

No. 31015/32/2018-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 24.04.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Synchem Laboratories Private Limited (hereinafter called the applicant) against notification S.O. 1461(E), dated 02.04.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) revising the ceiling price of Oral Rehydration Salts.

2. The applicant has contended as under:-

2.1 The ceiling price of oral rehydration salts IP has been fixed as under:-

S. O. No.	Date	S. No.	Formulation	Strength	Unit	Ceiling Price Rs. /gram
S.O. 1461(E)	02.04.2018	594	Oral Rehydration Salt Powder for Solution (ORS	AS per IP	1 gm	0.74

2.2 Therefore the Maximum retail price for the following pack size should be as follows:-

S. No.	Content in gm	Ceiling Price per gm as per S.O. 1461(E) dt. 02/04/2018	Ceiling Price per Sachet	MRP Inc. GST per Sachet
	(A)	(B)	(C)	(D)
1.	for a 4.2 gm ORS	0.74 Rs per gram	3.108	MRP Rs. 3.26
2.	for a 4.4 gm ORS	0.74 Rs per gram	3.256	MRP Rs. 3.42

2.3 Given below are the MRP & Mfg Date of Electral & Walyte vis-à-vis company's product Frutolyte. It is observed that MRP of Electral & Walyte is more than ceiling price notified by the NPPA vide S.O. No. 1461(E) dated 02/04/2018, as well as S.O. 1039(E) dated 01/04/2017.

S. No.	Brand Name & manufacturer name	Pack	Ceiling Price per pack incl. GST, as per NPPA	MRP on Pack	Overcharging
	(A)	(B)	(C)	(D)	(D)-(C)
1.	<u>Walyte</u> (Mfr. Wallace Pharm. Ltd.)	4.2 gm Per Sachet	MRP Rs. 3.26	Rs. 4.02	Rs. 0.76 Per Sachet
2.	<u>Electral</u> (Mfr. FDC Limited)	4.2 gm Per Sachet	MRP Rs. 3.42	Rs. 4.13	Rs. 0.71 Per Sachet
3.	<u>Frutolyte</u> (Mfr. Synchem)	4.4 gm Per Sachet	MRP Rs. 3.42	Rs. 3.42	Nil Per Sachet

2.4 Company has observed that FDC Ltd. has filed a Review Application dated 23.05.2016 under Para 31 of DPCO 2013, with Department of Pharmaceuticals, Govt. of India against price fixation of Oral Rehydration Salts by NPPA S.O. 1816(E) dated 18.05.2016 at Sr. No. 19.

On the basis of hearing, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, has passed the following decision no. 31015/30/2016- PI.I dated 14.09.2016:

“The NPPA’s price fixation was deficient in so much that a non-pharmaceutical item was included in their calculation sheet in arriving at ceiling price. Therefore, the NPPA notification, fixing the ceiling price of the aforesaid product of the petitioner company is stayed. The ceiling price of the product category should be fixed afresh with correct calculation within a period of one month of the decision to this regard.”

2.5 Moreover, Wallace Pharm. Ltd. has also increased the MRP of Walyte, may be, on basis of Bombay High Court decision WP (551/2016) dated 24.08.2016. And that, Wallace Pharma Ltd. has also filed a Review Application dated 24.06.2016 under Para 31 of DPCO 2013, with Department of Pharmaceuticals, Govt. of India, against price fixation of Oral Rehydration Salts by NPPA S.O.1816(E) dated 18.05.2016 at S.No.19.

2.6 On the basis of hearing, Deputy Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide their decision no. 31015/82/2016-PI.I dated 05.04.2017, commented as follows :

“Thereafter, based on stay of Bombay High Court, the company revised its price in compliance with the previous SO 644(E), dated 3rd March, 2016 to avoid further unnecessary losses as the company had already suffered financial loss for a period of six months in 2013 for the exact same mistake.”

And directed NPPA as follows:

“NPPA is hereby directed to consider revising/refixing the ceiling price of the formulation “Walyte - Oral Rehydration Salts” by excluding FSSAI licensed products, on getting clarification from DCG(I). NPPA is also directed to refix the ceiling price in accordance with the provisions of DPCO by considering the PTR of 12 formulations only having more than 1% market share.”

2.7 Company further submitted that inspite of DoP's clear instructions to NPPA, to refix the Price of Oral Rehydration Salt with correct calculation, within one month. Till date NPPA has neither corrected the same, instead, issued subsequent price revision S.O. 1039(E) dt. 01.04.2017 and 1461(E) dated 02.04.2018, as per annual WPI increase. If the base (S.O. 1816(E) dated 18.05.2016) is incorrect then all subsequent ceiling prices for WPI increase are going to be incorrect.

2.8 Company submitted that they are small scale pharmaceutical manufacturer and new entrant in ethical marketing of Oral Rehydration Salt, under the brand name - Frutolyte, having the market share of 2.05% only. Given below are the MRP of Top Two Brands - Electral & Walyte vis - a - vis Frutolyte:-

	Electral 4.4 gm	Walyte 4.2 gm	Frutolyte 4.4 gm	Ceiling price incl. GST 4.4 gm/4.2 gm
MRP per Sachet	Rs. 4.13	Rs. 4.02	Rs. 3.42	Rs. 3.42/3.26
Market Share (as per NPPA's working sheet)	57.69%	13.45%	2.05%	

2.9 Company has submitted that Frutolyte has the MRP of Rs. 3.42 per sachet only. However, other brands are selling at Rs. 4.13 & 4.02, as they have obtained stay on implementation of S.O. No.1816(E) dated 18.05.2016 from DOP. Company has already incurred huge financial loss for a period of twenty three months (from implementation of S.O. No. 1816(E) dated 18.05.2016 to till date). Company further submitted that if they continue to sell at such a reduced price, this would cause further huge financial loss to their company. Moreover, their product Frutolyte will be out of market due to tough competition with established top brands like Electral (FDC- market share of 57.69%) & Walyte (Wallace - market share of 13.45%).

2.10 In view of the above, company prayed as under:-

- (a) Kindly grant stay on implementation of entry no. 594 for Oral Rehydration Salts (Rs. 0.74 per gm) of S.O. No. 1461(E) dated 02.04.2018, since it is based on erroneous entry no.19 for Oral Rehydration Salts (Rs. 0.72 per gm) of S.O. No. 1816(E) dated 18.05.2016 (if the base is wrong, then all the subsequent calculations are going to be wrong).
- (b) Kindly allow the company to sell their product as per entry no. 390 for Oral Rehydration Salts (Rs. 0.90 per gm) S.O. 644(E) dated 02.03.2016, with immediate effect, as granted to FDC Ltd.

Since all the manufacturers has to implement same ceiling price notification. If any ceiling price notification is stayed for one manufacturer, then it seem logical, that same notification need to be stayed for all the manufacturers.

- (c) Kindly direct NPPA, to implement decision of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, no. 31015/30/2016-PI.I dated 14.09.2016, as nineteen months are already passed, to refix the ceiling price of the Oral Rehydration Salts with correct calculation immediately and allow subsequent

price revision as per annual WPI increase for 2016-17 & 2017-18 to all the manufacturers of Oral Rehydration

3. Comments of NPPA:

3.1 NPPA fixed ceiling price Rs. 0.71 per gm for Oral rehydration salts (as license) vide S.O. 1819(E) dated 18.05.2016 under para 4,10,11,14,16,17 and 18 of DPCO, 2013 to which company has never challenged vide any review application.

3.2 NPPA issued the notification No. SO 1461 (E) dated 02.04.2018 just to give effect of WPI on the earlier applicable ceiling price and therefore review against this notification is not sustainable.

3.3 The issue of non compliance of ceiling price by some of the companies viz M/s Wallace Pharma Ltd. and FDC Limited for their products Walyte and Electrol respectively will be examined separately by NPPA for appropriate action.

4. Examination:

4.1 NPPA has notified SO 1461(E), dated 2.4.2018 to revise the ceiling prices of all scheduled formulations only for giving Annual Wholesale Price Index @ 3.43812% increase effective from 1.4.2018.

4.2 The ceiling price of Oral Rehydration Salts was fixed vide S.O. 1819(E) dated 18.05.2016. The company should have filed the review application at the time when the ceiling price of the subject formulation was fixed in May, 2016. Company can file representation to DoP/NPPA about the issues raised in review application in regard to M/s Wallace Pharma Ltd. and FDC Limited for their products Walyte and Electrol respectively. Filing of review application against notification SO 1461(E) dated 02.04.2018, which is meant just to give effect of WPI on the earlier applicable ceiling price is not sustainable.

4.3 In view of the above, the grievances raised by the company have got no relevance and the review application stands rejected.

5. Decision:

“NPPA notified SO 1461(E), dt.02.04.2018 only to give WPI increase effective from 01.04.2018 to all the scheduled formulations and not meant to re-fix the ceiling price of any formulation. Therefore, the grievances raised by the company have got no relevance and the review application stands rejected.”

Issued on this date, the 4th day of September, 2018.

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

Copy to:-

1. Synchem Laboratories Private Limited, 103, Anand Apartment, Sayajiganj, Vadodara-390 005. (Gujarat)
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