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

Subject: Minutes of the 46th meeting of the Multidisciplinary Committee of Experts held on 19.10.2022 at 11:30 AM.

46<sup>th</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 19.10.2022 at 11:30 AM 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
- Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli through video conferencing
- Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopea Commission – Co-opted member through video conferencing
- Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, Gol & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member through video conferencing
- Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS-New Delhi through video conferencing

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

- 1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- 2. 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 seven applications have been received for retail price fixation of four 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 (extended release) tablet, (iv) Sitagliptin 50 mg + Metformin 500 mg (extended release) tablet, (v) Sitagliptin 50 mg + Metformin 1000 mg (extended release) tablet, and (vi) Sitagliptin 100 mg + Metformin 500 mg (extended release) tablet. The Committee further noted that the formulation 'Sitagliptin' has become off-patent on 5th/6th July 2022.
- 1.2. The Committee recalled the decision taken in its 40<sup>th</sup> meeting dated 14.03.2022 and approved by the Authority in its 96<sup>th</sup> meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet' in which the Authority decided as follows:
  - (i) The Authority noted that the formulation "Sitagliptin" has become/ is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.



(ii) The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line decision taken in the 89th Authority meeting dated 28.06.2021, recommended

to fix the retail price as per the following methodology:

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

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

Multidisciplinary Committee of Experts.

1.3 The Committee also noted the decision taken in its 41st, 42nd, 43rd, 44th and 45th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022 and 13.09.2022 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, 99th meeting dated 28.06.2022, 100th meeting dated 05.08.2022, 101st meeting dated 07.09.2022 and 102<sup>nd</sup> meeting dated 27.09.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet'.

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 eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Ravenbhel Healthcare Private Limited (Manufacturer) and M/s Lupin Limited (Marketer) at Rs. 21.56 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
8	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release Form)	Detail price (as per	37.27
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 data)	07.27



(b)	50% of (a)	551V.III(VOI.VI)	40.00
			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		39.28
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(i)	Recommended retail price		21.56

1.4.2 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Ravenbhel Healthcare Private Limited (Manufacturer) and M/s Unison 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 eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg (as Extended Release)		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per February, 2022 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		18.67



S. No.	Particulars	Source/Method	Amount (Rs.)
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(i)	Recommended retail price		18.67

1.4.3 Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Mediforce Healthcare Private Limited (Manufacturer) and M/s Mankind Prime Labs Private Limited (Marketer) at Rs. 18.34 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		0.1.07
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per February, 2022 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		22.00
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for February, 2022		22.39
(i)	Recommended retail price		18.34

<sup>1.4.4</sup> Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Mediforce Healthcare Private Limited (Manufacturer) and M/s Mankind Prime Labs Private Limited (Marketer) at Rs. 20.02 per tablet excluding GST as detailed below:



S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per February, 2022 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		25.00
h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for February, 2022		22.97
i)	Recommended retail price		20.02

1.4.5 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Ravenbhel Healthcare Private Limited (Manufacturer) and M/s Unison Pharmaceuticals Private Limited (Marketer) at Rs. 20.06 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
(a)	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release)  Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per February, 2022 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated	3.66



S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(d)	Retail Price		20.79
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.73
(f)	Worked out Retail Price (d)-(e)		20.06
(g)	Claimed Retail price		20.06
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(i)	Recommended retail price		20.06

1.4.6 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Ravenbhel Healthcare Private Limited (Manufacturer) and M/s Unison Pharmaceuticals Private Limited (Marketer) at Rs. 20.17 per tablet excluding GST as detailed below:

6. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release)	Petail price (as	37.27
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 data)	57.27
(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		20.17



S. Particulars Source/Method Amount (Rs.)

(h) Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for February, 2022

(i) Recommended retail price 20.17

1.4.7 Each film coated bilayered tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Ravenbhel Healthcare Private Limited (Manufacturer) and M/s Unison 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 eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000		
(a)	mg (as Extended Release)  Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 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		21.56
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(i)	Recommended retail price		21.56

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013 - Fixed Dose Combinations (FDCs) of Dapagliflozin + Sitagliptin + Metformin tablet.



The Committee noted that three applications have been received for retail price fixation of two Fixed Dose Combinations (FDCs) of Dapagliflozin + Sitagliptin + Metformin tablets i.e. (i) Dapagliflozin 10 mg + Sitagliptin 100 mg + Metformin (ER) 1000 mg Tablet, (ii) Dapagliflozin 10 mg + Sitagliptin 100 mg + Metformin (ER) 500 mg tablet. The Committee further noted that the formulation 'Dapagliflozin and Sitagliptin' of the FDCs was patented and the patent expired on 02.10.2020 and 5th/ 6th July 2022 respectively.

- In this connection, it is mentioned that the Authority in its 96th meeting dated 2.2. 24.03.2022 (based on the recommendation of the Committee of Experts in its 40th meeting dated 14.03.2022) approved the retail price of the FDC of Sitagliptin + Metformin tablet in line with the following methodology as detailed below:
  - (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
  - (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.
- The Committee also noted the decision taken in its 41st, 42nd, 43rd, 44th and 45th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022 and 13.09.2022 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, 99th meeting dated 28.06.2022, 100th meeting dated 05.08.2022, 101st meeting dated 07.09.2022 and

102<sup>nd</sup> meeting dated 27.09.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet'.

- 2.4. Accordingly, the retail price of FDCs of Dapagliflozin + Sitagliptin + Metformin tablets has been attempted in line with principles as adopted earlier i.e. reduction of 50% from the patented component i.e. Dapagliflozin and Sitagliptin and then adding the ceiling price of the scheduled components as applicable six month earlier from the date of application [termed as (d)]. From the total, a reduction of 20% of the lower of three component in line with the recommendation of the Pronab Sen Committee is provided.
- 2.5. Accordingly, the Committee deliberated upon the same and recommended the retail price of FDCs of Dapagliflozin + Sitagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:
- 2.5.1 Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Sun Pharma Laboratories Limited (Manufacturer and Marketer) at Rs. 22.32 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amoun t (Rs.)
	Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per February, 2022 data)	18.28
(b)	50% of Patent Component		9.14
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee report		0.73
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		30.70
(h)	Claimed Retail price		22.32



S. No.	Particulars	Source/Method	t (Rs.)
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(j)	Recommended retail price	1.	22.32

2.5.2. Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/sAlkem Laboratories Limited (Manufacturer and Marketer) at Rs. 29.31 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amoun t (Rs.)
	Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release)		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per February, 2022 data)	18.28
(b)	50% of Patent Component		9.14
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(f)	Less 20% of the lower of (d) or (e) as recommended in the Pronab Sen Committee report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		29.31
(h)	Claimed Retail price		44.64
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA



S. No.	Particulars	Source/Method	Amount (Rs.)
(j)	Recommended retail price		29.31

2.5.3. Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg and Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Alkem Laboratories Limited (Manufacturer and Marketer) at Rs. 30.70 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amoun t (Rs.)
	Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release)		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per February, 2022 data)	18.28
(b)	50% of Patent Component		9.14
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per February, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(f)	Less 20% of the lower of (d) or (e) as recommended in the Pronab Sen Committee report		0.73
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		30.70
(h)	Claimed Retail price		46.42
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for February, 2022		NA
(j)	Recommended retail price		30.70

3. Agenda No. 3 - Retail price fixation under Para 5 of DPCO, 2013- Each Sachet Contains: Pantoprazole Sodium Eq. to Pantoprazole 40mg (Sodium



## File No.12(7)/2021/DP/NPPA/DIV.II(Vol.VI) Bicarbonate as buffer) for M/s Alkem Laboratories Ltd. (Manufacturer & Marketer).

- 3.1 The matter was deliberated in 45<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 and the retail price of Rs. 7.30 per tablet excluding GST calculated for Pantoprazole 40 mg tablet was extended to Sachet Containing Pantoprazole Sodium Eq. to Pantoprazole 40mg (Sodium Bicarbonate as buffer). This was done because the Committee was of the opinion that there is no variation in the route of administration between tablet and sachet and both the dosage form can be considered as similar for therapeutic point of view.
- 3.2 M/s Alkem Laboratories Limited represented vide letter dated 26.09.2022 and stated that their formulation is different from conventional tablet in view of low-RH area, micronized API, special equipment used for drying process of excipients, filling sealing and nitrogen purging in sachets, special packing materials benefits of pan insta technology etc.
- 3.3 The matter was also placed before the Authority in its 102<sup>nd</sup> meeting held on 27.09.2022 in which the Authority noted the representation of M/s Alkem Laboratories Ltd and decided that the matter be referred back to the Committee of Experts for examination of the representation.
- 3.4 Further, M/s Alkem Laboratories Itd also submitted letter dated 07.10.2022 vide its e-mail dated 08.10.2022 requesting for consideration of equivalence of pantoprazole sachet with Omeprazole Sachet and equivalence of Omeprazole Tab/Capsules with Pantoprazole Tab/Capsules for calculation of retail price.
- 3.5 M/s Alkem Laboratories Ltd gave a presentation before the committee through VC on their claim made vide representation dated 26.09.2022 & 08.10.2022 of their formulation.
- 3.6. Committee noted the presentation and agreed that the formulation Pantoprazole powder for oral suspension may be useful in patients who have difficulty in swallowing tablets like patients with dysphagia, oesophageal strictures, recent radiation or chemotherapy.
- 3.7. The Committee further noted that the formulation "Pantoprazole" and "Omeprazole" are of same therapeutic category and accordingly the retail price of Pantoprazole Sachet can be calculated based on the equivalent pricing structure/ drug contents/ dosage type and strength as that of Omeprazole. Therefore, the committee recommended the retail price of each Sachet Containing Pantoprazole Sodium Eq. to Pantoprazole 40mg (Sodium Bicarbonate as buffer) for M/s Alkem Laboratories Ltd. (Manufacturer & Marketer) as below:
  - a. Applicable Ceiling price of Omeprazole 20mg tablet as on November 2021 = Rs. 4.94 per tablet excluding GST [SO. 1330(E) dated 25.03.2021]
  - b. Applicable Ceiling price of Omeprazole Powder for oral suspension 20mg as on November 2021 = Rs. 6.15 per sachet containing 5gm of finished formulation excluding GST (Rs. 1.23 per gram excluding GST [SO. 1330(E) dated 25.03.2021])
  - c. Derived ratio of Omeprazole 20mg Tablet & 20mg powder for oral suspension (5gm)

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= Rs. 6.15 / Rs. 4.94 = 1.24

- d. Retail price of Pantoprazole 40mg tablet as per Pharmatrac database for the month of November 2021 = Rs. 7.30 per tablet
- e. Derived Retail Price of Pantoprazole 40mg Powder for Oral suspension (5gm of finished formulation) by applying ratio (as per point C) on the price as per point (d) above
- = Rs. 7.30 per tablet X 1.24 = Rs. 9.05 per sachet of 5gm finished formulation containing 40mg Pantoprazole excluding GST
- f. Retail Price claimed by the company = Rs. 44 per sachet of 5gm excluding GST
- g. Recommended Price of Pantoprazole 40mg for M/s Alkem Laboratories Ltd. (Manufacturer & Marketer): Lower of (e) & (f) above:
- = Rs. 9.05 per sachet of 5gm finished formulation containing 40mg Pantoprazole excluding GST
- 4. Agenda No. 4 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).
- 4.1 The matter was deliberated in 45<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 and retail price of Lidocaine 700mg patch was calculated by applying the ratio of Fentanyl Injection to Patches on Lidocaine Injection to patches. Committee recommended the retail price of each Adhesive Patch containing "Lidocaine 700mg in an aqueous base (50mg per gm adhesive) for M/s Hetero Healthcare Limited (Manufacturer and Marketer) at Rs 9.94 per patch excluding GST (being lower than the price claimed by the company at Rs. 44.64 per patch excluding GST).
- 4.2 M/s Hetero Healthcare Ltd made representation on the price recommended by the Committee vide letter dated 20.09.2022 and stated that patches cannot be considered at par with injection as both have different drug delivery system. The company further submitted the list of prices of fentanyl patches with MRP and the list of Lidocaine patches available in the market.
- 4.3 The matter was also placed before the Authority in its 102<sup>nd</sup> meeting held on 27.09.2022 in which the Authority noted the representation of M/s Hetero Healthcare Ltd and decided that the matter be referred to the Committee for examination of the representation.
- 4.4 M/s Hetero Healthcare Ltd made presentation in person before the Committee and also furnished the sample of Lidocaine Patch 350mg of another manufacturer available in the market. Company also stated that Lidocaine Patches are available in the market as claimed for other manufacturers also, but the same are not reflected in AWACS database due to low demand of the patches.
- 4.5 Committee noted the submission of the company and after deliberation decided that the claim of the company may be verified and retail prices may be calculated based on the market data of others manufacture/marketer companies.

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- 5. Agenda No. 5: Application by M/s Sachin Parenterals Ltd for Price approval of (i) Dextrose Injection IP (5% w/v) 250ml and (ii) Glucose 5% with sodium chloride 0.9% w/v 250ml having special features- Euro Head bottle.
- 5.1 The matter was deliberated in 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022 and recommended separate ceiling prices. The recommendation of MDC was placed in 102<sup>nd</sup> meeting of the Authority held on 27.09.2022 in which the Authority noted that the separate price as recommended for these IV fluids are not in line with the special ceiling price provided to other strength/pack size of IV fluids and decided that the matter be referred to the Committee for reexamination.
- 5.2 Committee noted the decision of the Authority and after deliberation decided that the detailed examination based on Authority's observation be placed in next meeting of the Multidisciplinary Committee of Experts.
- 6. Agenda No. 6: 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.
- 6.1 The matter was deliberated in 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022, wherein the committee recommended additional 15 percent price over the present applicable ceiling price of the formulation for incremental innovation of the packaging.
- 6.2 M/s Gufic Biosciences Ltd made representation on the recommendation made by the Multidisciplinary Committee of Experts vide letter dated 23.09.2022. The matter was also placed before the Authority in its 102<sup>nd</sup> meeting held on 27.09.2022 in which the Authority decided that the representation of the company be referred to the Committee for examination.
- 6.3 Committee noted the representation of the company and after deliberation decided that the company may be asked to submit the additional literature to substantiate their claim and also to make presentation in the next meeting of the committee.
- 7. Agenda No. 7: Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg and Bempedoic Acid 180mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Limited (marketer).
- 7.1 The committee observed that the therapeutic category/use of formulation claimed by the applicant "For short term treatment of moderate pain" is not correct. Further, it is also observed that Cardiovascular medicines is stated in size of packs. Therefore, Committee noted that the therapeutic category of the formulation is Lipid Lowering Agent.
- 7.2 The committee recommended the retail price of Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg and Bempedoic Acid 180mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Zydus Healthcare Limited (marketer) as below:



S. No	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg and Bempedoic Acid 180mg		
(a)	Derived retail price of Atorvastatin 80 mg tablet	Retail price (as per the formula of Pranob Sen Committee) – Note 1	34.81
(b)	Derived retail price of Bempedoic Acid 180 mg tablet	Retail Price [as per Pharmatrac data for the period from June, 2021 to May, 2022 as no data is available in Pharmatrac database for the months prior to 6 months before the date of application and Pharmatrac database used is for the month of September, 2022]	19.88
c)	Total (a) + (b)		54.69
d)	Less 20% of the lower of (a) or (b) as recommended in the Pronab Sen Committee report		3.98
e)	Worked out Retail Price (c)-(d)		50.71
f)	Claimed Retail price		98.00
g)	Recommended retail price		50.71

Note 1:

Derived retail price as per recommendation of Pronab Sen committee:

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

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

 $P^*$  = price ceiling for reference strength  $s^*$ 

s = strength in terms of API content

s\* = reference strength

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

- a) Ceiling price of Atorvastatin 40 mg tablet as on March, 2022 = Rs. 19.34 per tablet excluding GST [S.O. No. 1330(E) dated 25.03.2021]
- b) Derived price of Atorvastatin 80mg tablet after applying the formula of Pronab Sen Committee on the price as per (a) above
- = 19.34[1+0.80{80-40/40] = Rs.34.81 per tablet excluding GST
- Agenda No. 8: Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg 8. and Bempedoic Acid 180mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Sun Pharma Laboratories Limited (marketer).
- 8.1 The committee recommended the retail price of Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg and Bempedoic Acid 180mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Sun Pharma Laboratories Limited (marketer) as below:

S. No	Particulars	Source / Method	Amount (Rs.)
	Each film coated tablet containing Atorvastatin Calcium IP eq. to Atorvastatin 80mg and		SA <sub>ER</sub>
(a)	Derived retail price of Atorvastatin 80 mg tablet	Retail price (as per the formula of Pranob Sen Committee) – Note 1	34.81
(b)	Derived retail price of Bempedoic Acid 180 mg tablet	Retail Price [as per Pharmatrac data for the period from June, 2021 to May, 2022 as no data is available in Pharmatrac database for the months prior to 6 months before the date of application and Pharmatrac database used is for the month of September, 2022]	
(c)	Total (a) + (b)		54.69
(d)	Less 20% of the lower of (a) or (b) as recommended in the Pronab Sen Committee report		3.98
(e)	Worked out Retail Price (c)-(d)		50.71
(f)	Claimed Retail price		53.57
(g)	Recommended retail price	· / 2	50.71

Note 1:

Derived retail price as per recommendation of Pronab Sen committee:



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

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

P\* = price ceiling for reference strength s\*

s = strength in terms of API content

s\* = reference strength

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

- a) Ceiling price of Atorvastatin 40 mg tablet as on March, 2022 = Rs. 19.34 per tablet excluding GST [S.O. No. 1330(E) dated 25.03.2021]
- b) Derived price of Atorvastatin 80mg tablet after applying the formula of Pronab Sen Committee on the price as per (a) above
- = 19.34[1+0.80{80-40/40] = Rs.34.81 per tablet excluding GST
- 9. Agenda No. 9: Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 5mg for M/s Micro Labs Limited (manufacturer and marketer).
- **9.1** The committee recommended the retail price of Each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 5mg for M/s Micro Labs Limited (manufacturer and marketer) as below:

S. No	Particulars	Source / Method	Amount (Rs.)
	Each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 5mg		
(a)	Telmisartan IR 40 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	6.61
(b)	Derived retail price of Bisoprolol Fumarate IP 5mg tablet	Retail price (as per March, 2022 data)	6.50
(c)	Total (a) + (b)		13.11
(d)	Less 20% of the lower of (a) or (b) as recommended in the Pronab Sen Committee report		1.30
(e)	Worked out Retail Price (c)-(d)		11.81
(g)	Claimed Retail price		19.64
(i)	Recommended retail price		11.81



### HIIE NO.12(7)/2021/DP/NPPA/DIV.II(VOI.VI)

- 10. Agenda No. 10: 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".
- 10.1 The committee noted that the matter was deliberated in 44<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 04.08.2022, wherein it recommended as follows:
  - 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."
- 10.2 Committee also noted the representation of M/s Zydus Healthcare Ltd received vide e-mail dated 23.08.2022 and representation of M/s Intas Pharmaceuticals Ltd dated 07.09.2022.
- 10.3 Committee deliberated on the matter in view of representations received and reiterated its decision taken in 44<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 04.08.2022 as mentioned above.

The meeting ended with a vote of thanks to all.

(Rashmi Tahiliani) Jt. Director (Pricing)

Copy to:

All members of the Committee.

Each film coated bilayered tablet containing Sitagliptin 50 mg	Number of Companies consisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation (in Lakhs)	7,728.31
	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
	96 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

								7728,31,152	1009	6		M3	
s.No.	पेक विकास Pack Description	BRAND	soft Company	Strength	Pack Size	Unit	PTR	MAT(Rs)	SKU wise MAT %	(ignorin	Y/N)		Price per unit (Rs.) Considered
1	ISTAVEL SO MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	50 MG	7	TABLET	206.43	214132523	27.71%	27.71%	Y	29.49	29.49
2	JANUMA 50 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	1	TABLET	207.14	558698629	72.29%	72.29%	Y	29.59	29.59
		Rs. Per Tablet			1			1		1			
	Worked out Retail Price	34.2	7 Excluding GST	1	-					1			

Computation of Retail Price based on February, 2022 Data under Para S of DPCO, 2013  ach film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50 mg + Metformin Hydrochioride IP 500 mg	Number of Companies consisting of Market Share of 1% & Above	21
Each test councy consuming, stealphore, i residuants accountable on a realizable to a realizable to the constitution of the co	Sum of MAT value considered for price calculation (in Lakhs)	45,971.08
	Sum of PTR per unit considered for price calculation	38,59
	Number of Packs considered	2
	Average PTR	19.30
	Add: 16% Retailer Margin	3.09
	Retail Price (without local taxes)	22.39
	% 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

								45971,08,381	1009			M3	
S.No.	देश विकास Pack Description	BRAND	toni Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	SKU wise MAT %		Qualify ( Y/N) Y=Yes N=No	10000	Price per unit (Rs.) Considered
1	ISTAMET SO/SOOMG TABLET 15	ISTAMET	SUN PHARMA LABORATORIES LTD.	50/500 MG	15	TABLET	289.51	1788618456	38.91%	38.91%	Y	19.30	19.30
2	JANUMET 50/500 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/500 MG	15	TABLET	289.29	2808489926	61.09%	61.09%	Y	19.29	19.29
		Rs. Per Tablet											2
-	Worked out Retail Price	2	2.39 Excluding GST			Test said	and the same of						7

Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin S0 mg + Metformin Hydrochloride IP 1000 mg	Number of Companie
	Sum of MAT value co

Number of Companies consisting of Market Share of 1% & Above	2
Sum of MAT value considered for price calculation (in Lakhs)	21,328.23
Sum of PTR per unit considered for price calculation	39.59
Number of Packs considered	2
Average PTR	19.80
Add: 16% Retailer Margin	3.17
Retail Price (without local taxes)	22.97
% 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

								21328,22,823	100%	10		M3	A second second second
S.No.	रेक किराण Pack Description	BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	SKU wise MAT %	E-17 S 54 S 24 S 45 S		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	297.44	575890473	27.00%	27.00%	У	19.83	19.83
2	JANUMET 50/1000 MG TABLET 15	JANUMET	MSD PHARMACEUTICALS PRIVATE LTD.	50/1000 MG	15	TABLET	296,43	1556932350	73.00%	73.00%	Y	19.76	19.76
		Rs. Per Tablet											-
	Worked out Retail Price	22.9	77 Excluding GST										1

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

								17987,13,303	1009	6		M3	
S.No.	रेक विकास Pack Description	BRAND	ert Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	SKU wise MAT %	A CONTRACTOR OF THE PARTY OF TH	Qualify ( Y/N) Y=Yes N=No		Price per unit (Rs.) Considered
1	ISTAVEL 100 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	100 MG	7	TABLET	225.00	440668575	24.50%	24.50%	Y	32.14	32.14
2	JANUVIA 100 MG TABLET 15	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	15	TABLET	481.57	147306003	8.19%	75.50%	Y	32.10	32.10
3	JANUVIA 100 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	7	TABLET	225.00	1210738725	67.31%	75.50%	Y	32.14	32.14
					do escentia de la composición dela composición de la composición de la composición de la composición dela composición de la composición de la composición dela composición dela composición de la composición de la composición de la composición dela composi								
		Rs. Per Tablet		-	-				Land to the same	-	-	-	-
-	Worked out Retail Price	37.2	7 Excluding GST		-								

Each film coated bilayered tablet containing Sitagliptin 50 mg	Number of Companies consisting of Market Share of 1% & Above	
	Sum of MAT value considered for price calculation (in Lakhs)	7,728.3
	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%

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

								7728,31,152	1009			M3	
S.No.	पेक विश्वल Pack Description	255	कार्ग Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	SKU wise MAT %	Brandwi se MAT (Ignorin g 0% MAT)	Qualify ( Y/N) Y=Yes N=No		Price per unit (Rs.) Considered
1	ISTAVEL SO MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	50 MG	7	TABLET	206.43	214132523	27.71%	27.71%	Y	29.49	29.49
2	IANUVIA SO MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	7	TABLET	207.14	558698629	72.29%	72.29%	Y	29.59	29.59
		Rs. Per Tablet											
-	Worked out Retail Price	34.27	Excluding GST		1			1					

0.0	Number of Companies consisting of Market Share of 1% & Above	2
	Sum of MAT value considered for price calculation (in Lakhs)	17,987.13
Each film coated tablet containing Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg	Sum of PTR per unit considered for price calculation	96.38
	Number of Packs considered	3
	Average PTR	32.13
	Add: 16% Retailer Margin	5.14
	Retail Price (without local taxes)	37.27
	% 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

								17987,13,303	1009	6		M3	
S.No.	चेत्र विचला Pack Description	BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	SKU wise MAT %	Brandwi se MAT (ignorin g 0% MAT)	Qualify ( Y/N) Y=Yes N=No		Price per unit (Rs.) Considered
1	ISTAVEL 100 MG TABLET 7	ISTAVEL	SUN PHARMA LABORATORIES LTD.	100 MG	7	TABLET	225.00	440668575	24.50%	24.50%	Y	32.14	32.14
2	JANUVIA 100 MG TABLET 15	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	15	TABLET	481.57	147306003	8.19%	75.50%	Y	32.10	32.10
3	JANUVIA 100 MG TABLET 7	ANUMAL	MSD PHARMACEUTICALS PRIVATE LTD.	100 MG	7	TABLET	225.00	1210738725	67.31%	75.50%	Y	32.14	32.14
		Rs Per Tablet			1-					-		Harmon W.	
	Worked out Retail Price		7.27 Excluding GST							-			

	Number of Companies consisting of Market Share of 1% & Above	14
	Sum of MAT value considered for price calculation (in Lakhs)	41,532.12
Each film coated tablet containing Depagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	Sum of PTR per unit considered for price calculation	252.17
Name of the second seco	Number of Packs considered	16
	Average PTR	15.76
	Add: 16% Retailer Margin	2.52
	Retail Price (without local taxes)	18.28
	96 Reduction with compared to Highest Price	61 5284

Minimum Price (Rs.)	7.74
Maximum Price (Rs.)	40.96
Average of all considered (Rs.)	15.76
Retail Price (Rs.)	18.28

								45664,83,474	1009	6		M3	
No.	the freew Pack Description	BRAND	tout Company	Strength	Pack Size	Unit	PTR	MAT(Rs.)	MAT %	Brandwi se MAT (ignorin g O% MAT)	Y/N)	Price per unit (Rs.)	Price per unit (Rs.) Considered
1	4 DAPA 10 MG TABLET 10	4 DAPA	4 CARE LIFESCIENCE PVT LTD	10 MG	10	TABLET	85.00	516545	0.01%	0.01%	N	8.50	
2	BIOXIGA 10 MG TABLET 10	BIOXIGA	BIOS LAB PVT.LTD	10 MG	10	TABLET	102.85	380160	0.01%	0.01%	N	10.29	
3	DAGUPACK 10 MG TABLET 10	DAGUPACK	KOYE PHARMACEUTICALS PVT, LTD.	10 MG	10	TABLET	99.29	3641659	0.08%	0.08%	N	9.93	
4	DARIO 10 MG TABLET 15	OILAG	MICRO LABS LTD	10 MG	15	TABLET	126.43	34826534	0.76%	0.76%	N	8.43	
5	DAMITA 10 MG TABLET 10	DAMITA	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	101.43	84620716	1.85%	1.85%	Y	10.14	10.14
6	DAPA GOLD 10 MG TABLET 15	DAPA GOLD	HBC LIFESCIENCES PVT LTD	10 MG	15	TABLET	150.00	11787298	0.26%	0.26%	N	10.00	
7	DAPABEST 10 MG TABLET 10	DAPABEST	PANACEA BIOTEC LTD	10 MG	10	TABLET	100.00	10531800	0.23%	0.23%	N	10.00	
8	DAPABITE 10 MG TABLET 10	DAPABITE	CORONA	10 MG	10	TABLET	106.43	94335933	2.07%	2.07%	Y	10.64	10.64
9	DAPABLIS 10 MG TABLET 10	DAPABUS	MED MANOR ORGANICS PVT LTD.	10 MG	10	TABLET	82.14	203214	0.00%	0.00%	N	8.21	5,4100.3
10	DAPACARE 10 MG TABLET 10	DAPACARE	OCTALIFE PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	78.57	446906	0.01%	0.01%	N	7.86	
11	DAPACONIC 10 MG TABLET 15	DAPACONIC	LA RENON	10 MG	15	TABLET	181.07	1991408	0.04%	0.04%	N	12.07	
12	DAPACOSE 10 MG TABLET 10	DAPACOSE	JB CHEMICALS	10 MG	10	TABLET	85.72	26433476	0.58%	0.58%	N	8.57	
13	DAPADEL 10 MG TABLET 10	DAPADEL	CADEUL HEALTH CARE PVT.LTD	10 MG	10	TABLET	106.43	3782522	0.08%	0.08%	N	10.64	
14	DAPAEASE 10 MG TABLET 10	DAPAEASE	JUBILANT GENERICS LIMITED	10 MG	10	TABLET	103.57	779364	0.02%	0.02%	N	10.36	
15	DAPAGAIN 10 MG TABLET 15	DAPAGAIN	SYSTOPIC LABORATORIES LTD-MEM	10 MG	15	TABLET	63.22	4215510	0.09%	0.09%	N	4.21	
16	DAPAGLYN 10 MG TABLET 15	DAPAGLYN	ZYDUS CADILA - ZHL	10 MG	15	TABLET	200.36	244538767	5.36%	5.36%	Y	13.36	13.36
17	DAPAGREAT 10 MG TABLET 15	DAPAGREAT	SINSAN PHARMACEUTICALS	10 MG	15	TABLET	142.14	6791876	0.15%	0.15%	N	9.48	
18	DAPAHENZ 10 MG TABLET 15	DAPAHENZ	LA RENON	10 MG	15	TABLET	181.07	4857203	0.11%	0.11%	N.	12.07	
19	DAPAKEY 10 MG TABLET 10	DAPAKEY	PRECIA PHARMA	10 MG	10	TABLET	103.57	6854263	0.15%	0.15%	N	10.36	
20	DAPALEX 10 MG TABLET 10	DAPALEX	AJANTA PHARMA LTD	10 MG	10	TABLET	110.71	33970448	0.74%	0.74%	N	11.07	
21	DAPAMAC 10 MG TABLET 10	DAPAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	101.43	133375277	2.92%	2.92%	Y	10.14	10.14
22	DAPANORM 10 MG TABLET 10	DAPANORM	ALKEM LABORATORIES LTD.	10 MG	10	TABLET	125.00	175967875	3.85%	3.85%	Y	12.50	12.50
23	DAPANOVA 10 MG TABLET 15	DAPANOVA	MEDLEY PHARMACEUTICALS	10 MG	15	TABLET	128.57	39512261	0.87%	0.87%	N	8.57	
24	DAPAONE 10 MG TABLET 10	DAPAONE	MSN LABORATORIES LTD	10 MG	10	TABLET	107.14	24719662	0.54%	0.54%	N	10.71	
25	DAPARAY 10 MG TABLET 10	DAPARAY	ICON LIFESCIENCES	10 MG	10	TABLET	69,64	738671	0.02%	0.02%	N	6.96	
26	DAPARYL 10 MG TABLET 10	DAPARYL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	169923043	3.72%	3.72%	Y	9.29	9.29
27	DAPASIS 10 MG TABLET 10	DAPASIS	AKESISS PHARMA (P) LTD	10 MG	10	TABLET	99.29	5990464	0.13%	0.13%	N	9.93	
28	DAPASPEC 10 MG TABLET 10	DAPASPEC	SPECTRA THERAPEUTICS PVT. LTD.	10 MG	10	TABLET	96.43	1376419	0.03%	0.03%	N	9.64	
29	DAPATEN 10 MG TABLET 15	DAPATEN	BAL PHARMA	10 MG	15	TABLET	117.54	78399	0.00%	0.00%	N	7.84	
30	DAPATRENO 10 MG TABLET 14	DAPATREND	ANTHEM BIOPHARMA PVT LTD	10 MG	14	TABLET	165.00	5398965	0.12%	0.12%	N	11.79	
31		DAPATURN	· LUPIN LTD	10 MG	10	TABLET	103.57	16091878	0.35%	0.35%	N	10.36	
32		DAPAVEL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	214524938	4.70%	4.70%	Y	9.29	9.29
33		DAPAYES	ANAX LIFE SCIENCES PVT_LTD	10 MG	10	TABLET	103.57	54685	0.00%	0.00%	N	10.36	

34	DAPAZOL 10 MG TABLET 10	DAPAZOL	ALTEUS BIOGENICS PVT.LTD.	10 MG	10	TABLET	96.43	439757	0.01%	0.01%	N	9.64	
35	DAPEFY 10 MG TABLET 14	DAPETY	SUN PHARMA LABORATORIES LTD	10 MG	14	TABLET	250.00	7324250	0.16%	016%	N	17.86	
36	DAPGUN 10 MG TABLET 10	DAPGUN	VASU ORGANICS PVT.LTD	10 MG	10	TABLET	83,57	31589	0.00%	0.00%	N	8.36	
37	DAPIXA 10 MG TABLET 10	DAPIXA	TAS MED (INDIA) PRIVATE LTD.	10 MG	10	TABLET	100.00	421200	0.01%	0.01%	N	10.00	
38	DAPLO 10 MG TABLET 10	DAPLO	OR REDDYS LABORATORIES LTD	10 MG	10	TABLET	107.14	67224779	1.47%	1.47%	Y	10.71	10,71
39	DAPNAT 10 MG TABLET 30	DAPNAT	NATCO PHARMA LTD	10 MG	30	TABLET	417.86	16425659	0.36%	0.36%	N	13.93	4,000
40	DAPRICA 10 MG TABLET 10	DAPRICA	APRICA HEALTHCARE PVT LTD	10 MG	10	TABLET	103.57	11520091	0.25%	0.25%	N	10.36	
41	DAXIGA 10 MG TABLET 10	DAXIGA	ACMEDIX PHARMA LLP	10 MG	10	TABLET	49.29	4269706	0.09%	0.09%	N	4.93	
42	DEPAJA 10 MG TABLET 10	DEPAIA	INDOCO REMEDIES LTD	10 MG	10	TABLET	82.14	4296251	0.09%	0.09%	N	8.21	
43	DEXIGLU 1D MG TABLET 10	DEXIGLU	FUSION HEALTHCARE PVT LTD	10 MG	10	TABLET	103.57	7781007	0.17%	0.17%	N	10.36	
44	DGSON 10 MG TABLET 10	DGSON	UNISON PHARMACEUTICALS	10 MG	10	TABLET	32.14	1698117	0.04%	0.04%	N	3.21	
45	DIABFLOZ 10 MG TABLET 10	DIABRIOZ	FINECURE PHARMACEUTICALS	10 MG	10	TABLET	82.14	3562576	0.08%	0.08%	N	821	
46	DIABIZ (BLUE) 10 MG TABLET 15	DIABIZ (BLUE)	BLUE CROSS LABORATORIES LTD	10 MG	15	TABLET	75.00	1450200	0.03%	0.03%	N	5.00	
47	DIFLUP 10 MG TABLET 10	DIFLUP	EXELTIS	10 MG	10	TABLET	110.71	15721	0.00%	0.00%	N	11.07	
48	DIFOZIN 10 MG TABLET 14	DIFCZIN	LINCOLN PHARMACEUTICALS LTD	10 MG	14	TABLET	149.29	89873	0.00%	0.00%	N	10.66	
49	DINECA 10 MG TABLET 14	DINECA	APOSTLE REMEDIES	10 MG	14	TABLET	100.00	137200	0.00%	0.00%	N	7.14	
50	DIOSGLT 10 MG TABLET 13	DIOSGLT	DIOS LIFESCIENCES PRIVATE LIMITED	10 MG	15	TABLET	133.93	374334	0.01%	0.01%	N	8.93	
51	DIUTEN 10 MG TABLET 10	DIUTEN	WOCKHARDT LTD	10 MG	10	TABLET	103.57	4661	0.00%	0.00%	N	10.36	
52	DPO 10 MG TABLET 10	DPO	RPG LIFE SCIENCES LTD.	10 MG	10	TABLET	85,71	74996	0.00%	0.00%	N	8.57	
53	ELDAPA 10 MG TABLET 10	ELDAPA	EL-DORADO BIO-TECH PVT LTD	10 MG	10	TABLET	71.43	96503	0.00%	0.00%	N	7.14	7.5
54	ESGEDAP 10 MG TABLET 14	ESGEDAP	EAST WEST PHARMA	10 MG	14	TABLET	145.00	331470	0.01%	0.01%	N	10.36	
55	FLOZIMAX 10 MG TABLET 15	FLOZIMAX	ALNIGHE LIFE SCIENCES PVT LTD	10 MG	15	TABLET	139.29	1211823	0.03%	0.03%	N	9.29	
56.	FORKIGA 10 MG TABLET 14	FORXIGA	ASTRAZENECA PHARMA INDIA LTD	10 MG	14	TABLET	573.50	1125311951	24.64%	24.64%	Y	40.96	40.96
57	GLEDEPA 10 MG TABLET 14	GLEDEPA	ABBOTT HEALTHCARE PVT, LTD	10 MG	14	TABLET	573.50	96380116	2.11%	2.11%	Y	40.96	40,96
58	GUFOPRIME 10 MG TABLET 10	GLIFOPRIME	PRIMUS REMEDIES PVT LTD	10 MG	10	TABLET	103.57	2468073	0.05%	0.05%	N	10.36	40.70
59	GLUCRETA 10 MG TABLET 10	GLUCRETA	TORRENT PHARMACEUTICALS LTD.	10 MG	10	TABLET	81.21	122838272	2.69%	2.69%	Y	8.12	8.12
60	GLUFLOZIN 10 MG TABLET 15	GLUFLOZIN	ARISTO PHARMACEUTICALS PVT.LTD	10 MG	15	TABLET	107.14	14332118	0.31%	0.31%	N	7.14	V.A.
61	GLUXIT 10 MG TABLET 10	GLUXIT	ERIS UFESCIENCES LTD	10 MG	10	TABLET	103.57	266500835	5.84%	5.84%	Y	10.36	10.36
62	AODAPA 10 MG TABLET 15	JODAPA	JARUN PHARMACEUTICALS	10 MG	15	TABLET	107.14	1110185	0.02%	0.02%	N	7.14	4.0.00
63	JUSTOZA 10 MG TABLET 10	JUSTOZA	MANKIND PHARMACEUTICALS LTD.	10 MG	10	TABLET	70.71	25224590	0.55%	0.55%	N	7.07	
64	MDAPA 10 10 MG TABLET 10	MDAPA 10	SINSAN PHARMACEUTICALS	10 MG	10	TABLET	96.43	1564191	0.03%	0.03%	N	9.64	
65	MDAPA 10 10 MG TABLET 15	MDAPA 10	SINSAN PHARMACEUTICALS	10 MG	15	TABLET	96.43	84087	0.00%	0.00%	N	6.43	
66	MYODA 10 MG TABLET 10	MYDDA	ERIS LIFESCIENCES LTD	10 MG	10	TABLET	103.57	9103389	0.20%	0.20%	N	10.36	
67	OPSICA 10 MG TABLET 15	OPSICA	OPSISCARE UFESCIENCSE PVT LTD	10 MG	15	TABLET	150.00	1411650	0.03%	0.03%	N	10.00	
68	OKRA 10 MG TABLET 14	OXRA	SUN PHARMA LABORATORIES LTD.	10 MG	14	TABLET	573.50	904118162	19.80%	19.80%	Y	40.96	40.96
69	SINXIGA 10 10 MG TABLET 10	SINXIGA 10	SINSAN PHARMACEUTICALS	10 MG	10	TABLET	96.43	64705	0.00%	0.00%	N	9.64	49,76
70	SUGAFLO 10 MG TABLET 15	SUGAFLO	LLOYD HEALTHCARE PVT_LTD	10 MG	15	TABLET	160.72	10033589	0.22%	0.22%	N	10.71	
71	SWITDAPA 10 MG TABLET 10	SWITDAPA	AKUMENTIS HEALTHCARE LTD	10 MG	10	TABLET	85.00	1517760	0.03%	0.03%	N	8.50	
72	T2C 10 MG TABLET 15	T2C	IPCA LABORATORIES PVT LTD.	10 MG	15	TABLET	182.14	14036255	0.31%	0.31%	N	12.14	
73	UDAPA 10 MG TABLET 10	UDAPA	USV PVT LTD	10 MG	10	TABLET	85.71	300049925	6.57%	6.57%	Y	8.57	8.57
74	VIVADAPA 10 MG TABLET 10	VIVADAPA	MITOCH PHARMA PVT LTD	10 MG	10	TABLET	100.00	8954100	0.20%	0.20%	N	10.00	9.37
75	VOAGE 10 MG TABLET 10	VOAGE	ALEMBIC LTD	10 MG	10	TABLET	77,43	73423812	1.61%	1.61%	Y	7.74	7.74
76	XGLET 10 MG TABLET 10	XGLET	ELINOR PHARMA	10 MG	10	TABLET	140.00	105560	0.00%	0.00%	N	14.00	7.09
77	ZANELLA 10 MG TABLET 10	ZANELLA	CADOMED PHARMACEUTICALS INDIA PVT.LTD	10 MG	10	TABLET	79.07	1364590	0.03%	0.03%	N	7.91	
78	ZINODAP 10 MG TABLET 10	ZINODAP	WOCKHARDT LTD	10 MG	10	TABLET	103.57	14368059	0.31%	0.31%	N	10.36	
79	ZUCAPRIDE 10 MG TABLET 15	ZUCAPRIDE	MICRO LABS LTD	10 MG	15	TABLET	126.43	80077601	1.75%	1.75%	Y	8.43	8.43
							1	777774	427.00	1.7.7.0		0.40	0.13
		Rs. Per Tablet	Name of the second seco								l-sub-		
					1			A CONTRACTOR OF THE PARTY OF TH					
	Worked out Retail Price	18	28 Excluding GST										

omputation of Retail Price based on May, 2022 Data under Para 5 of DPCD, 2013 ach film coated tablet containing Bempedoic Acid 180mg	Number of Companies cosisting of Market Share of 1% & Above	
ICH HILL FRATER FRANKE POLITABLIA DELL'ARCHITE LICENTE PROFILE	Sum of MAT value considered for price calculation (in Lakhs)	
	Sum of PTR per unit considered for price calculation	51.42
	Number of Packs considered	3
	Average PTR	17.14
	Add : 16% Retailer Margin	2.74
	Retail Price (without local taxes)	19.88
	% Reduction with compared to Highest Price	0.00%

Minimum Price (Rs.)	17.14
Maximum Price (Rs.)	17.14
Average of all considered (Rs.)	17.14
Retail Price (Rs.)	19.88

							TOTAL MAT	8,96,407	1009	6		M3	
S.No.	रैंक 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
	1 BEMDAC 180 MG TABLET 10	BEMDAC	ZYDUS CADILA - ZHL	180 MG	10	TABLET	171.43	427032.13	47.64%	47.64%	Y	17.14	17.14
	2 BEMPESTA 180 MG TABLET 10	BEMPESTA	TORRENT PHARMACEUTICALS LTD.	180 MG	10	TABLET	171.43	323145.55	36,05%	36,05%	Y	17.14	17,14
	3 BRILLO 180 MG TABLET 10	BRILLO	SUN PHARMA LABORATORIES LTD.	180 MG	10	TABLET	171.43	146229.79	16.31%	16.31%	Y	17.14	17.14
												-	-
		Rs. Per Tablet			+	-							
	Worked out Retail Price	19.88	Excluding GST										

Each film coated tablet containing Bisoprolol Furnarate IP Smg	Number of Companies cosisting of Market Share of 1% & Above	
***************************************	Sum of MAT value considered for price calculation (in Lakhs)	10,579.98
	Sum of PTR per unit considered for price calculation	33.61
	Number of Packs considered	6
	Average PTR	5.60
	Add: 16% Retailer Margin	0.90
	Retail Price (without local taxes)	6.50
	% Reduction with compared to Highest Price	26.02%

Minimum Price (Rs.)	3.04
Maximum Price (Rs.)	7.57
Average of all considered (Rs.)	5.60
Retail Price (Rs.)	6.5

							TOTAL MAT	10862,49,059	100%	-		M3	
0.	पैक विवरण	ख्यप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis		Price	Price per Unit
	Pack Description	BRAND	Company						MAT %	e MAT (ignoring O% MAT)	Y/N) Y=Yes N=No	per Unit (Rs.)	(Rs.) Considered
1	ACBISO 5 MG TABLET 10	ACBISO	ACMEDIX PHARMA LLP	5 MG	10	TABLET	20.71	63890.35	0.01%	0.01%	N	2.07	
- 2	BESICOR 5 MG TABLET 10	BESICOR	AJANTA PHARMA LTD	5 MG	10	TABLET	48.21	3519281.79	0.32%	0.41%	N	4.82	
-	BESICOR 5 MG TABLET 15	BESICOR	AJANTA PHARMA LTD	5 MG	15	TABLET	78.57	1030602.69	0.09%	0:41%	N	5.24	
-	BIBETA S MG TABLET 10	BIBETA	OPSISCARE LIFESCIENCSE PVT LTD	5 MG	10	TABLET	42.86	383639.86	0.04%	0.04%	N	4.29	
-	BISELECT S MG TABLET 10	BISELECT	INTAS PHARMACEUTICALS LTD	5 MG	10	TABLET	30.36	12183092.16	1,12%	1.12%	Y	3.04	3,04
-	BISOACE 5 MG TABLET 10	BISOACE	MOREPEN LABORATORIES LIMITED	5 MG	10	TABLET	8.77	14812.53	0.00%	0.00%	N	0.88	
	BISOBIS 5 MG TABLET 10	BISOBIS	CORONA	5 MG	10	TABLET	28.57	476661.88	0.04%	0.04%	N	2.86	
-	BISOHEART S MG TABLET 10	BISOHEART	MANKIND PHARMACEUTICALS LTD.	5 MG	10	TABLET	56.89	77802764	7.16%	7.16%	Y	5.69	5.69
-	BISOLONG 5 MG TABLET 10	BISOLONG	MICRO LABS LTD	5 MG	10	TABLET	46.43	3353824.62	0.31%	0.31%	N	4.64	
10	BISONEXT 5 MG TABLET 15	BISONEXT	LUPIN LTD	5 MG	15	TABLET	93.29	33627352.32	3,10%	3,10%	Y	6.22	6.22
-	BISOSAFE 5 MG TABLET 10	BISOSAFE	ABBOTT HEALTHCARE PVT. LTD	5 MG	10	TABLET	55	7150110	0.66%	0.66%	N	5.50	
1	BISOTAB 5 MG TABLET 10	BISOTAB	JB CHEMICALS	5 MG	10	TABLET	66.92	22401989.56	2.06%	2.06%	Y	6.69	6.69
1	3 BISVEDA 5 MG TABLET 10	BISVEDA	KEPLER HEALTH CARE	5 MG	10	TABLET	47.54	2514485.68	0.23%	0.23%	N	4.75	
_	4 BIZO 5 MG TABLET 10	BIZO	SPECTRA THERAPEUTICS PVT. LTD.	5 MG	10	TABLET	35.72	500901.56	0.05%	0.05%	N	3.57	
1	5 CONCOR S MG TABLET 10	CONCOR	MERCX SPECIALITIES PVT.LTD	5 MG	10	TABLET	75.68	781332862.2	71,93%	71.93%	Y	7.57	7.57
1	6 CONCOVAS 5 MG TABLET 10	CONCOVAS	VASU ORGANICS PVT_LTD	5 MG	10	TABLET	56.57	2489.08	0.00%	0.00%	N	5,66	
1	7 CORBIS 5 MG TABLET 15	CORBIS	TORRENT PHARMACEUTICALS LTD.	5 MG	15	TABLET	66.07	130650150.8	12.03%	12.03%	Y	4.40	4.40
1	8 ZABESTA 5 MG TABLET 10	ZABESTA	USV PVT LTD	5 MG	10	TABLET	49.43	9240147.62	0.85%	0.85%	N.	4.94	
_						P. C. S. C.		1.75	er j				
		Rs. Per Tablet							-	-	-	-	-
_	Worked out Retail Price	6.	50 Excluding GST		1 11 11 11 11								