

No. 31015/20/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 16.02.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Torrent Pharmaceuticals Limited (hereinafter called the applicant) against notification S.O. 544(E), dated 06.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Rosuvastatin + Aspirin + Clopidogrel Capsul (Rozucor Gold 10).

2. The applicant has contended as under:-

2.1 NPPA has notified retail price of Rs. 9.97 per Capsule on 6th February 2018 against our applied retail price of Rs.13.4/- per capsule.

2.2 Company submitted that on 16th January 2018 vide notification number 270(E), NPPA has already announced a retail price of Rs.11.70/- per capsule for same formulations of various manufacturers / marketers as given in below table.

Sr No	Notifi cation Sr No	Name of the Schedule Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.) *
1	8	Rosuvastatin + Aspirin + Clopidogrel Capsule (Unistar Gold 10/75)	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s GKM New Pharma / M/s Unichem Laboratories Ltd.	11.7
2	9	Rosuvastatin + Aspirin + Clopidogrel Capsule (Zyrova Gold 10)	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s GKM New Pharma M/s Cadila Healthcare Ltd.	11.7
3	10	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s GKM New Pharma / M/s Zuventus Healthcare Limited	11.7
4	11	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd /M/s Zydus Healthcare Limited	11.7
5	12	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd / M/s Mankind Pharma Limited	11.7
6	13	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel	1 Capsule	M/s Synokem Pharmaceuticals Ltd / M/s Cadila Pharmaceuticals Limited	11.7

			75mg			
7	14	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Jubilant Life Sciences Limited	11.7
8	15	Rosuvastatin + Aspirin + Clopidogrel Capsule	Rosuvastatin 10 mg + Aspirin IP 75mg + Clopidogrel 75mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd / M/s Eris Lifesciences Ltd.	11.7

2.3 In view of above, company requested this Department to review the notified retail price for their formulation and direct NPPA to revise the retail price considering notifications no. 270(E) dated 16/01/2018.

3. Comments of NPPA:

NPPA fixed the retail price of Rozucor Gold 10 capsule at Rs. 9.97 per capsule vide S.O. 544(E) dated 06.02.2018 on the basis of decision taken in the 51st Authority meeting, wherein it was decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. However, on re-examination it was observed that the price of Rosuvastatin 10 mg + Aspirin 75mg + Clopidogrel 75 mg tablet fixed for M/s Safetab Life Science/ M/s Intas Pharmaceuticals limited vide SO 3915 (E) dated 18.12.2017 at Rs 9.97 per tablet was inadvertently extended to Rozucore Gold 10 capsule of M/s Torrent Pharmaceutical Limited.

3.2 The price of tablet was inadvertently extended to capsule of the same formulation. The retail price of capsule of the subject formulation was notified for other companies at Rs 11.70 per capsule vide SO 270 (E) dated 16.01.2018.

4. Examination:

4.1 NPPA fixed the retail price of formulation **Rozucor Gold 10 mg capsules** containing Rosuvastatin 10 mg + Aspirin 75mg + Clopidogrel 75 mg hard gelatin capsule vide SO 544(E), dated 06.02.2018 as Rs.9.97 per capsule. The retail price has been fixed on the basis of request made by M/s Torrent Pharmaceuticals Ltd. under para 2(u) of DPCO, 2013 and filed Form I for fixation of retail price for their formulation Rozucor Gold 10 mg capsules, being new drug.

4.2 NPPA stated that it was decided in 51st Authority meeting held on 15.12.2017 that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. However, on re-examination it was observed that the price of Rosuvastatin 10 mg + Aspirin 75mg + Clopidogrel 75 mg tablet fixed for M/s Safetab Life Science/ M/s Intas Pharmaceuticals limited vide SO 3915(E) dated 18.12.2017 at Rs 9.97 per tablet was inadvertently extended to Rozucore Gold 10 capsule of M/s Torrent Pharmaceutical Limited. **The retail price of capsule of the subject formulation was notified for other companies at Rs 11.70 per capsule vide SO 270(E) dated 16.01.2018.**

4.3 **In the instant case, NPPA, itself admitted that the retail price of Rosuvastatin 10 mg+Aspirin 75mg+Clopidogrel 75mg tablet fixed for M/s Safetab Life Science/M/s Intas Pharmaceuticals limited vide SO 3915(E) dated 18.12.2017 at Rs.9.97 per tablet was inadvertently extended to Rozucore Gold 10 capsule.**

4.4 The retail price of Rosuvastatin 10 mg + Asprin 75mg+Clopidogrel 75mg was notified for other companies at Rs.11.70 per capsule vide SO 270(E) dated 16.01.2018 as per provisions of para 5, 11 and 15 of DPCO, 2013 by considering the PTR of available drugs in the market, taking simple average of all those who have more than 1% market share and considering the new drug price as per the simple average formula as contained in para 4(1) of DPCO, 2013.

4.5 Since NPPA has recently notified the retail price of the subject formulation for other companies at Rs 11.70 per capsule vide S.O. 270(E) dated 16.01.2018, the same retail price be made applicable in case of M/s Torrent Pharmaceuticals Limited.

5. **Decision:**

“NPPA has fixed the retail price of Rosuvastatin 10 mg + Asprin 75mg+Clopidogrel 75mg at Rs.11.70 per capsule vide SO 270(E) dated 16.01.2018 as per provisions of para 5, 11 and 15 of DPCO, 2013 for other companies. The same retail price be made applicable in case of M/s Torrent Pharmaceuticals Limited for its product Rozucor Gold 10 mg capsules containing the similar formulation within a period of 30 days from the date of issue of this order.”

Issued on this date, the 8th day of June, 2018.

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

Copy to:-

1. M/s Torrent Pharmaceuticals Limited, Torrent House, Off Ashram Road, Ahmedabad-380 009.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website