

F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-IV
National Pharmaceutical Pricing Authority

Subject: Minutes of the 43rd meeting of the Multidisciplinary Committee of Experts held on 04.07.2022 at 11:30 AM.

43rd meeting of the "Multidisciplinary Committee of Experts" was held on 04.07.2022 at 11:30 A.M. under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting:-

1. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO through video conferencing
2. Dr. J. J. Cherian, Scientist-D, ICMR through video conferencing
3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli through video conferencing
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member

The following officers of NPPA attended and presented the cases before the Committee

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
2. Shri Prasenjit Das, Deputy Director (Pricing), NPPA
3. Shri Mahaveer Saini, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 – Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablet.

1.1 The Committee noted that twenty six applications have been received for retail price fixation of eleven Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin (SR) 500 mg tablet, (ii) Sitagliptin 50 mg + Metformin (SR) 1000 mg tablet, (iii) Sitagliptin 100 mg + Metformin (SR) 1000 mg tablet, (iv) Sitagliptin 50 mg + Metformin (ER) 500 mg tablet (v) Sitagliptin 100 mg + Metformin (ER) 1000 mg tablet, (vi) Sitagliptin 100 mg + Metformin (ER) 500 mg tablet, (vii) Sitagliptin 50 mg + Metformin 500 mg tablet, (viii) Sitagliptin 50 mg + Metformin 800 mg tablet, (ix) Sitagliptin 50 mg + Metformin 1000 mg tablet (x) Sitagliptin 50 mg + Metformin (ER) 1000 mg tablet and (xi) Sitagliptin 100 mg + Metformin (SR) 500 mg tablet . The Committee further noted that the formulation 'Sitagliptin' is on the verge of becoming off-patent in July 2022.

1.2. The Committee recalled the decision taken in its 40th meeting dated 14.03.2022 and approved by the Authority in its 96th meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet' in which the Authority decided as follows:

(i) The Authority noted that the formulation "Sitagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into



consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

“...The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed.”

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the price of new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

1.3 The Committee also noted the decision taken in its 41st and 42nd meeting dated 08.04.2022 and 02.06.2022 is in line with the decision taken as mentioned Para 1.2 above and the same was approved by the Authority in its 97th meeting dated 06.05.2022 and 99th meeting dated 28.06.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet'. The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available in some cases and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers on account of the drug becoming off-patented. The Committee therefore recommended that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 40th, 41st and 42nd meeting held on 14.03.2022, 08.04.2022 & 02.06.2022 and the same were approved by the Authority in its 96th, 97th and 99th meeting held on 24.03.2022, 06.05.2022 and 02.06.2022.

1.4 Accordingly, the Committee recommended the retail price of FDCs of Sitagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:



1.4.1 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form) for M/s Pure & Cure Healthcare Private Limited (manufacturer) and M/s Cadila Pharmaceuticals Limited (marketer) at Rs. 18.67 per tablet excluding GST as detailed below:

Sl. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.055
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		21.42
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (SR) tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.67

1.4.2 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form) for M/s Pure & Cure Healthcare Private Limited (manufacturer) and M/s Cadila Pharmaceuticals Limited (marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		20.063
(g)	Claimed Retail price		24.100
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (SR) tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.06

1.4.3 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form) for M/s Pure & Cure Healthcare Private Limited (manufacturer) and M/s Cadila Pharmaceuticals Limited (marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per November, 2021 data)	37.27

S. No.	Particulars	Source / Method	Amount (Rs.)
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		26.780
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (SR) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		21.56

1.4.4 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form) for M/s Torrent Pharmaceuticals Limited (manufacturer and marketer) at Rs. 18.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.055
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen		0.384

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Committee report		
(f)	Worked out Retail Price (d)-(e)		18.671
(g)	Claimed Retail price		18.000
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.00

1.4.5 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form) for M/sTorrent Pharmaceuticals Limited (manufacturer and marketer) at Rs. 20.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per November, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		20.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA

S. No.	Particulars	Source / Method	Amount (Rs.)
(i)	Recommended retail price		20.00

1.4.6 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IPEq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Micro Labs Limited (marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		20.063
(g)	Claimed Retail price		20.500
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.06

1.4.7 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IPEq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Micro Labs Limited (marketer) at Rs. 18.67 per tablet excluding GST as detailed below:

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S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.055
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		18.671
(g)	Claimed Retail price		19.000
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.67

1.4.8 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Micro Labs Limited (marketer) at Rs. 20.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per November, 2021 data)	37.27

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S. No.	Particulars	Source / Method	Amount (Rs.)
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		20.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.00

1.4.9 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IPEq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Micro Labs Limited (marketer) at Rs. 21.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per November, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295

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S. No.	Particulars	Source / Method	Amount (Rs.)
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		21.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		21.00

1.4.10 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Sai Primus Life Biotech Private Limited (manufacturer) and M/s Primus Remedies Private Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343
(g)	Claimed Retail price		24.100
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per		22.390



S. No.	Particulars	Source/Method	Amount (Rs.)
	Pharmatrac Data for November, 2021		
(i)	Recommended retail price		18.34

1.4.11 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg for M/s Sai Primus Life Biotech Private Limited (manufacturer) and M/s Primus Remedies Private Limited (marketer) at Rs. 19.26 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 850 mg	Retail price (as per November, 2021 data)	2.660
(d)	Retail Price		19.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.532
(f)	Worked out Retail Price (d)-(e)		19.263
(g)	Claimed Retail price		24.100
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet' as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		19.26

1.4.12 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Sai Primus Life Biotech Private Limited (manufacturer) and M/s Primus



Remedies Private Limited (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.722
(f)	Worked out Retail Price (d)-(e)		20.023
(g)	Claimed Retail price		24.100
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for November, 2021		22.970
(i)	Recommended retail price		20.02

1.4.13 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Torrent Pharmaceuticals Limited (marketer) at Rs. 20.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November,	34.27

S. No.	Particulars	Source / Method	Amount (Rs.)
		2021 data)	
(b)	50% of (a)		17.135
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		20.063
(g)	Claimed Retail price		20.000
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.00

1.4.14 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IPeq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form) for M/sRavenbhel Healthcare Private Limited (manufacturer) and M/s Torrent Pharmaceuticals Limited (marketer) at Rs. 18.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per November, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555

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S. No.	Particulars	Source / Method	Amount (Rs.)
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		18.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.00

1.4.15 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Alembic Pharmaceuticals Limited (marketer) at Rs. 16.07 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered Tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		16.071
(h)	Retail price of FDC of 'Sitagliptin 100mg +		N.A.

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Metformin 500mg (SR) tablet" as per Pharmatrac Data for October, 2021		
(i)	Recommended retail price		16.07

1.4.16 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Alembic Pharmaceuticals Limited (marketer) at Rs. 17.85 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered Tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		17.857
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (SR) tablet" as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		17.85

1.4.17 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg&Metformin Hydrochloride (as an extended

release form) IP 1000mg for M/s Intas Pharmaceuticals Limited (manufacturer and marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form) IP 1000mg		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		23.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		21.56

1.4.18 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg&Metformin Hydrochloride (as an extended release form) IP 500mg for M/s Intas Pharmaceuticals Limited (manufacturer and marketer) at Rs. 18.67 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended		

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S. No.	Particulars	Source/Method	Amount (Rs.)
	release form) IP 500mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.055
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		18.671
(g)	Claimed Retail price		20.500
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		18.67

1.4.19 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg&Metformin Hydrochloride (as an extended release form) IP 1000mg for M/s Intas Pharmaceuticals Limited (manufacturer and marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended release form) IP 1000mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated	3.66

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S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(d)	Retail Price		20.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		20.063
(g)	Claimed Retail price		22.500
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mgtablet (ER) " as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		20.06

1.4.20 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg&Metformin Hydrochloride (as an extended release form) IP 500mg for M/s Exemed Pharmaceuticals(manufacturer) and Intas Pharmaceuticals Limited (marketer) at Rs. 20.17 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form) IP 500mg		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384

S. No.	Particulars	Source/Method	Amount (Rs.)
(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		21.500
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mgtablet (ER) " as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		20.17

1.4.21 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg&Metformin Hydrochloride (as an extended release form) IP 500mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Cipla Limited (marketer) at Rs. 18.67 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended release form) IP 500mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.055
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		18.671
(g)	Claimed Retail price		18.830
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mgtablet (ER) " as per Pharmatrac Data for October, 2021		NA

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S. No.	Particulars	Source/Method	Amount (Rs.)
(i)	Recommended retail price		18.67

1.4.22 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg&Metformin Hydrochloride (as an extended release form) IP 1000mg for M/s Exemed Pharmaceuticals(manufacturer) and M/s Cipla Ltd. (marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride (as an extended release form) IP 1000mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.795
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		20.063
(g)	Claimed Retail price		21.070
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mgtablet (ER) " as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		20.06

1.4.23 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg&Metformin Hydrochloride (as an extended release form) IP 500mg for M/s Exemed Pharmaceuticals(manufacturer) and M/s Cipla Ltd. (marketer) at Rs. 20.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form) IP 500mg		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.384
(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		20.000
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg tablet (ER) ' as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		20.00

1.4.24 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg&Metformin Hydrochloride (as an extended release form) IP 1000mg for M/s Exemed Pharmaceuticals(manufacturer) and M/s Cipla Ltd. (marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as an extended release form) IP 1000mg		
(a)	Derived retail price of Sitagliptin 100 mg	Retail price (as per	37.27

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S. No.	Particulars	Source/Method	Amount (Rs.)
	tablet	October, 2021 data)	
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		22.230
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for October, 2021		NA
(i)	Recommended retail price		21.56

1.4.25 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mgeq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/sBajaj healthcare Limited (manufacturer) and M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.645

S. No.	Particulars	Source/Method	Amount (Rs.)
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343
(g)	Claimed Retail price		21.000
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for November, 2021		22.390
(i)	Recommended retail price		18.34

1.4.26 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mgeq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/sBajaj healthcare Limited (manufacturer) and M/s J. B. Chemicals & Pharmaceuticals Limited (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per November, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.722
(f)	Worked out Retail Price (d)-(e)		20.023
(g)	Claimed Retail price		22.400
(h)	Retail price of FDC of 'Sitagliptin 50mg		22.970

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S. No.	Particulars	Source/Method	Amount (Rs.)
	+ Metformin 1000mg tablet" as per Pharmatrac Data for November, 2021		
(i)	Recommended retail price		20.02

2. Agenda No. 2 - Application by M/s Axa Parenterals Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (ii) Mannitol injection 20 gm per 100ml in 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head (iii) Metronidazole Injection IP 500mg/100ml in 100ml 100 ml pack in Non-glass with special feature for in LDPE container with Euro Head.

2.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Axa Parenterals Ltd was directed to "provide the documents/ literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

2.2 The Committee deliberated upon the matter in detail and decided that M/s Axa Parenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made.

3. Agenda No. 3 - Application by M/s Axa Parenterals Ltd. for separate price for Non-Glass with special feature for (i) Ciprofloxacin Injection IP, Compound Sodium lactate Injection IP (Ringer Lactate Solution for injection IP), Dextrose Injection IP (10% w/v), Dextrose Injection (5% w/v) and Fluconazole Injection USP 100 ml in LDPE container with Euro Head.

3.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Axa Parenterals Ltd was directed to "provide the documents/ literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

3.2 The Committee deliberated upon the matter in detail and decided that M/s Axa Parenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

4. Agenda No. 4 - Application by M/s Axa Parenterals Ltd. for separate price non-glass innovative single use eye drops (preservative free).

4.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Axa Parenterals Ltd was directed to *"provide the published literature/ journal showing the advantages of single use eye drops over the normal eye drops. The Committee also directed to provide the published literature/ journal/ study showing harmful effects of using preservative and percentage of preservative that may be harmful to the eyes, evidence with respect to unit dose vial with clean orifice, the details of additives used in the eyedrops made by the company and how they are different from preservatives and data with respect to improve user experience and no burning sensation as claimed by the company. The Company should also give a report to substantiate their statement that aluminium cap can lead to loss of sterility"*. The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

4.2 The Committee deliberated upon the matter in detail and decided that M/s Axa Parenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

5. Agenda No. 5 - Application for extension of ceiling price of Sodium Chloride Injection 0.9% in 500 ml with packaging in non glass with special feature in line with S.O.1500(E) dated 30.03.2022.

5.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Puerto Life Sciences Pvt. Ltd was directed to *"provide the documents/ literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages"*. The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

5.2 The Committee deliberated upon the matter in detail and decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

6. Agenda No. 6 - Application for extension of ceiling price of (i) Glucose Injection 5% in 500ml Non Glass With special features with Euro Head and (ii) Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) in 500ml Non Glass With special features with Euro Head in line with S.O.1500(E) dated 30.03.2022.

6.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Puerto Life Sciences Pvt. Ltd was directed to *"provide the documents/*



literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

6.2 The Committee deliberated upon the matter in detail and decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

7. Agenda No. 7 – Application for extension of ceiling price of Ringer lactate injection with packaging in non glass with special feature in line with S.O. 1501(E) dated 30.03.2022.

7.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Puerto Life Sciences Pvt. Ltd was directed to "*provide the documents/literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages".* The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

7.2 The Committee deliberated upon the matter in detail and decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

8. Agenda No. 8: Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non glass with special features "SAFE PORT" dated 09.05.2022 being filed by M/s Sachin Parenteral Pvt. Ltd.

8.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Sachin Parenteral Pvt. Ltd was directed to "*provide the documents/literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages".* The Committee also examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

8.2 The Committee deliberated upon the matter in detail and decided that M/s Sachin Parenteral Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.



9. Agenda No. 9: Application for Price approval of Dextrose Injection IP (5% w/v) 250ml, Dextrose Injection IP (25% w/v) in 100ml, Glucose 5% with sodium chloride 0.9% w/v 250ml, Metronidazole Injection IP 100ml, Mannitol Injection IP (20% w/v) 100ml non-glass having special features- Euro Head bottle dated. 16.05.2022.

9.1 The Committee noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Sachin Parenteral Pvt. Ltd was directed to *"provide the documents/literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages"*. The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product.

9.2 The Committee deliberated upon the matter in detail and decided that M/s Sachin Parenteral Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their own product for which the application for separate price has been made.

10. Agenda No. 10: Application for "Special Feature rate" for scheduled products (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactam 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactam 500 mg under Para 11(3) of DPCO 2013.

10.1 The Committee examined the noted the decision taken in the 42nd meeting held on 02.06.2022 in which M/s Gufic Biosciences Ltd was directed to *"provide the documents/literature/data showing the stability of the products from moisture & light in the special packages and dissolving of the products. The Committee also directed to provide data on the instances of reduction in environmental load & hospital wastages and data on needle stick injuries that arise due to use of conventional injection, issues of dosage accuracy and reduction in transport cost, fuel charges with respect to its products as claimed by the company"*. The Committee also examined the documents submitted by the company.

10.2 The Committee deliberated upon the matter in detail and decided that M/s Gufic Biosciences Ltd be directed to provide the documents/data generated based on the study specific to their own product highlighting the advantages of the product, as claimed, for which the application for separate price has been made.

11. Agenda No. 11: Retail price fixation under Para 5 of DPCO, 2013-Each vial containing Human Coagulation Factor VIII – 1000 IU, Human Von Willebrand Factor (vWF:RCo) – 750 IU, Human Albumin Ph.Eur: 23.3 – 60 mg, Glycine Ph. Eur/USP/JP: 50 mg, Lysine. HCl Ph. Eur/USP/JP: 50 mg, Sodium chloride Ph. Eur/USP/JP: 20 mg, Trisodium citrate. 2H₂O Ph. Eur/USP/JP: 50 mg, Calcium chloride. 2H₂O Ph. Eur/USP/JP: 6.2 mg, Sterilized Water for Injections Ph. Eur/USP: 10 ml for M/s Baxalta Bioscience India Private Limited (importer and marketer).

11.1 The Committee deliberated upon the matter in detail and recommended the retail price of each vial containing Human Coagulation Factor VIII – 1000 IU, Human Von Willebrand Factor (vWF:RCo) – 750 IU, Human Albumin Ph.Eur: 23.3 – 60 mg,



Glycine Ph. Eur/USP/JP: 50 mg, Lysine. HCl Ph. Eur/USP/JP: 50 mg, Sodium chloride Ph. Eur/USP/JP: 20 mg, Trisodium citrate. 2H₂O Ph. Eur/USP/JP: 50 mg, Calcium chloride. 2H₂O Ph. Eur/USP/JP: 6.2 mg, Sterilized Water for Injections Ph. Eur/USP: 10 ml for M/s Baxalta Bioscience India Private Limited (importer and marketer) at Rs. 11,606.67 per vial excluding GST, being lower than the claimed price of Rs. 17517.14 per vial excluding GST, as detailed below:

Derived retail price as per recommendation of pronab sen committee:

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*) / s^*\}]$$

Where : P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a = 0.8 for tablet / capsule and 0.7 for injectibles.

Calculation based on ceiling price of Coagulation Factor VIII Powder for Injection 250 IU as on November 2021 i.e. six month prior to the date of application.

Ceiling Price for Coagulation Factor VIII powder for Injection 250 IU = Rs.3744.09 per vial excluding GST [SO. 1330(E) dated 25.03.2021]

Derived Retail price for Human Coagulation Factor VIII, Virus Inactivated I.P. 1000 IU in a vial = 3744.09[1+0.70{1000-250/250}] = Rs. 11,606.67 per vial.

12. Agenda No. 12: Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Linagliptin + Metformin Hydrochloride IP.

12.1 The Committee noted that two applications have been received for retail price fixation of two Fixed Dose Combinations (FDCs) of Linagliptin and Metformin tablets i.e. (i) Linagliptin 2.5 mg + Metformin 1000 mg tablet, and (iii) Linagliptin 5 mg + Metformin 1000 mg tablet. The Committee further noted that M/s NATCO Pharma Limited vide email dated 08.03.2022 informed that the Patent No. IN 227719 (Claims Linagliptin generally) expired on 21.02.2022 and Patent No. IN 243301 (Claims Linagliptin generally and specifically) will be expiring on 18.08.2023.

12.2. The Committee recalled the decision taken in its 40th meeting dated 14.03.2022 and approved by the Authority in its 96th meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Linagliptin and Metformin tablet' in which the Authority decided as follows:

(i) The Authority noted that the formulation "Linagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.

(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line with decision taken in the 89th Authority meeting dated 28.06.2021, recommended to fix the retail price as per the following methodology:

“ The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed.”

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.

12.3 The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 40th meeting held on 14.03.2022 and approved by the Authority in its 96th meeting held on 24.03.2022. The Committee also observed that the retail price of FDCs of Linagliptin +Metformin tablet was also recommended in the same line in its 41st meeting dated 08.04.2022 and approved by the Authority in its 97th meeting held on 06.05.2022.

12.4 Accordingly, the Committee recommended the retail price of FDCs of Linagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:

12.4.1 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP (as extended release) 1000mg for M/s Eris Lifesciences Limited (Marketer) and M/s MSN Laboratories Private Limited (Manufacturer) at Rs. 16.37 per tablet excluding GST as detailed below:



S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg (extended release)		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per November 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg (extended release)	Ceiling Price	3.66
(e)	Sub of (c) and (d)		17.103
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.732
(g)	Worked Out Retail Price (e) – (f)		16.371
(h)	Claimed Retail Price		22.32
(i)	Retail Price as per Pharmatrac based on November, 2021 data		24.88
(j)	Recommended Retail Price		16.37

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

$$P(s) = P^*[1+A\{(S-S^*)/S^*\}]$$

Where: P(s) = Price of the strength s
P* = Price of the reference strength s*
S = Strength in terms of API content
S* = reference strength
A = 0.8 for pack / capsule and 0.7 for injectibles

$$P(s) = 44.81 [1+0.8\{2.5-5/5\}] = 26.886$$

12.4.2. Each film coated tablet containing Linagliptin 5mg + Metformin Hydrochloride IP (as extended release) 1000mg for M/s Eris Lifesciences Limited (Marketer) and M/s MSN Laboratories Private Limited (Manufacturer) at Rs. 25.33 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 5mg + Metformin Hydrochloride IP 1000mg (extended release)		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per November 2021 data)	44.81
(b)	50% of (a)		22.405
(c)	Metformin 1000 mg (extended release)	Ceiling Price	3.66
(d)	Sub of (b) and (c)		26.065
(e)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked Out Retail Price (d) – (e)		25.333
(g)	Claimed Retail Price		26.79
(h)	Retail Price as per Pharmatrac based on November, 2021 data		NA
(i)	Recommended Retail Price		25.33

13. Agenda No. 13: Retail price fixation under Para 5 of DPCO, 2013 - Each capsule contains: Acetazolamide IP 500mg (as an Extended Release) for M/s Sidmak Laboratories (India) Pvt. Ltd. (Manufacturer) and M/s Sun Pharma Laboratories Limited (Marketer).

13.1 The Committee deliberated upon the matter in detail and recommended the retail price of each capsule containing Acetazolamide IP 500mg (as an Extended Release) for M/s Sidmak Laboratories (India) Pvt. Ltd. (Manufacturer) and M/s Sun Pharma Laboratories Limited (Marketer) at Rs. 8.15 per capsule excluding GST, being lower than the claimed price of Rs. 9.82 per capsule excluding GST, as detailed below:

Derived retail price as per Pronab Sen Committee Report

$$P(s) = P^*[1+A\{(S-S^*)/S^*\}]$$

Where:

P(s) = Price of the strength s

P* = Price of the reference strength s*

S = Strength in terms of API content

S* = reference strength

A = 0.8 for tablet/capsule and 0.7 for injectibles

Calculation of price of Acetazolamide IP 500mg Capsule (as an Extended Release)

Ceiling price for Acetazolamide IP 250mg Capsule = Rs. 4.53 per capsule [SO.1330(E) dated 25.03.2021]

Derived retail price for Acetazolamide IP 500mg Capsule =
 $4.53[1+0.80\{(500-250)/250\}] = \text{Rs. } 8.15$ per capsule

The meeting ended with a vote of thanks to all.


(Rashmi Tahiliani)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

2	27,800.03	Sum of MAT value considered for price calculation (in Lakhs)
	77.28	Sum of PTR per unit considered for price calculation
Retail price fixation under Para 5 of DPCO, 2013-Composition:- Linnalipin 5mg		
	2	Number of packs considered
	38.63	Average PTR
	6.18	Add : 15% Retailer Margin
	44.81	Retail Price (without local taxes)
		% Reduction with compared to Highest Price

38.63	Minimum Price (Rs.)
38.63	Maximum Price (Rs.)
38.63	Average of all considered (Rs.)
44.81	Retail Price (Rs.)

S.No.	Drug Name	Brand	Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise Quality (Y=Yes, N=No)	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ONDRO 5 MG TABLET 10	ONDRO	LUPIN LTD	5 MG	10	Tablet	386.25	1229552839	44.07%	44.07%	38.63	38.63
2	TRAVENTA 5 MG TABLET 10	TRAVENTA	BOEHRINGER INGELHEIM	5 MG	10	Tablet	386.25	1560450521	56.83%	56.83%	38.63	38.63
		TOTAL MAT						2,79,00,03,360	100%			

Worked out Retail Price	Rs. Per tablet	44.81	Excluding GST
Claimed Retail Price	Excluding GST	-	
Proposed retail Price	Excluding GST	-	

