

**No. 31015/60/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

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A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject:** Review application of M/s Alembic Pharmaceuticals Limited against price fixation of “Erythromycin Estolate Tablets 250mg; Erythromycin Estolate Tablets 500mg and Erythromycin Estolate Syrup 125mg./5ml” vide NPPA order No. S.O. 1526(E), dated 11.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref:**

- 1) Review application dated 31.05.2017
- 2) NPPA notification under review S.O. 1526(E), dated 11.05.2017
- 3) Record Note of discussions held in the personal hearing held in the matter on 11.07.2017.

The Review Order no. 31015/60/2017-Pricing dated 24/08/2017 has been re-examined based on the suggestion received from National Pharmaceutical Pricing Authority (NPPA) vide their letter No. 20(249)/2017/DP/NPPA/Vol.II dated 20/09/2017.

2. It has been decided that, in supersession of the review order No.31015/60/2017-Pricing, dated 24/08/2017, the Examination portion and Government decision in para 5 and 6 of the review order, be substituted as follows :-

**Examination:**

The ceiling prices of the formulations Erythromycin Estolate Tablets 250mg, Erythromycin Estolate Tablets 500mg, Erythromycin Estolate Syrup 125mg./5ml. and Chloroquine Phosphate Injection 40mg/ml were fixed by NPPA vide SO 1526(E), dated 11.05.2017 to comply with the Review Order No.31015/20/2015-PI.I, issued by DoP on 30<sup>th</sup> August, 2016. The Review order was issued on the review petitions filed by M/s IPCA Laboratories Ltd. in April, 2015 against SO No.834(E), dated 25.3.2015. At that time, the subject formulations were scheduled medicines in NLEM 2011. However, NLEM, 2015 came into force vide DoP notification SO 701(E), issued on 10<sup>th</sup> March, 2016, in which the all the four formulations, Erythromycin Estolate Tablets 250mg, Erythromycin Estolate Tablets 500mg, Erythromycin Estolate Syrup 125mg.5ml. and Chloroquine Phosphate Injection 40mg/ml, were shifted to non-scheduled category.

The review order No. 31015/20/2015-PI.I, dated 30<sup>th</sup> August, 2016, was issued by DoP, to settle the grievances raised by M/s IPCA Laboratories Ltd. against the ceiling prices fixed for Erythromycin Estolate Tablets 250mg, Erythromycin Estolate Tablets 500mg, Erythromycin Estolate Syrup 125mg./5ml. and Chloroquine Phosphate Injection 40mg/ml by NPPA vide SO 834(E), dated 25.3.2015. At the time of notification, the aforesaid formulations were scheduled medicines. However, by the time the Review Order was issued (on 30.8.2016), all the four medicines, viz.

Erythromycin Estolate Tablets 250mg, Erythromycin Estolate Tablets 500mg, Erythromycin Estolate Syrup 125mg./5ml. and Chloroquine Phosphate Injection 40mg/ml, have been shifted to non-scheduled category. Fixation of ceiling prices of non-scheduled formulations is contrary to the provisions of DPCO, 2013. In view of this, NPPA may be directed to set aside the SO 1526(E), dated 11.5.2017, as all the four formulations, i.e. Erythromycin Estolate Tablets 250 mg, Erythromycin Estolate 500mg, Erythromycin Estolate Syrup 125mg/5ml and Chloroquine Injection 40mg/ml, have been shifted to non-scheduled category vide SO 701(E), dated 10.3.2016.

**Government decision:**

**“NPPA is hereby directed to set aside the SO 1526(E), dated 11.5.2017, as all the four formulations, i.e. Erythromycin Estolate Tablets 250 mg, Erythromycin Estolate 500mg, Erythromycin Estolate Syrup 125mg/5ml and Chloroquine Injection 40mg/ml, have been shifted to non-scheduled category vide SO 701(E), dated 10.3.2016.”**

Issued on this date, the 14<sup>th</sup> day of November, 2017.

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

To

1. M/s Alembic Pharmaceuticals Limited,  
Prithvi Mansion, 4/8, Asaf Ali Road,  
New Delhi-110002.
2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001

Copy to:

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website