## (Published in Part II, Section 3, Sub-section (ii) of the Gazette of India) Extraordinary) Government of India Ministry of Chemicals and Fertilizers Department of Pharmaceuticals National Pharmaceutical Pricing Authority

ORDER

New Delhi, the 2<sup>nd</sup> April 2018

**S.O.** 1463(E) In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers and in supersession of the order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O 1993(E) dated 3rd June 2016 read with Corrigendum order S.O 2062 dated 9th June, 2016, S.O 2210(E) dated 24th June 2016, S.O 2578(E) dated 1st August 2016, S.O. 3161(E) dated 6th October 2016, S.O. 1051(E) dated 1st April 2017 and S.O. 2062(E) dated 30<sup>th</sup> June 2017 in so far as they relate to formulation packs of Non-Glass with special features (mentioned as Non-PVC in S.O. 1993(E) dated 3rd June 2016) mentioned in the Table A herein below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby revises the price based on Wholesale price index(WPI) of 2017 as specified in column (5) of the Table A herein below as separate 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 and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

SI No	Medicines	Dosage form and Strength	Unit/packaging	Ceiling price (wef 01.4.2017 with WPI @ 3.43812%)
(1)	(2)	(3)	(4)	(5)
1	Glucose	Injection 5%	1000ml Non Glass with	71.70
			special features	
2	Glucose	Injection 5%	500ml Non Glass with	62.03
			special features	
3	Glucose (A) +	Injection 5% (A) +	1000ml Non Glass with	75.35
	Sodium Chloride (B)	0.9% (B)	special features	
4	Glucose (A) +	Injection 5% (A) +	500ml Non Glass with	64.47
	Sodium Chloride (B)	0.9% (B)	special features	
5	Sodium Chloride	Injection 0.9%	100ml Non Glass with	31.71
			special features	
6	Sodium Chloride	Injection 0.9%	250ml Non Glass with	46.82
			special features	
7	Sodium Chloride	Injection 0.9%	500ml Non Glass with	66.30
			special features	
8	Glucose (A) +	Injection 5% (A) +	1000ml Non Glass with	74.26
	Sodium Chloride (B)	0.9% (B)	special features	

SI. No.	Name of Manufacturer	Product /Brand Name
(1)	(2)	(3)
1	M/s B.Braun Medical (I) Pvt Ltd.	Ecoflac Plus bottle with Eurohead
2	M/s Amanta Healthcare Ltd.	Steriport bottle
3	M/s Aculife Healthcare Pvt Ltd.	Aculife bottle with Eurohead
4	M/s Albert David Limited	Albert David bottle with Eurohead
5	M/s Denis Chem Limited	Aquapulse with Eurohead
6	M/s Claris Life Sciences Limited	Claris bottle with Eurohead
7	M/s Fresenius Kabi India Pvt Limited	Freeflex bags
8	M/s Otsuka Pharmaceutical India Private Ltd. (previously known as Claris Otsuka Private Limited)	Unibag
9	M/s Aishwarya Lifesciences	Lifusion Eurohead bottle
10	M/s Baxter (India) Pvt. Ltd.	Viaflex bags
11	M/s Otsuka Pharmaceutical India Private Ltd. (previously known as Claris Otsuka Private Limited)	Eurohead bottle
12	M/s Fresenius Kabi India Pvt Limited	Eurohead bottle

TABLE 'B'

- (a) The ceiling prices are applicable with effect from 01.4.2018 (ceiling prices are inclusive of Wholesale Price Index (WPI) @3.43812% for the year 2017 over 2016).
- (b) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus goods and services tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 3.43812% for year 2017 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.
- (d) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (e) Any other manufacturer claiming separate ceiling price for Non-Glass with special feature shall apply to NPPA for separate ceiling price approval with details and demonstrate, that such pack has all of the features as (i) self collapsibility and selfsealability (ii) not having air-vent; and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels alongwith documentation and demonstration.
- (f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation
- (g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
- (h) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

- (i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
- (j) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- (I) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

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F. No. 8(56)/2018/D.P./NPPA-Div.II

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