

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

**Subject: Minutes of the 42nd meeting of the Multidisciplinary Committee of Experts held on 02.06.2022 at 11:00 AM.**

42<sup>nd</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 02.06.2022 at 11:00 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
5. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – 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 thirty four applications have been received for retail price fixation of ten Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin 500 mg tablet, (ii) Sitagliptin 50 mg + Metformin 1000 mg tablet, (iii) Sitagliptin 50 mg + Metformin 1000 mg (sustained release) tablet, (iv) Sitagliptin 50 mg + Metformin 500 mg (sustained release) tablet (v) Sitagliptin 100 mg + Metformin 1000 mg (sustained release) tablet, (vi) Sitagliptin 50 mg + Metformin 850 mg tablet, (vii) Sitagliptin 100 mg + Metformin 500 mg (extended release) tablet, (viii) Sitagliptin 100 mg + Metformin 1000 mg (extended release) tablet, (ix) Sitagliptin 50 mg + Metformin 500 mg (extended release) tablet and (x) Sitagliptin 50 mg + Metformin 1000 mg (extended release) 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 40<sup>th</sup> meeting dated 14.03.2022 and approved by the Authority in its 96<sup>th</sup> 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 41<sup>st</sup> meeting dated 08.04.2022 in line with the decision taken as mentioned Para 1.2 above and the same was approved by the Authority in its 97<sup>th</sup> meeting dated 06.05.2022 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 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 40<sup>th</sup> and 41<sup>st</sup> meeting held on 14.03.2022 and 08.04.2022 and approved by the Authority in its 96<sup>th</sup> and 97<sup>th</sup> meeting held on 24.03.2022 and 06.05.2022.

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 tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Alembic Pharmaceuticals Limited (manufacturer/marketer) at Rs. 16.96 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated 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 September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		16.96
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for September, 2021		21.67
(i)	Recommended retail price		16.96

1.4.2 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Alembic Pharmaceuticals Limited (manufacturer/marketer) at Rs. 18.75 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		18.75
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for September, 2021		22.26
(i)	Recommended retail price		18.75

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

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release Form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27

S. No.	Particulars	Source/Method	Amount (Rs.)
(b)	50% of (a)		17.13
(c)	Metformin SR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.79
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		20.25
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet (SR)' as per Pharmatrac Data for September, 2021		N.A.
(i)	Recommended retail price		20.06

1.4.4 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release Form) for M/s Akums Drugs & Pharmaceuticals Limited (manufacturer) and M/s Abbott Healthcare Private Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg (as Sustained Release Form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin SR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.05
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen		0.38

S. No.	Particulars	Source/Method	Amount (Rs.)
	Committee report		
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		18.34
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (SR) tablet" as per Pharmatrac Data for September, 2021		N.A.
(i)	Recommended retail price		18.34

1.4.5 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release Form) for M/s Akums Drugs & Pharmaceuticals Limited (manufacturer) and M/s Abbott Healthcare Private Limited (marketer) at Rs. 19.81 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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 September, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin SR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.29
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		21.56
(g)	Claimed Retail price		19.81
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (SR) tablet" as per Pharmatrac Data for September, 2021		N.A.
(i)	Recommended retail price		19.81

1.4.6 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Torrent Pharmaceuticals Limited (manufacturer/marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		21.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for September, 2021		21.67
(i)	Recommended retail price		18.34

1.4.7 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg for M/s Torrent Pharmaceuticals Ltd. (manufacturer/marketer) at Rs. 19.14 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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 September, 2021 data)	34.27

S. No.	Particulars	Source/Method	Amount (Rs.)
(b)	50% of (a)		17.13
(c)	Metformin 850 mg	Retail price (as per September, 2021 data)	2.51
(d)	Retail Price		19.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.50
(f)	Worked out Retail Price (d)-(e)		19.14
(g)	Claimed Retail price		22.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet' as per Pharmatrac Data for September, 2021		N.A.
(i)	Recommended retail price		19.14

1.4.8 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Torrent Pharmaceuticals Ltd. (manufacturer / marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated 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 September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		23.00



S. No.	Particulars	Source / Method	Amount (Rs.)
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for September, 2021		22.26
(i)	Recommended retail price		20.02

1.4.9 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Skymap Pharmaceuticals Private Limited (manufacturer and marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		26.78
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for September, 2021		21.67
(i)	Recommended retail price		18.34

1.4.10 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Skymap Pharmaceuticals Private Limited (manufacturer and marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		29.46
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for September, 2021		22.26
(i)	Recommended retail price		20.02

1.4.11 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Skymap Pharmaceuticals Private Limited (manufacturer) and M/s Glensmith Labs Private Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 500 mg	Ceiling Price [SO. 1330(E) dated	1.51

S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		26.78
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for September, 2021		21.67
(i)	Recommended retail price		18.34

1.4.12 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Skymap Pharmaceuticals Private Limited (manufacturer) and M/s Glensmith Labs Private Limited (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		29.46
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for September, 2021		22.26

S. No.	Particulars	Source/Method	Amount (Rs.)
(i)	Recommended retail price		20.02

1.4.13 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Micro Labs Limited (manufacturer and marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		18.35
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for September, 2021		21.67
(i)	Recommended retail price		18.34

1.4.14 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Micro Labs 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 tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg		

S. No.	Particulars	Source/Method	Amount (Rs.)
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		20.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for September, 2021		22.26
(i)	Recommended retail price		20.00

1.4.15 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release Form) for M/s Akums Drugs & Pharmaceuticals Limited (manufacturer) and M/s Zydus Healthcare Limited (marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release Form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin (SR) 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.79

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		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		35.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for September, 2021		N.A.
(i)	Recommended retail price		20.06

1.4.16 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release Form) for M/s Akums Drugs & Pharmaceuticals Limited (manufacturer) and M/s Zydus Healthcare Limited (marketer) at Rs. 18.67 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg (as Sustained Release Form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per September, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin (SR) 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.05
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		33.33
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet (SR) " as per Pharmatrac Data for September, 2021		N.A.

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

1.4.17 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (in Extended Release Form) for M/s Zydus Healthcare Limited (manufacturer and marketer) at Rs. 20.17 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 Extended Release Form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin (ER) 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.55
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		20.17
(g)	Claimed Retail price		42.85
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet (ER)' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		20.17

1.4.18 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (in Extended Release Form) for M/s Zydus Healthcare 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP		

S. No.	Particulars	Source/Method	Amount (Rs.)
	1000 mg (as Extended Release Form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin (ER) 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.29
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		21.56
(g)	Claimed Retail price		44.64
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg tablet (ER)' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		21.56

1.4.19 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (in Extended Release Form) for M/s Exemed Pharmaceuticals (manufacturer) and M/s Glenmark 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500 mg (as Extended Release Form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin (ER) 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.55



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		0.38
(f)	Worked out Retail Price (d)-(e)		20.17
(g)	Claimed Retail price		21.43
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg tablet (ER)' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		20.17

1.4.20 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (in Extended Release Form) for M/s Exemed Pharmaceuticals (manufacturer) and M/s Glenmark 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 100mg + Metformin Hydrochloride IP 1000 mg (as Extended Release Form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin (ER) 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.29
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		21.56
(g)	Claimed Retail price		23.21
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg tablet (ER)' as per Pharmatrac Data for October, 2021		N.A.

S. No.	Particulars	Source/Method	Amount (Rs.)
(i)	Recommended retail price		21.56

1.4.21 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (in Extended Release Form) for M/s Exemed Pharmaceuticals (manufacturer) and M/s Emcure 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 100mg + Metformin Hydrochloride IP 1000 mg (as Extended Release Form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin (ER) 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.29
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		21.56
(g)	Claimed Retail price		26.60
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg tablet (ER)' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		21.56

1.4.22 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Synkem Pharmaceuticals Limited (manufacturer) and M/s FDC Limited (marketer) at Rs. 10.41 per tablet excluding GST as detailed below:

Sl. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated Tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		10.41
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for October, 2021		22.97
(i)	Recommended retail price		10.41

1.4.23 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Synkem Pharmaceuticals Limited (manufacturer) and M/s FDC Limited (marketer) at Rs. 8.92 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated Tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51

S. No.	Particulars	Source/Method	Amount (Rs.)
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		8.92
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for October, 2021		22.39
(i)	Recommended retail price		8.92

1.4.24 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/s Exemed Pharmaceuticals (manufacturer) and M/s Emcure 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.55
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		20.17
(g)	Claimed Retail price		26.40
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per		N.A.

S. No.	Particulars	Source/Method	Amount (Rs.)
	Pharmatrac Data for October, 2021		
(i)	Recommended retail price		20.17

1.4.25 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Unison Pharmaceuticals Private Limited (manufacturer and Marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated Tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.64
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.30
(f)	Worked out Retail Price (d)-(e)		18.34
(g)	Claimed Retail price		18.34
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for October, 2021		22.390
(i)	Recommended retail price		18.34

1.4.26 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 Exemed Pharmaceuticals (manufacturer) and for M/s Eris Lifesciences 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg (as extended release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.05
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		19.64
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		18.67

1.4.27 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/s Exemed Pharmaceuticals (manufacturer) and for M/s Eris Lifesciences 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 50mg + Metformin Hydrochloride IP 1000 mg (as extended release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13

S. No.	Particulars	Source/Method	Amount (Rs.)
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.79
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		22.32
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		20.06

1.4.28 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/s Exemed Pharmaceuticals (manufacturer) and for M/s Eris Lifesciences 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500 mg (as extended release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.55
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		20.17

S. No.	Particulars	Source/Method	Amount (Rs.)
(g)	Claimed Retail price		24.55
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		20.17

1.4.29 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/s Exemed Pharmaceuticals (manufacturer) and for M/s Eris Lifesciences 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 100mg + Metformin Hydrochloride IP 1000 mg (as extended release form)		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per October, 2021 data)	37.27
(b)	50% of (a)		18.63
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.29
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		21.56
(g)	Claimed Retail price		26.78
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		21.56

1.4.30 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Unison Pharmaceuticals Private Limited (manufacturer and 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 50mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.74
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		20.02
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for October, 2021		22.97
(i)	Recommended retail price		20.02

1.4.31 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 Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated	1.92

S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(d)	Retail Price		19.05
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		33.33
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		18.67

1.4.32 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/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare 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 50mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.79
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		35.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet" as per		N.A.

S. No.	Particulars	Source/Method	Amount (Rs.)
	Pharmatrac Data for October, 2021		
(i)	Recommended retail price		20.06

1.4.33 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 Alkem Healthscience (manufacturer) and M/s Alkem Laboratories 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 containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		19.05
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.38
(f)	Worked out Retail Price (d)-(e)		18.67
(g)	Claimed Retail price		22.76
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		18.67

1.4.34 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/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories 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 50mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per October, 2021 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		20.79
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		24.55
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for October, 2021		N.A.
(i)	Recommended retail price		20.06

**2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg (as sustained release form) for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Obsurge Biotech Ltd. (marketer).**

2.1. The Committee deliberated upon the matter in detail and recommended the retail price of each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg (as sustained release form) for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Obsurge Biotech Ltd. (marketer) at Rs. 14.04 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Derived retail price of Medroxyprogesterone Acetate Sustained Release Tablets 30 mg	Note 1	Rs. 14.04 per tablet excluding GST
Company Claimed Price excluding GST (per tablet)		Rs. 22.32
Recommended price excluding GST (per tablet)		Rs. 14.04

Note 1. Derived retail price as per recommendation of pronab sen committee:

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

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 of price Medroxyprogesterone Acetate Sustained Release Tablets 30 mg

Ceiling Price for Medroxyprogesterone Acetate tablet 10 mg = Rs. 5.40 per tablet  
[SO. 1330(E) dated 25.03.2021

Derived Retail price for Medroxyprogesterone Acetate tablet 30 mg in line with the formula as Pronab Sen Committee Report=  $5.40[1+0.80\{(30-10)/10\}]$  = Rs. 14.04 per tablet.

**3. Agenda No. 3 - 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**

3.1 The Committee noted the application filed 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 pack in Non-glass with special feature for in LDPE container with Euro Head and the demonstration made by M/s Axa Parenterals Ltd before the Committee.

3.2 The Committee deliberated upon the matter in details and decided that M/s Axa Parenterals Ltd be 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 is being produced and its advantages.

**4. Agenda No. 4 - Application by M/s AxaParenterals 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**

4.1 The Committee noted the application filed 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 and the demonstration made by M/s Axa Parenterals Ltd before the Committee.

4.2 The Committee deliberated upon the matter in details and decided that M/s Axa Parenterals Ltd be 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 is being produced and its advantages.

**5. Agenda No. 5 - Application by M/s AxaParenterals Ltd. for separate price non-glass innovative single use eye drops (preservative free)**

5.1 The Committee noted the application filed by M/s Axa Parenterals Ltd for separate price non-glass innovative single use eye drops (preservative free) and the demonstration made by M/s Axa Parenterals Ltd before the Committee.

5.2 The Committee deliberated upon the matter in detail and directed that M/s Axa Parenterals Ltd be 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.

**6. Agenda No. 6 - 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.**

6.1 The Committee noted the application filed by M/s Puerto Life Sciences Pvt. Ltd 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 and the demonstration made by M/s Puerto Life Sciences Pvt. Ltd before the Committee.

6.2 The Committee deliberated upon the matter in details and decided that M/s Puerto Life Sciences Pvt. Ltd be 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 is being produced and its advantages.

**7. Agenda No. 7 - 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.**

7.1 The Committee noted the application filed by M/s Puerto Life Sciences Pvt. Ltd 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 and the demonstration made by M/s Puerto Life Sciences Pvt. Ltd before the Committee.

7.2 The Committee deliberated upon the matter in details and decided that M/s Puerto Life Sciences Pvt. Ltd be 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 is being produced and its advantages.

**8. Agenda No. 8 – 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.**

8.1 The Committee noted the application filed by M/s Puerto Life Sciences Pvt. Ltd 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 and the demonstration made by M/s Puerto Life Sciences Pvt. Ltd before the Committee.

8.2 The Committee deliberated upon the matter in details and decided that M/s Puerto Life Sciences Pvt. Ltd be 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 is being produced and its advantages.

**9. Agenda No. 9: Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non glass with special features "SAFE PORT" being filed by M/s Sachin Parenteral Pvt. Ltd.**

9.1 The Committee noted the application filed by M/s Sachin Parenteral Pvt. Ltd for extension of different dosage forms and strength of I.V Fluids with packaging in non glass with special features in line with S.O. 1500(E) dated 30.03.2022 and S.O. 1501(E) dated 30.03.2022 and the demonstration made by M/s Sachin Parenterals Pvt. Ltd before the Committee.

9.2 The Committee deliberated upon the matter in details and decided that M/s Sachin Parenteral Pvt. Ltd be 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 is being produced and its advantages.

**10. Agenda No. 10: 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**

10.1 The Committee noted the application filed by M/s Sachin Parenteral Pvt. Ltd for separate ceiling price 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 for non-glass having special features and the demonstration made by M/s Sachin Parenteral Pvt. Ltd before the Committee.

10.2 The Committee deliberated upon the matter in details and decided that M/s Sachin Parenteral Pvt. Ltd be 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 together with the specification with which the packages are being produced and its advantages.

**11. Agenda No. 11: 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**

11.1 The Committee noted the application filed by M/s Gufic Biosciences Ltd 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 and the demonstration made by M/s Gufic Biosciences Ltd before the Committee.

11.2 The Committee deliberated upon the matter in details and decided that M/s Gufic Biosciences Ltd be 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 meeting ended with a vote of thanks to all.

Copy to:  
All members of the Committee.

*Rashmi*  
*10/6/2022*  
**(Rashmi Tahiliani)**  
Jt. Director (Pricing)