



**What's New**

**19.04.2018**

### **Constitution of Task Force on Active Pharmaceutical Ingredients**

India is a leading manufacturer and exporter of Pharmaceutical items specially generics, there is still scope for further integration along the value chain in terms of manufacturing of APIs and Research and Development where the country is importing essential APIs. There is a need for concerned efforts to harness the opportunities in the sector.

Department of Pharmaceuticals has Constituted a Task Force on Active Pharmaceutical Ingredients in order to formulate a roadmap for the enhanced production of APIs in the country.

The Taskforce will formulate a Roadmap for the sector with implementable recommendations. The interventions recommended will include that concerning the Central Government, State Governments and Regulatory Bodies where applicable. The role of industry may also be clearly delineated.

The specific areas of focus may include the following:

- Research and Development
- Acquisition & Commercialisation
- Application and adoption in specific sectors
- Development of the Industry
- Regulatory framework
- Potential impact on industry, job creation, investments, contribution to the economy, technology infusion, exports, integration with value chain etc.

The Taskforce may study global practices and interact with relevant stakeholders as required.

The Taskforce shall continue till the final report is accepted by the Government.

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**Task Force on Active Pharmaceutical Ingredients**

2	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 30gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	30 GM	M/Sun Pharmaceuticals Industries Ltd.	187.50
3	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 40gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	40 GM	M/Sun Pharmaceuticals Industries Ltd.	231.250
4	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 60gm Pack)	contains: Diclofenac Diethylamine BP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w & Menthol IP 5% w/w	60 GM	M/Sun Pharmaceuticals Industries Ltd.	318.75
5	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	4.12
6	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As granules) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as to film coated tablets) Aspirin IP 75mg (As EC tablet),	1 Capsule	M/s GKM New Pharma / M/s Cadila Healthcare Ltd.	5.56
7	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	4.12
8	Atorvastatin + Aspirin + Clopidogrel capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As granules) Aspirin IP 75mg (As EC tablet), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as two film coated tablets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	5.56

S.O.\_\_\_\_\_ In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified in mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation(s) specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit /packaging	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date
1	Phenytoin	Oral Liquid 30mg/5 ml	1 ML	0.29	31015/38/2017- Pricing dated 09.02.2018	1461(E) dated 02.04.2018 (at Sl. No. 646)

S.O....In exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes/revises the prices as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit /packaging	Ceiling Price (Rs.)
1	BCG Vaccine		Each dose	5.59

S.O Whereas the National Pharmaceutical Pricing Authority(NPPA), Department of Pharmaceuticals, Ministry of Chemical and Fertilizers has fixed the ceiling price under paragraph 19 of the Drug (Prices Control) order 2013, of (i) Ferrous Salt (A) + Folic acid (B) – 100 mg(A) + 500mcg(B) Tablet and (ii) Ferrous Salt (A) + Folic acid (B) – 45 mg(A) + 400mcg(B) Tablet vide notification number SO 3091(E) dated 20.09.2017 based on the procurement prices of Government procurement agencies, in the absence of the relevant market based data in the Pharmatrac report of AIOCDAWACS. The ceiling prices were revised on the basis of WPI vide SO 1461(E) dated 2.4.2018.

Whereas M/s Bochem Healthcare Pvt Ltd has prayed to the NPPA for upward revision of the ceiling prices of (i) Ferrous Salt (A) + Folic acid (B) – 100 mg(A) + 500mcg(B) Tablet and (ii) Ferrous Salt (A) + Folic acid (B) – 45 mg(A) + 400mcg(B) Tablet stating that the price fixed by the NPPA are unviable. M/s Bochem Healthcare Pvt Ltd also claimed that the 98 percent of the supply is for NRHM.

Whereas the Authority noted that the the Hon'ble High Court of Madhya Pradesh at Jabalpur vide its order dated 19.03.2018 in WP 1550/2018 in the matter of M/s Bochem Healthcare Pvt Ltd. Vs Union of India has given direction : “let decision be taken reviewing the notification dated 20.09.2017 within two weeks on or before 9.4.2018”. The Hon'ble High Court has granted additional time for review at the request of the NPPA.

Whereas the petitioner company M/s Bochem Healthcare Pvt Ltd. has in its petition to the Hon'ble Court stated that the grievance does not relate to 45mg tablet as it is competitively placed.

Whereas it is also noticed that the ceiling price of lower strength is more than the ceiling prices of higher strength.

Whereas the NPPA in its 188th Authority meeting held on 23-4-2018, decided that ceiling price may be fixed/ revised under para 19 of the DPCO 2013 considering the petition and grievances of M/s Bochem Healthcare Pvt Ltd, decided to withdraw the notification in respect of Ferrous Salt(A) + Folic acid (B) - (100mg + 500mcg) Tablet.

Now, in exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby withdraw the ceiling price notification number SO 1461(E) dated 2nd April 2018 and SO 3091(E) dated 20.09.2017, with effect from the date of this notification, to the extent it belong to following formulation.

<b>Sl. No.</b>	<b>Formulation</b>
1	Ferrous Salt(A) + Folic acid (B) - (100mg + 500mcg) Tablet

All the other ceiling prices and notes shall continue to be operation unless specifically amended/revised.

[Click here for Notifications](#)

[Retail price of 27 scheduled formulations of Schedule-I under Drugs \(Prices Control\) Order, 2013.](#)

[Retail price of 8 scheduled formulations of Schedule-I under Drugs \(Prices Control\) Order,2013.](#)

[Revised Ceiling price\(Review\) of 1 scheduled formulation of Schedule-I under Drugs \(Prices Control\) Order, 2013.](#)

Revised Ceiling price of 1 scheduled formulation of Schedule-I under para 19 of Drugs (Prices Control) Order,2013.

Withdrawal of Ceiling price of 1 scheduled formulation of Schedule-I under para 19 of Drugs (Prices Control) Order,2013.