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

Subject: Minutes of the 41stmeeting of the Multidisciplinary Committee of Experts held on 08.04.2022 at 2:30 PM.

41stmeeting of the "Multidisciplinary Committee of Experts" was held on 08.04.2022 at 2:30 P.M. under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting through video conferencing:-

- 1. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
- 2. Dr. J. J. Cherian, Scientist-D, ICMR
- 3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli
- Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, Gol& Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member
- Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS-New Delhi.

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 seventeen applications have been received for retail price fixation of three 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 850 mg tablet and (iv) Sitagliptin 100 mg + Metformin 1000 mg (extended release) tablet. The Committee further noted that the formulation 'Sitagliptin' is on the verge of becoming off-patent.
- 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 new drugs as per the methodology stated by the Multidisciplinary Committee of Experts.
- 1.3 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 40thmeeting held on 14.03.2022 and approved by the Authority in its 96th meeting held on 24.03.2022.
- 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 Aristo Pharmaceuticals Pvt. Ltd. (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 50 mg + Metformin Hydrochloride		



	IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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	-	24.15
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		18.34

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 Aristo Pharmaceuticals Pvt. Ltd. (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 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		24.75



İ	(h) ·	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021	·	22.26	
	(i)	Recommended retail price		20.02	

1.4.3 Each film coated tablet containing Sitagliptin Phosphate Monohydrate 64.25 mg eq. to Sitagliptin 50 mg + Metformin HCL IP 500 mg for M/s Bajaj Healthcare Ltd. (manufacturer) and M/s Lupin Ltd. (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 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		28.92
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		18.34

1.4.4 Each film coated tablet containing Sitagliptin Phosphate Monohydrate 64.25 mg eq. to Sitagliptin 50 mg + Metformin HCL IP 1000 mg for M/s Bajaj Healthcare Ltd. (manufacturer) and M/s Lupin Ltd. (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)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		29.91
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021		22.26
(i)	Recommended retail price		20.02

1.4.5 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Intas Pharmaceuticals Ltd. (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 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		19.00

(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021	21.67	
(i)	Recommended retail price	18.34	

1.4.6 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Intas Pharmaceuticals Ltd. (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 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		20.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021		22.26
(i)	Recommended retail price		20.00

1.4.7 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (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		
	50 mg + Metformin Hydrochloride IP 500 mg		



(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		20.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		18.34

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 Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (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)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		25.00



(h)	Retail price of FDC of 'Sitagliptin 50mg + . Metformin 1000mg tablet" as per Pharmatrac Data for August, 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 850 mg for M/s Optimus Pharma Pvt. Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (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)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 850 mg	Retail price as per Para 4 of DPCO 2013 based on August 2021 data	2.51
(d)	Retail Price		19.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.502
(f)	Worked out Retail Price (d)-(e)		19.143
(g)	Claimed Retail price		22.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet" as per Pharmatrac Data for August, 2021		N.A.
(i)	Recommended retail price		19.14

1.4.10 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 500 mg for M/s Windlas Biotech Limited (Manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 8.92 per tablet excluding GST as detailed below:

S.	Particulars	Source/Method	Amount
No.			(Rs.)



	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		8.92
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		8.92

1.4.11 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25mg eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000 mg for M/s Windlas Biotech Limited (Manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 9.82 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)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72



(f)	Worked out Retail Price (d)-(e)	20.025
(g)	Claimed Retail price	9.82
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021	22.26
(i)	Recommended retail price	9.82

1.4.12 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Sun Pharma Laboratories 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 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		22.91
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		18.34

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

S.	Particulars	Source /	Amount
No.		Method	(Rs.)



	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		23.80
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021		22.26
(i)	Recommended retail price	,	20.02

1.4.14 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as extended release form) for M/s Sun Pharma Laboratories Limited (manufacturer and marketer) at Rs. 19.81 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amoun t (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride (as extended release form) IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 100 mg tablet	Retail price (as per August, 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		0.732

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Worked out Retail Price (d)-(e)	21.563
Claimed Retail price	22.02
Retail price of FDC of 'Sitagliptin 100mg + Metformin (ER) 1000mg tablet" as per Pharmatrac Data for August, 2021	19.81
Recommended retail price	19.81
	Worked out Retail Price (d)-(e) Claimed Retail price Retail price of FDC of 'Sitagliptin 100mg + Metformin (ER) 1000mg tablet" as per Pharmatrac Data for August, 2021

1.4.15 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Eris Life Sciences 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 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		25.89
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for August, 2021		21.67
(i)	Recommended retail price		18.34

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

S.	Particulars	Source / Method	Amount



No.			(Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 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		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		29.46
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for August, 2021		22.26
(i)	Recommended retail price		20.02

1.4.17 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 850 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Eris Life Sciences Limited (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)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per August, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 850 mg	Retail price as per Para 4 of DPCO 2013 based on August 2021 data	2.51
(d)	Retail Price		19.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.502

(f)	Worked out Retail Price (d)-(e)	19.143
(g)	Claimed Retail price	27.67
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 850mg tablet" as per Pharmatrac Data for August, 2021	N.A.
(i)	Recommended retail price	19.14

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated tablet containing Linagliptin + Metformin Hydrochloride IP.

- 2.1 The Committee noted that five applications have been received for retail price fixation of three Fixed Dose Combinations (FDCs) of Linagliptin and Metformin tablets i.e. (i) Linagliptin 2.5 mg + Metformin 500 mg tablet, (ii) Linagliptin 2.5 mg + Metformin 850 mg tablet and (iii) Linagliptin 2.5 mg + Metformin 1000 mg tablet. The Committee further noted that the formulation 'Linagliptin' has become/ on the verge of becoming off-patent.
- 2.2. 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.
- 2.3 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.
- 2.4 Accordingly, the Committee recommended the retail price of FDCs of Linagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:
- 2.4.1 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 14.65 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 500mg	*	
(a)	Derivedretailprice of Linagliptin 5mg	Retail price (as per August 2021 data)	44.81
(b)	Derivedretailprice of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) – (f)		14.651
(h)	Claimed Retail Price		30.00
(i)	Retail Price as per Pharmatrac based on August, 2021data		23.93

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

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

2.4.2 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Alkem Laboratories Limited (Marketer) and M/s AlkemHealthscience (A unit of Alkem Laboratories Limited) (Manufacturer) at Rs. 14.65 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 500mg		
(a)	Derivedretailprice of Linagliptin 5mg	Retail price (as per August 2021 data)	44.81
(b)	Derivedretailprice of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) – (f)		14.651
(h)	Claimed Retail Price		18.75
(i)	Retail Price as per Pharmatrac based on August, 2021data		23.93
(j)	Recommended Retail Price		14.65

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

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

2.4.3 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Alkem Laboratories Limited (Marketer) and M/s AlkemHealthscience (A unit of Alkem Laboratories Limited) (Manufacturer) at Rs. 16.33 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		
(a)	Derivedretailprice of Linagliptin 5mg	Retail price (as per August 2021 data)	44.81
(b)	Derivedretailprice of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg	Ceiling Price	3.61
(e)	Sub of (c) and (d)		17.053
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.722
(g)	Worked Out Retail Price (e) - (f)		16.331
(h)	Claimed Retail Price		25.89
(i)	Retail Price as per Pharmatrac based on August, 2021data		24.88
(j)	Recommended Retail Price		16.33

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

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

2.4.4 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 16.33 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		
(a)	Derivedretailprice of Linagliptin 5mg	Retail price (as per August 2021 data)	44.81
(b)	Derivedretailprice of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg	Ceiling Price	3.61
(e)	Sub of (c) and (d)		17.053
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.722
(g)	Worked Out Retail Price (e) – (f)		16.331
(h)	Claimed Retail Price		40.00
(i)	Retail Price as per Pharmatrac based on August, 2021data		24.88
(j)	Recommended Retail Price		16.33

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

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

2.4.5 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 850mg for M/s Mankind Pharma Limited (Marketer) and M/s Mediforce Healthcare Private Limited (Manufacturer) at Rs. 15.45 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 850mg		
(a)	Derivedretailprice of Linagliptin 5mg	Retail price (as per August 2021 data)	44.81
(b)	Derivedretailprice of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)	,	26.886
(c)	50% of (b)	*.	13.443
(d)	Metformin 850 mg (August, 2021)	Retail Price	2.51
(e)	Sub of (c) and (d)		15.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.502
(g)	Worked Out Retail Price (e) – (f)		15.451
(h)	Claimed Retail Price		35.00
(i)	Retail Price as per Pharmatrac based on August, 2021data		24.36
(j)	Recommended Retail Price		15.45

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

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

4

- 3. Agenda No. 3 Application by M/s AxaParenterals 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 was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.
- 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 was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.
- 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 was appraised that M/s AxaParenterals Ltd vide its e-mail dated 08.04.2022 requested that due to unavoidable circumstances they would make demonstration of the product regarding claim for special pricing of the special feature bottle in the next meeting. Accordingly, the Committee decided to defer the agenda till the next meeting and directed that M/s AxaParenterals Ltd to make presentation in the next meeting.
- 6. Agenda No. 6 Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin PR capsule contains Tacrolimus IP 3 mg for M/s Cadila Healthcare Ltd. (manufacturer and marketer)
- 6.1 The Committee noted the clarification dated 07.04.2022 received from the Office of the Central Drugs Standard Control Organisation (CDSCO) that they have not received any application of M/s Cadila Healthcare Ltd for manufacture/ import of Tacrolimus Prolonged Release hard gelatine capsules 3 mg. The Committee also observed Para 2(w) (iv) and Explanation to Para 2(w) of New Drugs and Clinical Trials Rules, 2019 which states as follows:

Para 2(w)(iv) – a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority, or

Explanation: The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permissions granted by Central Licensing Authority"

The Committee deliberated upon the matter in detail and is of the opinion that since Tacrolimus Prolonged Release hard gelatine capsule 3 mg would continue to be new drugs after promulgation of New Drugs and Clinical Trials Rules, 2019, M/s Cadila Healthcare Ltd would require specific approval from CDSCO to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg in India. Accordingly, the Committee decided to reject the application of M/s Cadila Healthcare Ltd for retail price fixation of Tacrolimus Prolonged Release hard gelatine capsules 3 mg since CDSCO has not given approval to M/s Cadila Healthcare Ltd to import/ manufacture the formulation Tacrolimus Prolonged Release hard gelatine capsule 3 mg.

7. Agenda No. 7 - Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015).

7.1 The Committee noted the clarification dated 07.04.2022 received from the Office of the Central Drugs Standard Control Organisation (CDSCO) that the formulation Clotrimazole 1% mouth paint is not approved by CDSCO. The Committee deliberated upon the matter in detail and is of the opinion that since Clotrimazole 1% mouth paint is not approved by CDSCO, it cannot be categorised as scheduled formulation as per Explanation-I of DPCO 2013. Accordingly, the Committee decided that Clotrimazole 1% mouth paint is not a scheduled formulation as per Explanation-I of DPCO 2013 and hence its ceiling price not to be fixed.

8. Agenda No. 8 - Other issues

8.1 The Committee is of the conscious view that the benefit of price reduction due to expiry of the patents is to be passed on the consumers for which the reduction of 50% on the patented component of the scheduled formulation is allowed in respect of FDCs of 'Sitagliptin+ Metformin tablet' and 'Linagliptin+ Metformin tablet'. The Committee deliberated upon the matter in details and is of the opinion that the benchmark of 50% may be examined on case-to-case basis by the Committee for the medicines which has become/ is on the verge of becoming off-patent. Accordingly, the Committee decided that the issue may be undertaken in its next meeting for deliberation so as take considered view on the matter.

The meeting ended with a vote of thanks to all.

(Prasenjit Das)

Deputy Director (Pricing)

Copy to:

All members of the Committee.

Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		
	Number of Companies cosisting of Market Share of 1% & Above	7
	Sum of MAT value considered for price calculation (in Lakhs)	193.84
	Sum of PTR per unit considered for price calculation 15.10	
Retail price fixation under Para 5 of DPCO, 2013- Composition:- Metformin 850		
	Number of Packs considered 7	
	Average PTR 2.16	
	Add: 16% Retailer Margin 0.35	
	Retail Price (without local taxes) 2.51	
	% Reduction with compared to Highest Price 20.30%	

Minimumum Price (Rs.)	1.50
Maximum Price (Rs.)	2.71
Average of all considered (Rs.)	2.16
Retail Price (Rs.)	2.51

							TOTAL MAT	11,97,16,868	100%			М3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price	Price per Unit
	Pack Description	BRAND	Сотрапу			-		į	MAT %	e MAT	Y/N)	per Unit	(Rs.) Considered
	•					ļ				(ignoring	Y=Yes	(Rs.)	
		ł				ł				O% MAT)	N≔No		
	1	ļ				ļ			!			İ	
1	BIGOMET 850 MG TABLET 10	BIGOMET	ARISTO PHARMACEUTICALS PVT.LTD	850 MG	10	Tablet	14.97	2235627	1.87%	1.87%	Υ	1.50	1,50
2	DIAFER FORTE 850 MG TABLET 10	DIAFER	EAST WEST PHARMA	850 MG	10	Tablet	10.64	253253	0.21%	0.21%	N	1.06	
3	DIAMET 850 MG TABLET 15	DIAMET	BAL PHARMA	850 MG	15	Tablet	20.71	9243	0,01%	0.01%	N	1.38	
. 4	EXERMET 850 MG TABLET 15	EXERMET .	CIPLA LTD.	850 MG	15	Tablet	24	1643424	1.37%	1.37%	Υ	1.60	1.60
5	G MET (EAST WEST) FORTE 850 MG TABLET	G MET (EAST WEST)	EAST WEST PHARMA	850 MG	10	Tablet	10.54	47125	0.04%	0.04%	N	1.06	
€	GLUFORMIN 850 MG TABLET 10	GLUFORMIN .	ABBOTT HEALTHCARE PVT. LTD	850 MG	10	Tablet	25.99	5936558	4.96%	4.96%	Y	2.60	2.60
7	GLYCIPHAGE 850 MG TABLET 10	GLYCIPHAGE _	FRANCO INDIAN PHARMACEUTICALS PV	850 MG	10	Tablet	19.86	47754999	39.90%	39.90%	Y	1.99	1.99
8	GLYCOMET 850 MG TABLET 10	GLYCOMET /	USV PVT LTD	850 MG	10	Tablet	23.57	52922782	44.21%	44.21%	Y	2.36	2,36
- 9	INCONTROL 850 MG TABLET 10	INCONTROL ;	FUSION HEALTHCARE PVT LTD	850 MG	10	Tablet	25.71	22548	0.02%	0,02%	N	2.57	
10	MET DM 850 MG TABLET 10	MET DM 🎺 .	SHRRISHTI HEALTHCARE	850 MG	10	Tablet	13.58	1181	0.00%	0.00%	N	1.36	
11	WALAPHAGE 850 MG TABLET 15	WALAPHAGE	WALLACE PHARMACEUTICALS LTD.	850 MG	15	Tablet	35.14	4677701	3.91%	3.91%	Υ	2.34	2,34
12	X-MET 850 MG TABLET 15	X-MET	GLENMARK PHARMACEUTICALS LTD.	850 MG	15	Tablet	40.71	4202428	3.51%	3,51%	Y	2.71	2.71
		Rs. Per Gram											
	Worked out Retail Price	2.51	Excluding GST			i							
	Claimed Retail Price	-	Excluding GST			İ							
	Proposed retail Price		Excluding GST										

Minimumum Price (Rs.)	18.62
Maximum Price (Rs.)	19.76
Average of all considered (Rs.)	19.19
Retail Price (Rs.)	22.26

							TOTAL MAT	2,12,59,60,849	100%			М3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price	Price per Unit
	Pack Description	BRAND	Company							e MAT (ignoring O% MAT)	Y=Yes	per Unit (Rs.)	(Rs.) Considered
	ISTAMET 50/1000 MG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/1000 MG	15	TABLET	279.29	577622271.5	27,17%	27.17%	Y	18,62	18.62
	JANUMET 50/1000 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/1000 MG	15	TABLET	296.43	1548338578	72.83%	72.83%	. Y	19,76	19,76
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<u> </u>		Rs. Per Tablet	ļ .					<u> </u>	!		<u> </u>		ļ <u>_</u>
									!	<u> </u>	!	!	<u> </u>
	Worked out Retail Price		Excluding GST		1		J		1		!	ţ	
	Claimed Retail Price	l	Excluding GST	!					i				
L_	Proposed retail Price *	22.26	Excluding GST	Í	ĺ				•		i –		

Computation of Retail Price based on August 2021 Data under Para 4 of DPCO, 2013	·		
	Number of Companies cosisting of Market Share of 1% & Above		2
	Sum of MAT value considered for price calculation (in Lakhs)		 3,712.77
Each film coated tablet containing Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg	Sum of PTR per unit considered for price calculation		34.16
	Number of Packs considered		2
	Average PTR		17:08
	Add: 16% Retailer Margin	``I	2.73
	Retail Price (without local taxes)		19,81
	% Reduction with compared to Highest Price		0.06%

Minimumum Price (Rs.)	17.07
Maximum Price (Rs.)	17.09
Average of all considered (Rs.)	17.08
Retail Price (Rs.)	19.81

							TOTAL MAT	ļ .	37,12,76,933	100%			M3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)		SKU wise	Brandwis	Qualify (Price	Price per Unit
	Pack Description	BRAND	Сотрапу							MAT %	e MAT (ignoring O% MAT)		per Unit (Rs.)	(Rs.) Considered
	I ISTAMET XR CP 100/1000 MG TABLET 14	ISTAMET	SUN PHARMA LABORATORIES LTD.	100/1000 MG	14	TABLET	239.29		105393126.9	28,39%	28,39%	Υ-	17.09	17.09
	ANUMET XR CP 100/1000 MG TABLET 14	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	100/1000 MG	14	TABLET	239.01		265883806.4	71.61%	71,51%	Y	17,07	17.07
	 	-		-	-				-	-	-	 	┼	 -
													=	
	-	Rs. Per Tablet			-	-								
	Worked out Retail Price	19.83	Excluding GST	- 	-	-					1	-	+	
	Claimed Retail Price		Excluding GST				T				İ			
	Proposed retail Price	19.81	Excluding GST		1	1								

Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		
	Number of Companies cosisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation (in Lakhs)	7,661.53
Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg	Sum of PTR per unit considered for price calculation	59,08
	Number of Packs considered	2
	Average PTR	 29.54
	Add : 16% Retailer Margin	4.73
	Retail Price (without local taxes)	34,27
	% Reduction with compared to Highest Price	0.17%

Minimumum Price (Rs.)	29.45
Maximum Price (Rs.)	29.55
Average of all considered (Rs.)	29.54
Retail Price (Rs.)	34.27

			**				TOTAL MAT	ļ .	76,61,52,585	100%			M3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)			Brandwis	Qualify (Price per Unit
	Pack Description	BRAND	Company				,		-	MÄT %	e MAT (ignoring O% MAT)	Y=Yes	per Unit (Rs.)	(Rs.) Considered
1-	1 ISTAVEL 50 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	50 MG	7	TABLET	205.43	i	209904836.2	27,40%	27.40%	Y	29.49	29.49
	2 JANUVIA SO MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	7	TABLET	207.14		556247748.9	72.60%	72.60%	Y	29.59	29,59
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-		Rs, Per Tablet				_	 	 			-			
		1					1	i						
	Worked out Retail Price	34.27	Excluding G5T					!						
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Minimumum Price (Rs.)	32.10
Maximum Price (Rs.)	32.14
Average of all considered (Rs.)	32.13
Retail Price (Rs.)	37.27

							TOTAL MAT	1,76,94,66,287	100%]		M3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price per Unit
	Pack Description	BRAND	Company						MAT %		Y/N)		(Rs.) Considered
	1	!	·							(ignoring	Y=Yes	(Rs.)	
	1	ł								O% MAT)	N≖No		!
		1									L		1
	1 ISTAVEL 100 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	100 MG	7	TABLET	225	455354325	25.73%	25.73%	Y	32.14	32.14
	2 JANUVIA 100 MG TABLET 15	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	15	TABLET	481.57	173195687.4	9.79%	74.27%	Y	32.10	32,10
	3 JANUVIA 100 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	7	TABLET	225	1140916275	64.48%	74.27%	Y	32.14	32.14
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	'	Rs. Per Tablet											
										1.			
	Worked out Retail Price	37.27	Excluding GST							<u> </u>			
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Computation of Retail Price based on August 2021 Data under Para 4 of DPCO, 2013		
	Number of Companies cosisting of Market Share of 1% & Above	
	Sum of MAT value considered for price calculation (in Lakhs)	44,472.
Each film coated tablet containing Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg	Sum of PTR per unit considered for price calculation	37,36
<u> </u>	Number of Packs considered	2
	Average PTR	_ 18.68
	Add: 16% Retailer Margin	2.99
	Retail Price (without local taxes)	21.67
	% Reduction with compared to Highest Price	3,16%

Minimumum Price (Rs.)	18.07
Maximum Price (Rs.)	19.29
Average of all considered (Rs.)	18.58
Retail Price (Rs.)	21.67

							TOTAL MAT	4,44,72,87,728	100%]		M3	
S.No.	पैक विवरण	काम	कंपती	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price	Price per Unit
	Pack Description	BRAND	Company							e MAT (ignoring O% MAT)	Y=Yes	per Unit (Rs.)	(Rs.) Considered
	1 ISTAMET SO/SOO MG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/500 MG	15	TABLET	271.07	1713401213	38.53%	38.53%	Y	18.07	18.07
	2 JANUMET 50/500 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/500 MG	15	TABLET	289.29	2733886516	61.47%	61.47%	Y	19.29	19.29
<u> </u>				-	-	<u> </u>	-			1	 	 	-
		-											
	-	Rs. Per Tablet	_	- -				<u> </u>			<u> </u>		
	Worked out Retail Price	21.67	Excluding GST	_!									
	Claimed Retail Price		Excluding GST		1		ļ	!		ļ			
	Proposed retail Price	21.67	Excluding GST	1	ı	1	1	1	l	I	1	1	1

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Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		- 1
	Number of Companies cosisting of Market Share of 1% & Above	29.767.28
	Sum of MAT value considered for price calculation (in Lakhs)	77.26
	Sum of PTR per unit considered for price calculation	(1.20
Retail price fixation under Para 5 of DPCO, 2013- Composition:- Linagliptin 5mg		2
	Number of Packs considered	38.63
	Average PTR	6.18
	Add : 16% Retailer Margin	44.81
	Retail Price (without local taxes)	
	% Reduction with compared to Highest Price	%
	% Reduction with compared to make a rice	

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

							TOTAL MAT	2,97,67,28,317	100%			М3	
			·	Ctananth	Pack Size		PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price	Price per Unit (Rs.) Considered
S.No.	पैक विवरण		कंपनी	Strength	FACK 3120	101111	1 /////////////////////////////////////		MAT %	e MAT	Y/N)	per Unit	(Rs.) Considered
	Pack Description	BRAND	Company							(ignoring		(Rs.)	
					Ì					O% MAT)	NENn		
					1	Į.		1		J 7		1	
1									15 0 101	42.84%	- , -	38,63	38.63
1	ONDERO 5 MG TABLET 10	ONDERO	LUPIN LTD	5 MG	10	Tablet	386.25				 		38.63
			BOEHRINGER INGELHEIM	5 MG	10	Tablet	386.25	1701529316	57,16%	57.16%	\ <u> </u>	38.63	30.03
_	TRAJENTA S MG TABLET 10	TRAJENTA	BOEHRINGEN INGERTERIA									<u></u>	
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-		Rs. Per Gram						 		 	 		
\vdash	Worked out Retail Price	44.81	Excluding GST		<u> </u>	↓	<u> </u>		 	+-		 	
\vdash	Claimed Retail Price		Excluding GST			L	ļ		 	+		┼───	
\vdash			Excluding GST				1	<u> </u>	J		i		
	Proposed retail Price		Innermonia and										

Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		 7
	Number of Companies cosisting of Market Share of 1% & Above	
\	Sum of MAT value considered for price calculation (in Lakhs)	 14,096.33
	Sum of PTR per unit considered for price calculation	41.26
]	
Retail price fixation under Para 5 of DPCO, 2013- Composition:- Linagliptin 2.5mg + Metformin 500mg	Number of Packs considered	, 2
	Average PTR	20.63
	Add: 16% Retaller Margin	3.30
	Retail Price (without local taxes)	23,93
	94 Reduction with compared to Highest Price	0.00%

Minimumum Price (Rs.)	20	0.63
Maximum Price (Rs.)	20). <u>63</u>
Average of all considered (Rs.	20	0,63
Retail Price (Rs.)	23	3.93

							TOTAL MAT	1,40,96,32,734	100%			M3	
S.No.	पैक विवरण Pack Description	BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwis e MAT (ignoring O% MAT)	Y/N) Y=Yes	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
		ONDERO MICE	LUPIN LTD	2.5/500 MG	10	Tablet	206.25	702233519.8	49.82%	49.82%	Y	20.63	20,63
	ONDERO MET 2.5/500 MG TABLET 10		BOEHRINGER INGELHEIM	2.5/500 MG	10	Tablet	206.25		50.18%	50.18%	Y	20.63	20.63
<u> </u>	TRAIENTA DUO 2.5/500 MG TABLET 10	TRAJENTA DUO	BOETAINGER INGELTEIN	2.5,500								<u> </u>	
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						 	 		1	<u> </u>			
	<u> </u>	Rs. Per Gram				 				1			
	Worked out Retail Price	23.93	Excluding GST		 	 			T	T			
	Claimed Retail Price		Excluding GST			 	 	 			1		
	Proposed retail Price	<u> </u>	Excluding GST		<u> </u>				·	-	•		

Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		-
composition of the control of the co	Number of Companies cosisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation (in Lakhs)	4,592.94
	Sum of PTR per unit considered for price calculation	42.90
Retail price fixation under Para 5 of DPCO, 2013- Composition:- Linagliptin 2.5mg + Metformin 1000mg		
	Number of Packs considered	2
•	Average PTR	21.45
	Add: 16% Retailer Margin	3.43
	Retail Price (without local taxes)	24,88
	W Padjustion with compared to Mighest Price	0.00%

Minimumum Price (Rs.)	21.45
Maximum Price (Rs.)	21.45
Average of all considered (Rs.)	21.45
Retail Price (Rs.)	24.88

			,											
							TOTAL MAT		45,92,94,414	100%			м3	
S.No.	पैक दिवरण Pack Description	1	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)		MAT %	Brandwis e MAT (ignoring O% MAT)	Y/N) Y=Yes	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
<u> </u>	ONDERO MET 2.5/1000 MG TABLET 10	ONDERO MET	LUPIN LTD	2.5/1000 MG	10	Tablet	214.50		208308862	45.35%	45,35%	Y	21.45	21,45
	TRAIENTA DUO 2.5/1000 MG TABLET 10	TRAIENTA DUO	BOEHRINGER INGELHEIM	2.5/1000 MG	10	Tablet	214.50		250985552	54.65%	54.65%	Y	21.45	21,45
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		Rs. Per Gram			_ -		+	 				1	 	1
L	Worked out Retail Price		Excluding GST	 -		 	 	 	 -			-	 	<u> </u>
	Claimed Retail Price		Excluding GST	_		├	+	-			\leftarrow		 	1
	Proposed retail Price		Excluding GST		ــــــــــــــــــــــــــــــــــــــ	<u> </u>		l		L	٠			

Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		 a
Compatibility in recommendation	Number of Companies cosisting of Market Share of 1% & Above	
	Sum of MAT value considered for price calculation (in Lakhs)	 1,193.84
	Sum of PTR per unit considered for price calculation	 15.10
Retall price fixation under Para 5 of DPCO, 2013- Composition: - Metformin 850		
netan prior madon 4 man respectively	Number of Packs considered	
	Average PTR	2.16
•	Add: 16% Retailer Margin	0.35
	Retail Price (without local taxes)	2.51
	% Reduction with compared to Highest Price	20.30%

Minimumum Price (Rs.)	1.50
Maximum Price (Rs.)	2.71
Average of all considered (Rs.)	2.16
Retail Price (Rs.)	2.51

			-			TOTAL MAT	11,97,16,868	100%			М3	
पैक विवरण Pack Description	UIT BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwis e MAT (ignoring O% MAT)	Y/N) Y=Yes	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
BIGOMET 850 MG TABLET 10	BIGOMET	ARISTO PHARMACEUTICALS PVT.LTD	850 MG_	10	Tablet	14.97	2235627	1.87%	1.87%	Y	1.50	1,50
	DIAFER	EAST WEST PHARMA	850 MG	10	Tablet	10.64	253253	0.21%	0.21%	N	1.06	ļ
DIAMET 850 MG TABLET 15	DIAMET	BAL PHARMA	850 MG	15	Tablet	20.71	9243	0.01%	0.01%	N_	1,38	
EXERMET 850 MG TABLET 15	EXERMET	CIPLA LTD.	850 MG	15	Tablet	24	1643424	1.37%	1.37%	Y	1.60	1.60
G MET (EAST WEST) FORTE 850 MG TABLET			850 MG	10	Tablet	10.64	47125	0,04%	0.04%	N	1.06	
GLUFORMIN 850 MG TABLET 10	GLUFORMIN	ABBOTT HEALTHCARE PVT. LTD	850 MG	10	Tablet	25.99	5936558	4.96%	4,96%	Y	2.60	2.60
	GLYCIPHAGE	FRANCO INDIAN PHARMACEUTICALS PV		10	Tablet	19.86	47764999	39.90%	39.90%	Y	1.99	1,99
OLI GITTI TOLI GOOD TO TO TO TO TO TO TO TO TO TO TO TO TO	GLYCOMET	USV PVT LTD	850 MG	10	Tablet	23.57	52922782	44.21%	44,21%	Y	2.36	2.36
GLYCOMET 850 MG TABLET 10	INCONTROL	FUSION HEALTHCARE PVT LTD	850 MG	10	Tablet	25.71	22548	0,02%	0.02%	_ N _	2.57	
INCONTROL 850 MG TABLET 10		SHRRISHTI HEALTHCARE	850 MG	10	Tablet	13.58	1181	0.00%	0.00%	N	1.36	
MET DM 850 MG TABLET 10	MET DM	WALLACE PHARMACEUTICALS LTD.	850 MG	15	Tablet	35.14	4677701	3.91%	3.91%	Y	2.34	2.34
4471Q 11 11 10 Q Q Q Q T 11 1 1 1 1 1 1 1 1 1 1 1 1 1	WALAPHAGE	GLENMARK PHARMACEUTICALS LTD.	850 MG	15	Tablet	40.71	4202428	3.51%	3.51%	Y	2.71	2.71
X-MET 850 MG TABLET 15	X-MET Rs. Per Gram	GLENMARK FRARMACEUTICALS LTD.	030 1910								<u> </u>	
Worked out Retail Price	2.51	Excluding GST		ļ	<u> </u>	 	ļ-—		 	 	-	
Claimed Retail Price		Excluding GST		ļ	 	_				├ ──	-	
Proposed retail Price		Excluding GST	l	l					<u> </u>	ل		

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Computation of Retail Price based on August, 2021 Data under Para 4 of DPCO, 2013		
	Number of Companies coststing of Market Share of 1% & Above	1,192.12
	Sum of MAT value considered for price calculation (in Lakhs) 42.0	
	Sum of PTR per unit considered for price calculation	
Some State of State o		
Retail price fixation under Para 5 of DPCO, 2013- Composition:- Linagliptin 2.5mg + Metformin 850mg		
	21.0	
	Average PTR 3.3.	.6
	Add: 16% Retailer Margin Retail Price (without local taxes)	36
		1%
	% Reduction with compared to Highest Price	

Minimumum Price (Rs.)	21.00
Maximum Price (Rs.)	21.00
Average of all considered (Rs.)	21.00
Retail Price (Rs.)	24.36

		TOTAL MAT 11,					11,92,11,718	100%	100% M3				
S.No.	पैक दिवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwis e MAT (ignoring O% MAT)	Y/N) Y=Yes	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
				2.5/850 MG	10	Tablet	210.00	55778227.7	48.79%	48.79%	<u> </u>	21.00	21.00
	1 ONDERO MET 2.5/850 MG TABLET 10		LUPIN LTD	2.5/850 MG	10	Tablet	210.00		53.21%	53.21%	ΥΥ	21.00	21.00
	2 TRAJENTA DUO 2.5/850 MG TABLET 10	TRAIENTA DUO	BOEHRINGER INGELHEIM	2.3/650 MG									
													
		Rs. Per Gram				+			1				
	Worked out Retail Price	24.36	Excluding GST		 	+	╅		 	1	1		
	Cialmed Retail Price	<u> </u>	Excluding GST			+	 		 	1	1		I
	Proposed retail Price	1 •	Excluding GST		L								

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