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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 44thmeeting of the Multidisciplinary Committee of Experts held on 04.08.2022 at 12:00noon.

44thmeeting of the "Multidisciplinary Committee of Experts" was held on 04.08.2022 at 12:00 noon 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 Pharmacopea 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
6. 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 fourteen applications have been received for retail price fixation of eleven Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin 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 1000 mg (sustained release) tablet (v) Sitagliptin 100 mg + Metformin 500 mg (sustained release) tablet, (vi) Sitagliptin 50 mg + Metformin 500 mg (extended release) tablet, (vii) Sitagliptin 100 mg + Metformin 500 mg (extended release) tablet, (viii) Sitagliptin 100 mg + Metformin 1000 mg (extended release) tablet. The Committee further noted that the formulation 'Sitagliptin' has become off-patent in 5th/6th July 2022.

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

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

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

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

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

1.3 The Committee also noted the decision taken in its 41st and 42nd meeting dated 08.04.2022 and 02.06.2022 is in line with the decision taken as mentioned Para 1.2 above and the same was approved by the Authority in its 97th meeting dated 06.05.2022 and 99th meeting dated 28.06.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet'. The Committee also noted that it also recommended the retail price of FDCs of 'Sitagliptin+ Metformin' tablet as per the methodology mentioned in Para 1.2 in its 43rd meeting dated 04.07.2022. The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available in some cases and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become would not pass 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 off-patent so as to pass the benefit of price reduction to the consumers on account of the drug becoming off-patented. The Committee therefore recommended that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 40th , 41st and 42nd meeting held

on 14.03.2022, 08.04.2022 &02.06.2022 and the same were approved by the Authority in its 96th, 97th and 99th meeting held on 24.03.2022, 06.05.2022 and 02.06.2022.

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

1.4.1 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aprica Healthcare Limited (marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 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		20.08
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for November, 2021		22.39
(i)	Recommended retail price		18.34

1.4.2 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (As Sustained Release Form) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aprica 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 50 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form)		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 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		24.55
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (SR) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.67

1.4.3 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (As Sustained Release Form) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aprica 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 50 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form)		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 2021	34.27

		data)	
(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		26.78
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (SR) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.06

1.4.4 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aprica Healthcare Limited (marketer) at Rs. 20.02 per tablet excluding GST as detailed below:

S. No.	**Particulars**	**Source / Method**	**Amount (Rs.)**
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 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		22.32
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for November, 2021		22.97
(i)	Recommended retail price		20.02

1.4.5 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 Theon Pharmaceuticals Limited (manufacturer) and M/s German Remedies Pharmaceuticals Private 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 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 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		33.33
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		18.67

1.4.6 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 Theon Pharmaceuticals Limited (manufacturer) and M/s German Remedies Pharmaceuticals Private Limited (marketer) at Rs. 20.17per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release form)		
(a)	Derivedretailprice of Sitagliptin 100 mg tablet	Retail price (as per November, 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		40.00
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.17

1.4.7 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 Theon Pharmaceuticals Limited (manufacturer) and M/s German Remedies Pharmaceuticals Private Limited (marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate		

	Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended-Release form)		
(a)	Derivedretailprice of Sitagliptin 100 mg tablet	Retail price (as per November, 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		41.67
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		21.56

1.4.8 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 Theon Pharmaceuticals Limited (manufacturer) and M/s German Remedies Pharmaceuticals Private Limited (marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	**Particulars**	**Source/Method**	**Amount (Rs.)**
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release form)		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per November, 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 Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		20.06

1.4.9 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (As Sustained Release) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aristo Pharmaceuticals Private 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 100 mg + Metformin Hydrochloride IP 500 mg (as Sustained Release form)		
(a)	Derivedretailprice of Sitagliptin 100 mg tablet	Retail price (as per November, 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		41.67
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (SR) tablet" as per		NA

	Pharmatrac Data for November, 2021		
(i)	Recommended retail price		20.17

1.4.10 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (As Sustained Release) for M/s Mascot Health Series Private Limited (manufacturer) and M/s Aristo Pharmaceuticals Private Limited (marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Sustained Release form)		
(a)	Derivedretailprice of Sitagliptin 100 mg tablet	Retail price (as per November, 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		42.56
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (SR) tablet" as per Pharmatrac Data for November, 2021		NA
(i)	Recommended retail price		21.56

1.4.11 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Hetero Labs Limited (manufacturer) and M/s Hetero Healthcare Limited (marketer) at Rs. 14.28 per tablet excluding GST as detailed below:

S.	Particulars	Source/Method	Amount

No.			(Rs.)
	Each film coated bilayered 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 December, 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		18.64
(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		14.28
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for December, 2021		22.39
(i)	Recommended retail price		14.28

1.4.12 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Hetero Labs Limited (manufacturer) and M/s Hetero Healthcare Limited (marketer) at Rs. 15.17 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 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per December, 2021 data)	34.27
(b)	50% of (a)		17.13

S. No.	Particulars	Source/Method	Amount (Rs.)
(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		15.17
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for December, 2021		22.97
(i)	Recommended retail price		15.17

1.4.13 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Psychotropics India Limited (manufacturer and marketer) at Rs. 17.87 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per December, 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		0.722

S. No.	Particulars	Source/Method	Amount (Rs.)
(f)	Worked out Retail Price (d)-(e)		20.02
(g)	Claimed Retail price		17.87
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for December, 2021		22.97
(i)	Recommended retail price		17.87

1.4.14 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Psychotropics India Limited (manufacturer and marketer) at Rs. 16.37 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derivedretailprice of Sitagliptin 50 mg tablet	Retail price (as per December, 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		16.37
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for December, 2021		22.39
(i)	Recommended retail price		16.37

2. Agenda No. 2 - 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.

2.1 The Committee noted that based on the demonstration made by M/s AxaParenterals Ltd in the 42nd meeting held on 02.06.2022 it was decided that M/s AxaParenterals 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 are being produced and its advantages*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Axa Parenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s AxaParenterals Ltd again provided the reply vide e-mail dated 15.07.2022.

2.2 The Committee examined the reply provided by the company and again noted that the company has not submitted the data/literature based on the study specific to their product. The Committee further noted that there is wide variance in the data of the flow rate as provided by the company.The company has not mentioned about the size of sample and the data provided does not have statistical power.The Committee deliberated upon the matter in detail and is of the opinion that the instances of leaching of the bottle also need to be looked into. Accordingly, the Committee decided that M/s Axa Parenterals Ltd be directed to conduct a proper study of their product and provide a report based on the data generated by it's quality control (QC) department and based on the study specific to their product, to provide the copy of the details of flow rate duly authenticated by it's QC department and the details of the study relating to leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

3. Agenda No. 3 - 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.

3.1 The Committee noted that based on the demonstration made by M/s AxaParenterals Ltd in the 42nd meeting held on 02.06.2022 it was decided that M/s AxaParenterals 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 are being produced and its advantages". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s AxaParenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s AxaParenterals Ltd again provided the reply vide e-mail dated 15.07.2022.

3.2 The Committee examined the reply provided by the company and noted that reply stated in point (a) and (b) of the mail dated 15.07.2022 under the head " agenda 4.2" are irrelevant and that the company has not submitted the data/literature based on the study specific to their product. The Committee further noted that there is wide variance in the data of the flow rate as provided by the company. The company has not mentioned about the size of sample and the data provided does not have statistical power. The Committee deliberated upon the matter in detail and is of the opinion that the instances of leaching of the bottle also need to be looked into. Accordingly, the Committee decided that M/s Axa Parenterals Ltd be directed to conduct a proper study of their product and provide a report based on the data generated by it's quality control (QC) department and based on the study specific to their product, to provide the copy of the details of flow rate duly authenticated by it's QC department and the details of the study relating to leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

4.1 The Committee noted that based on the demonstration made by M/s AxaParenterals Ltd in the 42nd meeting held on 02.06.2022 it decided that M/s AxaParenterals 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*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s AxaParenterals Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s AxaParenterals Ltd again provided the reply vide e-mail dated 15.07.2022

4.2 The Committee examined the reply provided by the company and noted that the claim of the company is not substantiated by any data and that the company has not

submitted the data/literature based on the study specific to their product 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 eye drops 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 Committee deliberated upon the matter in detail and is of the opinion that since the company has not provided specific study of their product, the claim of the company for separate price non-glass innovative single use eye drops (preservative free) be not considered. Accordingly, the Committee decided to reject the application of M/s AxaParenterals Ltd for separate price non-glass innovative single use eye drops (preservative free).

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

5.1 The Committee noted that based on the demonstration made by M/s Puerto Life Sciences Pvt. Ltd in the 42nd meeting held on 02.06.2022 it was 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 are being produced and its advantages*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s Puerto Life Sciences Pvt. Ltd again provided the reply vide e-mail dated 15.07.2022.

5.2 The Committee examined the reply provided by the company and found that there is a wide variation in the data relating to flow rate from 15 seconds to 40 seconds. The same is not desirable in a clinical set up and needs explanation. With respect to specification of packing material, committee mentioned that there should be no leaching and desired that the company should provide some documentary evidence to show that there exists a mechanism in the company to ensure that there is no leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

6.1 The Committee noted that based on the demonstration made by M/s Puerto Life Sciences Pvt. Ltd in the 42nd meeting held on 02.06.2022 it was 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 are being produced and its advantages". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s Puerto Life Sciences Pvt. Ltd again provided the reply vide e-mail dated 15.07.2022.

6.2 The Committee examined the reply provided by the company and found that there is a wide variation in the data relating to flow rate from 15 seconds to 40 seconds. The same is not desirable in a clinical set up and needs explanation. With respect to specification of packing material, committee was mentioned that there should be no leaching and desired that the company should provide some documentary evidence to show that there exists a mechanism in the company to ensure that there is no leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

7.1 The Committee noted that based on the demonstration made by M/s Puerto Life Sciences Pvt. Ltd in the 42nd meeting held on 02.06.2022 it was 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 are being produced and its advantages*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Puerto Life Sciences Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s Puerto Life Sciences Pvt. Ltd again provided the reply vide e-mail dated 15.07.2022.

7.2 The Committee examined the reply provided by the company and found that there is a wide variation in the data relating to flow rate from 15 seconds to 40 seconds. The same is not desirable in a clinical set up and needs explanation. With respect to specification of packing material, committee mentioned that there should be no leaching and desired that the company should provide some documentary evidence to show that there exists a mechanism in the company to ensure that there is no leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

8.1 The Committee noted that based on the demonstration made by M/s Sachin Parenteral Pvt. Ltd in the 42nd meeting held on 02.06.2022 it was decided that M/s Sachin Parenteral Pvt. Ltdbe directed to "*provide the documents/ literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Sachin Parenteral Pvt. Ltd be directed to provide the documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s Sachin Parenteral Pvt. Ltd again provided the reply vide e-mail dated 14.07.2022.

8.2 The Committee examined the reply provided by the company and noted that there is wide variance in the data of the flow rate as provided by the company. The company has not mentioned about the size of sample and the data provided does not have statistical power. The Committee deliberated upon the matter in detail and is of the opinion that the instances of leaching of the bottle also need to be looked into. Accordingly, the Committee decided that M/s Sachin Parenteral Pvt. Ltd be directed to conduct a proper study of their product and provide a report based on the data generated by it's quality control (QC) department and based on the study specific to their product, to provide the copy of the details of flow rate duly authenticated by it's QC department and the details of the study relating to leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

9.1 The Committee noted that based on the demonstration made by M/s Sachin Parenteral Pvt. Ltd in the 42nd meeting held on 02.06.2022 it was decided that M/s Sachin Parenteral Pvt. Ltdbe directed to "*provide the documents/ literature showing the advantages of these packages over the normal packages and the data showing the flow rate at the beginning, middle and towards the end of the flow. The Committee also directed to provide the details of materials with the specification with which the packages are being produced and its advantages*". The Committee examined the documents submitted by the company and observed that the company has not submitted the data/literature based on the study specific to their product. Accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that M/s Sachin Parenteral Pvt. Ltd be directed to provide the

documents/literature as sought in the 42nd meeting dated 02.06.2022 based on the study specific to their product for which the application for separate price has been made. M/s Sachin Parenteral Pvt. Ltd again provided the reply vide e-mail dated 14.07.2022.

9.2 The Committee examined the reply provided by the company and noted that there is wide variance in the data of the flow rate as provided by the company. The company has not mentioned about the size of sample and the data provided does not have statistical power. The Committee deliberated upon the matter in detail and is of the opinion that the instances of leaching of the bottle also need to be looked into. Accordingly, the Committee decided that M/s Sachin Parenteral Pvt. Ltd be directed to conduct a proper study of their product and provide a report based on the data generated by it's quality control (QC) department and based on the study specific to their product, to provide the copy of the details of flow rate duly authenticated by it's QC department and the details of the study relating to leaching. The Committee further decided that the company be called in the next meeting for further clarification on the matter.

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

10.1 The Committee noted that based on the demonstration made by M/s Gufic Biosciences Ltd in the 42nd meeting held on 02.06.2022 it was decided that M/s Gufic Biosciences Ltdbe directed to "*provide the documents/ literature/data showing the stability of the products from moisture & light in the special packages and dissolving of the products. The Committee also directed to provide data on the instances of reduction in environmental load & hospital wastages and data on needle stick injuries that arise due to use of conventional injection, issues of dosage accuracy and reduction in transport cost, fuel charges with respect to its products as claimed by the company*". The Committee examined the documents submitted by the company and accordingly, the Committee in its 43rd meeting held on 04.07.2022 decided that ...". M/s Gufic Biosciences Ltd be directed to provide the documents/data generated based on the study specific to their own product highlighting the advantages of the product, as claimed, for which the application for separate price has been made." M/s Sachin Parenteral Pvt. Ltd again provided the reply vide e-mail dated 20.07.2022 and 29.07.2022.

10.2 The Committee examined the reply provided by the company and noted thatin certain instances the company has provided the data. The Committee deliberated upon the matter in detail and decided that the company be called in the next meeting for further clarification on the matter

11. Agenda No. 11: Application by M/s Intas Pharmaceuticals Ltd for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulations "Clozapine Extended Release Capsules 12.5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg".

11.1 The Committee noted the application filed by M/s Intas Pharmaceuticals Ltd for exemption from the provisions of Drug Price Control Order 2013 under Para 32

(iii) for the formulations "Clozapine Extended Release Capsules 12.5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg".

11.2 The Committee deliberated upon the matter in detail and is of the opinion that the different variants of a drug like extended release, sustained release, modified release of a drug are in the market since a considerable period and also manufactured by a number of companies. Hence, it cannot be considered as 'a new delivery system' for qualifying for exemption under Para 32(iii) of DPCO 2013. Accordingly, the Committee decided to reject the application of M/s Intas Pharmaceuticals Ltd for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulations "Clozapine Extended Release Capsules 12.5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg."

12. Agenda No. 12: Retail price fixation under Para 5 of DPCO, 2013- Each Adhesive Patch contains "Lidocaine 700mg in an aqueous base (50mg per gm adhesive) for M/s Hetero Healthcare Limited (Manufacturer and Marketer).

12.1 The Committee deliberated upon the matter in detail and directed that the matter may be placed in the next meeting after further examination of the same.

13. Agenda No. 13: Retail price fixation under Para 5 of DPCO, 2013- Each Sachet Contains: Pantoprazole Sodium Eq. to Pantoprazole 40mg (Sodium Bicarbonate as buffer) for M/s Alkem Laboratories Ltd. (Manufacturer & Marketer)

13.1 The Committee deliberated upon the matter in detail and directed that the matter may be placed in the next meeting after further examination of the same.

14. Agenda No. 14: Retail price fixation under Para 5 of DPCO, 2013- Ibuprofen solution for infusion in which each 100ml contains Ibuprofen 400mg for M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer) and M/s Cipla Ltd. (Marketer)

14.1 The Committee deliberated upon the matter in detail and directed that the matter may be placed in the next meeting after further examination of the same.

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 November, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg

Number of Companies cosisting of Market Share of 1% & Above							2
Sum of MAT value considered for price calculation (In Lakhs)							7,798.75
Sum of PTR per unit considered for price calculation							59.080
Number of Packs considered							2
Average PTR							29.540
Add : 16% Retailer Margin							4.73
Retail Price (without local taxes)							34.270
% Reduction with compared to Highest Price							0.17%

Minimum Price (Rs.)			29.49
Maximum Price (Rs.)			29.59
Average of all considered (Rs.)			29.54
Retail Price (Rs.)			34.27

							TOTAL MAT	77,98,74,852	100%			M3	
S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAVEL 50 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	50 MG	7	TABLET	206.430	21265469.22	27.27%	27.27%	Y	29.49	29.49
2	JANUVIA 50 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	7	TABLET	207.140	56722016.88	72.73%	72.73%	Y	29.59	29.59
		Rs. Per tablet											
	Worked out Retail Price	34.27	Excluding GST										

Computation of Retail Price based on November, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg	Number of Companies cosisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation (in Lakhs)	16,009.71
	Sum of PTR per unit considered for price calculation	96.380
	Number of Packs considered	3
	Average PTR	32.130
	Add : 16% Retailer Margin	5.14
	Retail Price (without local taxes)	37.270
	% Reduction with compared to Highest Price	0.03%

Minimum Price (Rs.)	32.10
Maximum Price (Rs.)	32.14
Average of all considered (Rs.)	32.13
Retail Price (Rs.)	37.27

							TOTAL MAT	1,80,09,71,181	100%		M3		
S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAVEL 100 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	100 MG	7	TABLET	225.000	447230700.00	24.83%	24.83%	Y	32.14	32.14
2	JANUVIA 100 MG TABLET 15	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	15	TABLET	481.570	165623480.68	9.20%	75.17%	Y	32.10	32.10
3	JANUVIA 100 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	7	TABLET	225	1188117000	65.97%	75.17%	Y	32.14	32.14
		Rs. Per tablet											
	Worked out Retail Price	37.27	Excluding GST										

Computation of Retail Price based on November, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg and Metformin Hydrochloride IP 500 mg	
Number of Companies cosisting of Market Share of 1% & Above	2
Sum of MAT value considered for price calculation (in Lakhs)	45,483.37
Sum of PTR per unit considered for price calculation	38.590
Number of Packs considered	2
Average PTR	19.300
Add : 16% Retailer Margin	3.09
Retail Price (without local taxes)	22.390
% Reduction with compared to Highest Price	0.00%

Minimum Price (Rs.)	19.29
Maximum Price (Rs.)	19.30
Average of all considered (Rs.)	19.30
Retail Price (Rs.)	22.39

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	TOTAL MAT PTR(Rs.)	4,54,83,36,924 MAT(Rs.)	100% SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	M3 Quality (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAMET 50/500 MG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/500 MG	15	TABLET	289.510	1747585423.62	38.42%	38.42%	Y	19.30	19.30
2	JANUMET 50/500 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/500 MG	15	TABLET	289.290	2800751500.17	61.58%	61.58%	Y	19.29	19.29
		Rs. Per tablet											
	Worked out Retail Price	22.39	Excluding GST										

Computation of Retail Price based on December, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg & Metformin Hydrochloride IP 1000 mg	Number of Companies cosisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation [in Lakhs]	21,360.43
	Sum of PTR per unit considered for price calculation	39.590
	Number of Packs considered	2
	Average PTR	19.800
	Add : 16% Retailer Margin	3.17
	Retail Price (without local taxes)	22.970
	% Reduction with compared to Highest Price	0.15%

Minimum Price (Rs.)	19.76
Maximum Price (Rs.)	19.83
Average of all considered (Rs.)	19.80
Retail Price (Rs.)	22.97

							TOTAL MAT	2,13,66,42,732	100%			M3	
S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAMET 50/1000 MG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/1000 MG	15	TABLET	297.440	572333292.08	26.79%	26.79%	Y	19.83	19.83
2	JANUMET 50/1000 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/1000 MG	15	TABLET	296.430	1564309440.33	73.21%	73.21%	Y	19.76	19.76
		Rs. Per tablet											
	Worked out Retail Price	22.97	Excluding GST										

Computation of Retail Price based on December, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg & Metformin Hydrochloride IP 500 mg	Number of Companies cosisting of Market Share of 1% & Above							2
	Sum of MAT value considered for price calculation (in Lakhs)							45,809.23
	Sum of PTR per unit considered for price calculation							38.590
	Number of Packs considered							2
	Average PTR							19.300
	Add : 16% Retailer Margin							3.09
	Retail Price (without local taxes)							22.390
	% Reduction with compared to Highest Price							0.00%

Minimum Price (Rs.)			19.29
Maximum Price (Rs.)			19.30
Average of all considered (Rs.)			19.30
Retail Price (Rs.)			22.39

							TOTAL MAT	4,58,09,23,377	100%			M3	
S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAMET 50/500 MG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/500 MG	15	TABLET	289.510	1761706104.77	38.46%	38.46%	Y	19.30	19.30
2	JANUMET 50/500 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/500 MG	15	TABLET	289.290	2819217272.69	61.54%	61.54%	Y	19.29	19.29
		Rs. Per tablet											
	Worked out Retail Price	22.39	Excluding GST										

Computation of Retail Price based on December, 2021 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg	Number of Companies coisting of Market Share of 1% & Above							2
	Sum of MAT value considered for price calculation (In Lakhs)							7,802.80
	Sum of PTR per unit considered for price calculation							59.080
	Number of Packs considered							2
	Average PTR							29.540
	Add : 16% Retailer Margin							4.73
	Retail Price (without local taxes)							34.270
	% Reduction with compared to Highest Price							0.17%

Minimum Price (Rs.)			29.49
Maximum Price (Rs.)			29.59
Average of all considered (Rs.)			29.54
Retail Price (Rs.)			34.27

							TOTAL MAT	78,02,79,937	100%			M3	
S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	ISTAVEL 50 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	50 MG	7	TABLET	206.430	212678223.24	27.26%	27.26%	Y	29.49	29.49
2	JANUVIA 50 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	7	TABLET	207.140	567601713.76	72.74%	72.74%	Y	29.59	29.59
		Rs. Per tablet											
	Worked out Retail Price	34.27	Excluding GST										