pharmaceuticals Private Limited vide S.O. No. 878(E) dated 23.03.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 24th day of October, 2024.



24/10/2024

(Awadhesh Kumar Choudhary)

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

To:

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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