

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

Subject: Minutes of the 47th meeting of the Multidisciplinary Committee of Experts held on 02.12.2022 at 11:30 AM.

47th meeting of the "Multidisciplinary Committee of Experts" was held on 02.12.2022 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
3. 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

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
2. Shri Mahaveer Saini, Deputy Director (Pricing), NPPA
3. Ms. Yuvika Panwar, Assistant Director (Overcharging), NPPA
4. Sh. Shashi Bhushan represented Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member through video conferencing

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 two applications have been received for retail price fixation of two Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin 500 mg tablet and (ii) Sitagliptin 50 mg + Metformin 1000 mg 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 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:

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“....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, 45th and 46th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022, 13.09.2022 and 19.10.2022 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, 102nd meeting dated 27.09.2022 and 103rd meeting dated 10.11.2022 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 tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Pure & Cure Healthcare Private Limited (Manufacturer) and M/s Natco Pharma Limited (Marketer) at Rs. 12.45 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per April, 2022 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1499(E) dated	1.67

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S. No.	Particulars	Source / Method	Amount (Rs.)
		30.03.2022]	
(d)	Retail Price		18.80
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.33
(f)	Worked out Retail Price (d)-(e)		18.47
(g)	Claimed Retail price		12.45
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for April, 2022		22.39
(i)	Recommended retail price		12.45

1.4.2 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Pure & Cure Healthcare Private Limited (Manufacturer) and M/s Natco Pharma Limited (Marketer) at Rs. 13.25 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Meth hod	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per April, 2022 data)	34.27
(b)	50% of (a)		17.13
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.00
(d)	Retail Price		21.13
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.80
(f)	Worked out Retail Price (d)-(e)		20.33

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S. No.	Particulars	Source/Metho	Amount (Rs.)
(g)	Claimed Retail price		13.25
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet' as per Pharmatrac Data for April, 2022		22.97
(i)	Recommended retail price		13.25

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

2.1. The Committee noted that 26 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 in October, 2020 and 5th/6th July, 2022 respectively.

2.2. In this connection, it is mentioned that the Authority in its 96th meeting dated 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

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per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed."

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

2.3. The Committee also noted the decision taken in its 41st, 42nd, 43rd, 44th, 45th and 46th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022, 13.09.2022 and 19.10.2022 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, 102nd meeting dated 27.09.2022 and 103rd meeting dated 10.11.2022 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 calculated 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 (b) and (d)]. From the total, a reduction of 20% of the lower of three component [termed as (b), (d) and (e)] 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 IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s USV Private Limited (Marketer) at Rs. 26.78 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 2022 data)	37.27

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S. No.	Particulars	Source/Method	Amount (Rs.)
(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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		26.78
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		26.78

2.5.2. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s USV Private Limited (Marketer) at Rs. 28.57 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated	3.66

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S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(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)		30.11
(h)	Claimed Retail price		28.57
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		28.57

2.5.3. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Emcure Pharmaceuticals Limited (Marketer) at Rs. 22.90 per tablet excluding GST as detailed below:

S. No.	Particulars	Source / Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as		0.38

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S. No.	Particulars	Source / Method	Amount (Rs.)
	recommended in the Pronab Sen Committee Report		
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		22.90
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		22.90'

2.5.4. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Emcure Pharmaceuticals Limited (Marketer) at Rs. 24.10 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		24.10

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S. No.	Particulars	Source/Method	Amount (Rs.)
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		24.10

2.5.5. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Zydus Healthcare Limited (Marketer) at Rs. 30.11 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		56.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA

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S. No.	Particulars	Source/Method	Amount (Rs.)
(j)	Recommended retail price		30.11

2.5.6. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Zydus Healthcare Limited (Marketer) at Rs. 28.72 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		54.50
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		28.72

2.5.7. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed

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Pharmaceuticals (Manufacturer) and M/s Alembic Pharmaceuticals Limited (Marketer) at Rs. 17.85 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		17.85
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		17.85

2.5.8. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Alembic Pharmaceuticals Limited (Marketer) at Rs. 18.75 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
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S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		18.75
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		18.75

2.5.9. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Glenmark Pharmaceuticals Limited (Marketer) at Rs. 30.11 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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		

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S. No.	Particulars	Source/Method	Amount (Rs.)
	mg (as Extended Release)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		30.80
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		30.11

2.5.10. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Glenmark Pharmaceuticals Limited (Marketer) at Rs. 28.72 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March,	17.10

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S. No.	Particulars	Source/Method	Amount (Rs.)
		2022 data)	
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		29.46
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		28.72

2.5.11. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Intas Pharmaceuticals Limited (Marketer) at Rs. 21.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55

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S. No.	Particulars	Source/Method	Amount (Rs.)
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		21.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		21.00

2.5.12. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Intas Pharmaceuticals Limited (Marketer) at Rs. 19.00 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 2022 data)	37.27

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S. No	Particulars	Source/Method	Amount (Rs.)
(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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		19.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		19.00

2.5.13. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Eris Lifesciences Limited (Marketer) at Rs. 27.67 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 2022 data)	37.27
(d)	50% of Patent Component		18.63

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S. No.	Particulars	Source/Metho hod	Amount (Rs.)
(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)		30.11
(h)	Claimed Retail price		27.67
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		27.67

2.5.14. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Eris Lifesciences Limited (Marketer) at Rs. 25.89 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Metho d	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated	1.92

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S. No.	Particulars	Source/Method	Amount (Rs.)
		25.03.2021]	
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		25.89
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		25.89

2.5.15. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Cipla Limited (Marketer) at Rs. 28.72 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as recommended in the Pronab Sen Committee		0.38

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Report		
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		35.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		28.72

2.5.16. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Cipla Limited (Marketer) at Rs. 30.11 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		40.00

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S. No.	Particulars	Source/Method	Amount (Rs.)
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		30.11

2.5.17. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Micro Labs Limited (Marketer) at Rs. 24.10 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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 (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.38
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.72
(h)	Claimed Retail price		24.10
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet" as per Pharmatrac Data for March, 2022		NA



S. No.	Particulars	Source/Method	Amount (Rs.)
(j)	Recommended retail price		24.10

2.5.18. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Micro Labs Limited (Marketer) at Rs. 25.89 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 March, 2022 data)	17.10
(b)	50% of Patent Component		8.55
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per March, 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)		30.11
(h)	Claimed Retail price		25.89
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for March, 2022		NA
(j)	Recommended retail price		25.89

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2.5.19. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Torrent Pharmaceuticals Limited (Marketer) at Rs. 29.26 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		29.26
(h)	Claimed Retail price		32.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet' as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		29.26

2.5.20. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Torrent Pharmaceuticals Limited (Marketer) at Rs. 27.73 per tablet excluding GST as detailed below:

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.42
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		27.73
(h)	Claimed Retail price		31.00
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		27.73

2.5.21. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Abbott Healthcare Pvt. Limited (Marketer) at Rs. 20.53 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin		

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S. No.	Particulars	Source/Method	Amount (Rs.)
	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 April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		29.26
(h)	Claimed Retail price		20.53
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		20.53

2.5.22. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Abbott Healthcare Pvt. Limited (Marketer) at Rs. 19.64 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		

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S. No.	Particulars	Source/Method	Amount (Rs.)
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.42
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		27.73
(h)	Claimed Retail price		19.64
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		19.64

2.5.23. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Lupin Limited (Marketer) at Rs. 20.53 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per April, 2022 data)	14.79

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S. No.	Particulars	Source/Method	Amount (Rs.)
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.42
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		27.73
(h)	Claimed Retail price		20.53
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		20.53

2.5.24. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Lupin Limited (Marketer) at Rs. 22.32 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27

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S. No.	Particulars	Source/Method	Amount (Rs.)
		data)	
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		29.26
(h)	Claimed Retail price		22.32
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		22.32

2.5.25. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Cadila Pharmaceuticals Limited (Marketer) at Rs. 27.73 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated 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)		
	Patent Component		
(a)	Derived retail price of Dapagliflozin 10 mg tablet	Retail price (as per April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63

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S. No.	Particulars	Source/Method	Amount (Rs.)
(e)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.42
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		27.73
(h)	Claimed Retail price		35.71
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 500mg (ER) tablet' as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		27.73

2.5.26. Each film coated tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release) for M/s Exemed Pharmaceuticals (Manufacturer) and M/s Cadila Pharmaceuticals Limited (Marketer) at Rs. 29.26 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (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 April, 2022 data)	14.79
(b)	50% of Patent Component		7.39
(c)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per April, 2022 data)	37.27
(d)	50% of Patent Component		18.63
(e)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E)]	4.05

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S. No.	Particulars	Source/Method	Amount (Rs.)
		dated 30.03.2022]	
(f)	Less 20% of the lower of (b), (d) and (e) as recommended in the Pronab Sen Committee Report		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		29.26
(h)	Claimed Retail price		41.07
(i)	Retail price of FDC of 'Dapagliflozin 10mg + Sitagliptin 100mg + Metformin 1000mg (ER) tablet" as per Pharmatrac Data for April, 2022		NA
(j)	Recommended retail price		29.26

3. Agenda No. 3- Retail price fixation under Para 5 of DPCO, 2013- Each uncoated tablet containing Metronidazole IP 200mg, Furazolidone IP 100mg, Dicyclomine HCl IP 10mg for M/s Dallas Drugs Pvt. Ltd. (manufacturer) and M/s Micro Labs Pvt. Ltd. (marketer).

3.1 The Committee deliberated on the agenda item and recommended the retail price of Each uncoated tablet containing Metronidazole IP 200mg, Furazolidone IP 100mg, Dicyclomine HCl IP 10mg for M/s Dallas Drugs Pvt. Ltd. (manufacturer) and M/s Micro Labs Pvt. Ltd. (marketer) at Rs. 1.08 per tablet excluding GST as below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each uncoated tablet containing Metronidazole IP 200mg, Furazolidone IP 100mg, Dicyclomine HCl IP 10mg		
(a)	Metronidazole IP 200mg tablet	Ceiling price (S.O. 1330(E) dated 25.03.2021)	0.69
(b)	Dicyclomine HCl IP 10mg tablet	Ceiling price (S.O. 1330(E) dated 25.03.2021)	0.11
(c)	Derived retail price of Furazolidone IP 100mg tablet	Retail Price [as per Pharmatrac data for the period from April, 2021 to March, 2022 and Pharmatrac database used is for the month of October, 2022]	0.30
(d)	Less 20% of the lower of (a), (b) or (c) as recommended in the Pronab Sen Committee report		0.02
(e)	Worked out Retail Price(a)+(b)+(c)-(d)		1.08
(f)	Claimed Retail price		7.14
(g)	Recommended retail price		1.08

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4. Agenda No. 4 - 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 Torrent Pharmaceuticals Limited (marketer).

4.1. The committee deliberated on the agenda item and 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 Torrent Pharmaceuticals Limited (marketer) at Rs. 48 per tablet excluding GST 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 Pranab Sen Committee) NOTE 1	38.55
(b)	Derived retail price of Atorvastatin 80mg tablet	Retail price (as per Pharmatrac data for the period May, 2021 to April, 2022 is taken and Pharmatrac database month is October, 2022)	35.88
(c)	(a) or (b), whichever is lower		35.88
(d)	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 i.e 3.11.2022 and Pharmatrac database used is for the month of October, 2022]	19.88
(e)	Retail Price		55.76
(f)	Less 20% of the lower of (c) or (d) as recommended in the Pranab Sen Committee report		3.98
(g)	Worked out Retail Price (d)-(e)		51.78
(h)	Claimed Retail price		48.00
(j)	Recommended retail price		48.00

Note 1:

Derived retail price as per recommendation of Pranab 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

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

Ceiling price of Atorvastatin 40 mg tablet as on April, 2022 = Rs. 21.42 per tablet excluding GST [S.O. No. 1499(E) dated 30.03.2022]

Derived price of Atorvastatin 80mg tablet after applying the formula of Pronab Sen Committee on the price as per (a) above
= $21.42[1+0.80\{80-40/40\}]$ = Rs.38.55 per tablet excluding GST

5. Agenda No. 5 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 2.5mg for M/s Micro Labs Limited (manufacturer and marketer).

5.1. The committee recommended the retail price of each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 2.5mg for M/s Micro Labs Limited (manufacturer and marketer) at Rs. 10.92 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Telmisartan IP 40mg and Bisoprolol Fumarate IP 2.5mg		
(a)	Telmisartan IR 40 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	7.32
(b)	Derived retail price of Bisoprolol Fumarate IP 2.5mg tablet	Retail price (as per April, 2022 data)	4.49
(c)	Retail Price		11.81
(d)	Less 20% of the lower of (a) or (b) as recommended in the Pronab Sen Committee report		0.89
(e)	Worked out Retail Price (c)-(d)		10.92
(g)	Claimed Retail price		16.96
(i)	Recommended retail price		10.92

6. Agenda No. 6 - 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).

6.1 The matter was deliberated in 44th and 45th meeting of the Multidisciplinary Committee of Experts held on 4.08.2022 and 13.09.2022 respectively. In the 45th meeting, retail price of Lidocaine 700mg patch was calculated by applying the ratio of the price of Fentanyl Injection to Patches on Lidocaine Injection to patches since the data was not available in Pharmatrac database. 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).

6.2 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.

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6.3 The matter was also placed before the Authority in its 102nd 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.

6.4 M/s Hetero Healthcare Ltd made presentation in person before the Committee in its 46th meeting held on 19.10.2022 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 Pharmatrac database due to low demand of the patches.

6.5 Committee in its 46th Meeting 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 other manufacturer/marketer companies.

6.6 In view of above, data was sought from other companies manufacturing/marketing Lignocaine Patches vide letter dated 26.10.2022. Based on the data received from these companies, the committee deliberated upon the matter and recommended the retail price of each Adhesive Patch contains "Lidocaine 700mg in an aqueous base (50mg per gm adhesive) for M/s Hetero Healthcare Limited (Manufacturer and Marketer) at Rs.44.64 per patch excluding GST, being lower of the worked-out price and the claimed price by the company as follows:

1	Worked out Retail Price	Rs. 234.61 per patch (Each patch contains Lidocaine 700mg (50mg per gm adhesive) excluding GST (Annexure 1)
2	Retail Price claimed	Rs. 50 per patch (Each patch contains Lidocaine 700mg (50mg per gm adhesive) including GST
3	Proposed Retail Price	Rs. 50 per patch (Each patch contains Lidocaine 700mg (50mg per gm adhesive) including GST i.e., Rs.44.64 per patch (Each patch contains Lidocaine 700mg (50mg per gm adhesive) excluding GST

7. Agenda No. 7: Application for "Special Feature rate" for scheduled products (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactam 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactam 500 mg under Para 11(3) of DPCO 2013.

7.1 The matter was discussed in various meetings of Multidisciplinary Committee of Experts. As per the deliberations held in 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022, additional 15 percent price over the present applicable ceiling price of the formulation for incremental innovation of the packaging was recommended.

7.2 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 102nd meeting held on 27.09.2022 in which the Authority decided that the representation of the company be referred to the Committee for examination.

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7.3 Committee in its 46th meeting held on 20.10.2022 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. In view of this, letter was sent to M/s Gufic Biosciences Ltd on 27.10.2022 requesting to submit the additional literature to substantiate their claim and also to make presentation in the next meeting of the committee. The committee noted that company has not replied to NPPA's letter and no additional literature was submitted by the company to substantiate its claim. However, the company made a presentation through Video Conferencing before the Committee reiterating the same facts as in the earlier meetings.

7.4 In this context, the Committee was apprised that DoP has notified the revised Schedule-I (NLEM 2022) under DPCO, 2013 vide SO No. 5249 (E) dated 11.11.2022. Hence, as per the provisions of Para 17 of DPCO, 2013, NPPA is required to fix the ceiling prices within 60 days of notification by DoP.

7.5 The Committee deliberated on the matter and recommended that the matter of separate price approval on account special packaging may be placed before the committee for deliberations after notification of ceiling price of the formulations under Revised Schedule-I of DPCO 2013 and after the receipt of reply of NPPA letter dated 27.10.2022.

8. Agenda No. 8: 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.

8.1 The matter was discussed in various meetings (42nd to 46th Meeting) of Multidisciplinary Committee of Experts. As per the deliberations held in 45th meeting of the Multidisciplinary Committee of Experts held on 13.09.2022, separate ceiling price was recommended. The recommendation of MDC was placed in 102nd 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 re-examination.

8.2 Committee in its 46th meeting held on 19.10.2022 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.

8.3 The Committee was apprised that DoP has notified the revised Schedule-I (NLEM 2022) under DPCO, 2013 vide SO No. 5249 (E) dated 11.11.2022. Hence, as per the provisions of Para 17 of DPCO 2013, NPPA is required to fix the ceiling price within 60 days of notification by DoP.

8.4 The Committee deliberated on the matter and recommended that the matter of separate price approval on account special packaging may be taken up after notification of ceiling price of the formulation under Revised Schedule-I of DPCO, 2013.

9. Agenda 9: Retail Price fixation of Each 5ml contains: Levosalbutamol Sulphate IP eq. to Levosalbutamol 1 mg + Ambroxol Hydrochloride IP 30mg + Guaiphenesin IP 50mg for M/s Naxpar Pharma Pvt. Ltd.(manufacturer) and M/s Geno Pharmaceuticals Pvt. Ltd. (marketer)



9.1 NPPA received application from M/S Naxpar Pharma Pvt. Ltd.(manufacturer) and M/s Geno Pharmaceuticals Pvt. Ltd. (marketer)for retail price fixation of "Each 5ml contains: Levosalbutamol Sulphate IP eq. to Levosalbutamol 1 mg + Ambroxol Hydrochloride IP 30mg + Guaiphenesin IP 50mg".The matter was placed before the committee to deliberate whether the applicant's formulation is a new drug under Para 2 (1) (u) of DPCO 2013 and whether Salbutamol and Livosalbutamol are same and livosalbutalmol can be considered to be included in schedule I of DPCO 2013

9.2 In this context, it was observed that Salbutamol is a Scheduled formulation appearing at section 24.1.6 under Revised schedule I of DPCO 2013 notified by DoP vide SO No, 5249 (E) dated 11.11.2022 (NLEM 2022) and it was also a scheduled formulation under NLEM 2015 appearing at section 28.1.5of schedule I of DPCO, 2013..

9.3 The committee deliberated upon the matter and observed as below:

(i) Explanation 3 and 4 of DPCO, 2013 (NLEM, 2022) states

3. Different isomers of a molecule may differ with respect to potency / pharmacodynamics / safetyefficacy profile. Such different isomers have been considered as separate entities. Therefore, inclusion of one isomer of a molecule in this schedule does not imply inclusion of all other isomers of a molecule.
4. Prodrugs / analogues / derivatives of one active moiety are available as different medicines. They may differ with respect to potency / pharmacokinetics / pharmacodynamics / safety-efficacy profile. Inclusion of one form of such medicines in the schedule will not imply inclusion of other forms.

9.4 In view of above, the committeeopined that Salbutamol and Levosalbutamol are different drugs. Levosalbutamol is an isomer of salbutamol. Inclusion of salbutamol in the schedule I of DPCO 2013 does not imply inclusion of livosalbutamol unless specifically stated. Therefore, the FDC of Levosalbutamol Sulphate IP eq. to Levosalbutamol 1 mg + Ambroxol Hydrochloride IP 30mg + Guaiphenesin IP 50mg is not a new drug as per Para 2(1)(u) of DPCO, 2013.

10. Agenda 10: Retail Price fixation of formulation "Formoterol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP 100 mcg Inhaler (MDI) for M/s. Cipla Limited in view of DoP's Review Order dated 03.10.2022 – reg.

10.1 The Committee noted that DoP has issued Review order dated 03.10.2022 in respect of Review application dated 24.01.2020 filed by M/s. Cipla Limited under para 31 of the Drugs (Prices Control) Order, 2013 in the matter of Retail Price fixation of formulation "Formoterol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP100 mcg Inhaler (MDI), the prices of which were notified vide SO. No. 2944(E) dated 14.08.2019 The decision part of the said review order read as under:

"On careful consideration of the entire facts and circumstances, Reviewing Authority is of the opinion that the S.O. No. 2944(E) dated 14.08.2019 issued by NPPA warrants interference pursuant to directions of the Hon'ble High Court of Delhi and subsequent developments. Matter requires remand for fresh Order on merits by MDC and the NPPA, after analysis of the entire facts to avoid miscarriage of justice. Consequently, the impugned Order is referred back to

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NPPA to consider the issues raised by the applicant and to pass an appropriate order. The applicant will have liberty to file a Review before the department, if not satisfied by the fresh order passed by NPPA."

10.2 In this context, M/S Cipla limited gave a detailed presentation in the meeting through Video Conferencing and requested that matter may be given a *de novo* hearing as directed through the Review order. The Committee of experts had detailed discussion with the company wherein the Committee observed as below:

a) M/s Cipla Limited had submitted to DoP that Multidisciplinary Committee of Experts, in its 12th meeting held on 31.07.2019 had allotted a separate price to the product of M/s Glenmark that had an integrated dose counter. However, in the same meeting the product of M/S Cipla was not given a separate price inspite of having an integrated dose counter. In this context, the committee observed:

M/s Cipla Limited in their Form-I application dated 07.02.2019 had not mentioned the fact of digital dose counter and also not applied for special prices under Para 11(3). Further, M/s Cipla Limited has also not stated this fact of digital dose counter in their representation dated 17.05.2019. Application was filed initially in Form I and no special price was sought. Neither NPPA nor the committee of experts was made aware of this feature. Therefore, the benefit given to M/s Glenmark was not applied to M/s Cipla Limited.

b) After this the committee deliberated upon the therapeutic efficacy of the product on which M/S Cipla sought the incremental price stating its product to be an innovation. M/s Cipla Limited submitted that the formulation was already approved by DCGI on 5.11.2011 and had the same composition as that of competitor's product but had certain therapeutic advantages over the conventional inhaler. M/s Cipla Limited submitted that their product is an improved version, which will reach in small airways. M/s Cipla further claimed that its manufacturing process is highly complex compared to conventional formulation of the competitor (M/S Lupin).

c) The Committee noted the presentation given by M/s Cipla Ltd. and observed that although the company claimed its product to be a superior product compared to the product of M/s Lupin available in market, but the company had not claim the same before the licensing authority while obtaining the license to manufacture & market the product. Further, the license as well as product label also does not mention any such claim of special feature.

d) The committee further observed that M/s Cipla has neither applied nor obtained the separate licence for its product with the claim of improved efficacy and also did not apply to NPPA at any stage under para 11(3) for seeking separate price. Moreover, the company also does not have published literature of their product. The improved efficacy is also not apparent on the label of the product or through the licence.

e) The committee also noted that during the presentation M/s Cipla mentioned that the drug is not new drug, but earlier they applied to NPPA considering the same as new drug. Therefore, their stand is not very clear about its claim as the company also submitted before the Committee that its formulation is not a new drug under Para 2 (1) (u) DPCO 2013.

10.3 After detailed deliberations, the committee recommended that special pricing on account of improved formulations as claimed by M/s Cipla Limited may be considered for further examination, if the company submits published literature demonstrating the improved efficacy of its product and obtain the manufacturing permission/license from the licensing authorities along with the product label claim.

11. Agenda No. 11- Subject: Application by M/s Troikaa Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (i) to (iii) for the formulations "Paracetamol Injection (Intramuscular) 250mg/ml" – reg.

1. M/s Troikaa Pharmaceuticals Limited vide e-mail dated 01.10.2022 applied for exemption under Para 32 (i) to (iii) for the formulations "Paracetamol Injection (Intramuscular) 250mg/ml". The applicant vide letter dated 10.11.2022 submitted the copy of Patent issued by the Patent Office under Indian Patent Act, 1970 dated 09.11.2022 for "Novel Composition comprising Paracetamol and process for preparing the same" bearing registration no. 411067 along with the claim filed with Patent Office (Application No. 630/MUM/2010) dated 09.10.2010.
2. The committee deliberated in detail and recommended that confirmation should be sought from Patent office, whether the formulation for which exemption is sought is covered under the Patent granted to M/s Troikaa Pharmaceuticals Limited.

The meeting ended with a vote of thanks to all.

Rashmi
9/12/22
(Rashmi Tahiliani)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

Annexure to Agenda 1

Computation of Retail Price based on April, 2022 Data under Para 5 of DPCO, 2013

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)				7,743.20
	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

S.No.	पैक विवरण Pack Description	उत्प BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	77,43,19,788		100%		M3	
								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	206.43	215841969	27.88%	27.88%	Y	29.49	29.49
2	JANUVIA 50 MG TABLET 7	JANUVIA	MSD PHARMACEUTICALS PRIVATE LTD.	50 MG	7	TABLET	207.14	558477818	72.12%	72.12%	Y	29.59	29.59
		Rs. Per Tablet											
	Worked out Retail Price		34.27 Excluding GST										

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Computation of Retail Price based on March, 2022 Data under Para 5 of DPCO, 2013

Annexure to Appendix 2 -

Number of Companies consisting of Market Share of 1% & Above	14
Sum of MAT value considered for price calculation (in Lakhs)	38,293.10
Sum of PTR per unit considered for price calculation	235.79
Number of Packs considered	16
Average PTR	14.74
Add : 16% Retailer Margin	2.36
Retail Price (without local taxes)	17.10
% Reduction with compared to Highest Price	64.01%

Minimum Price (Rs.)	7.74
Maximum Price (Rs.)	40.96
Average of all considered (Rs.)	14.74
Retail Price (Rs.)	17.1

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	4,28,08,83,312	100%	M3			Price per unit (Rs.) Considered
								MAT(Rs.)	SKU wise MAT %	Brandwi se MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per unit (Rs.)	
1	4 DAPA 10 MG TABLET 10	4 DAPA	4 CARE LIFESCENCE PVT LTD	10 MG	10	TABLET	85.00	588710	0.01%	0.01%	N	8.50	
2	4 DAPA M 10 MG TABLET 10	4 DAPA M	4 CARE LIFESCENCE PVT LTD	10 MG	10	TABLET	100.00	3300	0.00%	0.00%	N	10.00	
3	BIOXIGA 10 MG TABLET 10	BIOXIGA	BIOS LAB PVT.LTD	10 MG	10	TABLET	92.57	459030	0.01%	0.01%	N	9.26	
4	DAGLIPACK 10 MG TABLET 10	DAGLIPACK	KOYE PHARMACEUTICALS PVT. LTD.	10 MG	10	TABLET	99.29	4034351	0.09%	0.09%	N	9.93	
5	DAJIO 10 MG TABLET 15	DAJIO	MICRO LABS LTD	10 MG	15	TABLET	126.43	36301340	0.85%	0.85%	N	8.43	
6	DAMITA 10 MG TABLET 10	DAMITA	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	87963619	2.05%	2.05%	Y	10.64	10.64
7	DAPA GOLD 10 MG TABLET 15	DAPA GOLD	HBC LIFESCENCES PVT LTD	10 MG	15	TABLET	150.00	12579075	0.29%	0.29%	N	10.00	
8	DAPABEST 10 MG TABLET 10	DAPABEST	PANACEA BIOTEC LTD	10 MG	10	TABLET	100.00	11684100	0.27%	0.27%	N	10.00	
9	DAPABITE 10 MG TABLET 10	DAPABITE	CORONA	10 MG	10	TABLET	117.07	99247456	2.32%	2.32%	Y	11.71	11.71
10	DAPABLIS 10 MG TABLET 10	DAPABLIS	MED MANOR ORGANICS PVT LTD.	10 MG	10	TABLET	82.14	255455	0.01%	0.01%	N	8.21	
11	DAPACARE 10 MG TABLET 10	DAPACARE	OCTALIFE PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	78.57	483441	0.01%	0.01%	N	7.86	
12	DAPACONIC 10 MG TABLET 15	DAPACONIC	LA RENON	10 MG	15	TABLET	181.07	2261202	0.05%	0.05%	N	12.07	
13	DAPACOSE 10 MG TABLET 10	DAPACOSE	JB CHEMICALS	10 MG	10	TABLET	85.72	28905213	0.68%	0.68%	N	8.57	
14	DAPADEL 10 MG TABLET 10	DAPADEL	CADELL HEALTH CARE PVT.LTD	10 MG	10	TABLET	106.43	3964943	0.09%	0.09%	N	10.64	
15	DAPAEASE 10 MG TABLET 10	DAPAEASE	JUBILANT GENERICS LIMITED	10 MG	10	TABLET	103.57	901577	0.02%	0.02%	N	10.36	
16	DAPAGAIN 10 MG TABLET 15	DAPAGAIN	SYSTOPIC LABORATORIES LTD-MEM	10 MG	15	TABLET	63.22	6620462	0.15%	0.15%	N	4.21	
17	DAPAGLYN 10 MG TABLET 15	DAPAGLYN	ZYDUS CADILA - ZHL	10 MG	15	TABLET	200.36	249140719	5.82%	5.82%	Y	13.36	13.36
18	DAPAGREAT 10 MG TABLET 15	DAPAGREAT	SINSAN PHARMACEUTICALS	10 MG	15	TABLET	142.14	6199863	0.14%	0.14%	N	9.48	
19	DAPAHENZ 10 MG TABLET 15	DAPAHENZ	LA RENON	10 MG	15	TABLET	181.07	5942717	0.14%	0.14%	N	12.07	
20	DAPAKEY 10 MG TABLET 10	DAPAKEY	PRECIA PHARMA	10 MG	10	TABLET	103.57	7249486	0.17%	0.17%	N	10.36	
21	DAPALEX 10 MG TABLET 10	DAPALEX	AJANTA PHARMA LTD	10 MG	10	TABLET	110.71	35122196	0.82%	0.82%	N	11.07	
22	DAPAMAC 10 MG TABLET 10	DAPAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	139135781	3.25%	3.25%	Y	10.64	10.64
23	DAPANORM 10 MG TABLET 10	DAPANORM	ALKEM LABORATORIES LTD.	10 MG	10	TABLET	125.00	184930875	4.32%	4.32%	Y	12.50	12.50
24	DAPANOVA 10 MG TABLET 15	DAPANOVA	MEDLEY PHARMACEUTICALS	10 MG	15	TABLET	140.71	40484036	0.95%	0.95%	N	9.38	
25	DAPAOONE 10 MG TABLET 10	DAPAOONE	MSN LABORATORIES LTD	10 MG	10	TABLET	107.14	25778205	0.60%	0.60%	N	10.71	
26	DAPARAY 10 MG TABLET 10	DAPARAY	ICON LIFESCENCES	10 MG	10	TABLET	69.64	813256	0.02%	0.02%	N	6.96	
27	DAPARYL 10 MG TABLET 10	DAPARYL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	179194593	4.19%	4.19%	Y	9.29	9.29
28	DAPASIS 10 MG TABLET 10	DAPASIS	AKESISS PHARMA (P) LTD	10 MG	10	TABLET	99.29	6631778	0.15%	0.15%	N	9.93	
29	DAPASPEC 10 MG TABLET 10	DAPASPEC	SPECTRA THERAPEUTICS PVT. LTD.	10 MG	10	TABLET	96.43	1500901	0.04%	0.04%	N	9.64	
30	DAPATEN 10 MG TABLET 15	DAPATEN	BAL PHARMA	10 MG	15	TABLET	117.54	165379	0.00%	0.00%	N	7.84	
31	DAPATREND 10 MG TABLET 14	DAPATREND	ANTHEM BIOPHARMA PVT LTD	10 MG	14	TABLET	165.00	5494170	0.13%	0.13%	N	11.79	
32	DAPATURN 10 MG TABLET 10	DAPATURN	LUPIN LTD	10 MG	10	TABLET	103.57	19909261	0.47%	0.47%	N	10.36	
33	DAPAVEL 10 MG TABLET 10	DAPAVEL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	225916739	5.28%	5.28%	Y	9.29	9.29
34	DAPAYES 10 MG TABLET 10	DAPAYES	ANAX LIFE SCIENCES PVT.LTD	10 MG	10	TABLET	103.57	68149	0.00%	0.00%	N	10.36	
35	DAPAZOL 10 MG TABLET 10	DAPAZOL	ALTEUS BIOGENICS PVT.LTD.	10 MG	10	TABLET	96.43	482828	0.01%	0.01%	N	9.64	
36	DAPEFY 10 MG TABLET 14	DAPEFY	SUN PHARMA LABORATORIES LTD.	10 MG	14	TABLET	250.00	9263250	0.22%	0.22%	N	17.86	
37	DAPGLIN 10 MG TABLET 10	DAPGLIN	VASU ORGANICS PVT.LTD	10 MG	10	TABLET	83.57	25238	0.00%	0.00%	N	8.36	
38	DAPIXA 10 MG TABLET 10	DAPIXA	TAS MED (INDIA) PRIVATE LTD.	10 MG	10	TABLET	100.00	493000	0.01%	0.01%	N	10.00	
39	DAPLO 10 MG TABLET 10	DAPLO	DR. REDDYS LABORATORIES LTD	10 MG	10	TABLET	117.86	71450998	1.67%	1.67%	Y	11.79	11.79
40	DAPNAT 10 MG TABLET 30	DAPNAT	NATCO PHARMA LTD	10 MG	30	TABLET	417.86	17451923	0.41%	0.41%	N	13.93	
41	DAPRICA 10 MG TABLET 10	DAPRICA	APRICA HEALTHCARE PVT LTD	10 MG	10	TABLET	103.57	11781916	0.28%	0.28%	N	10.36	
42	DAXIGA 10 MG TABLET 10	DAXIGA	ACMEDIX PHARMA LLP	10 MG	10	TABLET	49.29	4683240	0.11%	0.11%	N	4.93	
43	DEPAJA 10 MG TABLET 10	DEPAJA	INDOCO REMEDIES LTD	10 MG	10	TABLET	82.14	4593022	0.11%	0.11%	N	8.21	
44	DEXIGLU 10 MG TABLET 10	DEXIGLU	FUSION HEALTHCARE PVT LTD	10 MG	10	TABLET	103.57	8950727	0.21%	0.21%	N	10.36	
45	DGSON 10 MG TABLET 10	DGSON	UNISON PHARMACEUTICALS	10 MG	10	TABLET	32.14	2097746	0.05%	0.05%	N	3.21	
46	DIABFLOZ 10 MG TABLET 10	DIABFLOZ	FINECURE PHARMACEUTICALS	10 MG	10	TABLET	82.14	3685622	0.09%	0.09%	N	8.21	

Annexure to Agenda 2

Computation of Retail Price based on April, 2022 Data under Para 5 of DPCO, 2013

Number of Companies consisting of Market Share of 1% & Above	14
Sum of MAT value considered for price calculation (in Lakhs)	38,260.86
Sum of PTR per unit considered for price calculation	204.04
Number of Packs considered	16
Average PTR	12.75
Add: 16% Retailer Margin	2.04
Retail Price (without local taxes)	14.79
% Reduction with compared to Highest Price	68.87%

Minimum Price (Rs.)	7.74
Maximum Price (Rs.)	40.96
Average of all considered (Rs.)	12.75
Retail Price (Rs.)	14.79

S.No.	पैक विवरण Pack Description	छाप BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	4,32,05,10,981	100%	M3			
								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	4 DAPA 10 MG TABLET 10	4 DAPA	4 CARE LIFESCENCE PVT LTD	10 MG	10	TABLET	85.00	669205	0.02%	0.02%	N	8.50	
2	4 DAPA M 10 MG TABLET 10	4 DAPA M	4 CARE LIFESCENCE PVT LTD	10 MG	10	TABLET	100.00	3300	0.00%	0.00%	N	10.00	
3	BIOXIGA 10 MG TABLET 10	BIOXIGA	BIOX LAB PVT.LTD	10 MG	10	TABLET	102.85	555811	0.01%	0.01%	N	10.29	
4	DAGLIPACK 10 MG TABLET 10	DAGLIPACK	KOYE PHARMACEUTICALS PVT. LTD.	10 MG	10	TABLET	99.29	4410363	0.10%	0.10%	N	9.93	
5	DAJIO 10 MG TABLET 15	DAJIO	MICRO LABS LTD	10 MG	15	TABLET	126.43	37852889	0.88%	0.88%	N	8.43	
6	DAMITA 10 MG TABLET 10	DAMITA	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	91019063	2.11%	2.11%	Y	10.64	10.64
7	DAPA GOLD 10 MG TABLET 15	DAPA GOLD	HBC LIFESCENCES PVT LTD	10 MG	15	TABLET	150.00	13720846	0.32%	0.32%	N	10.00	
8	DAPABEST 10 MG TABLET 10	DAPABEST	PANACEA BIOTEC LTD	10 MG	10	TABLET	100.00	12462200	0.29%	0.29%	N	10.00	
9	DAPABITE 10 MG TABLET 10	DAPABITE	CORONA	10 MG	10	TABLET	117.07	102993442	2.38%	2.38%	Y	11.71	11.71
10	DAPABLIS 10 MG TABLET 10	DAPABLIS	MED MANOR ORGANICS PVT LTD.	10 MG	10	TABLET	82.14	314350	0.01%	0.01%	N	8.21	
11	DAPACARE 10 MG TABLET 10	DAPACARE	OCTALIFE PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	78.57	495148	0.01%	0.01%	N	7.86	
12	DAPACONIC 10 MG TABLET 15	DAPACONIC	LA RENON	10 MG	15	TABLET	181.07	2571556	0.06%	0.06%	N	12.07	
13	DAPACOSE 10 MG TABLET 10	DAPACOSE	JB CHEMICALS	10 MG	10	TABLET	85.72	31320888	0.72%	0.72%	N	8.57	
14	DAPADEL 10 MG TABLET 10	DAPADEL	CADELL HEALTH CARE PVT.LTD	10 MG	10	TABLET	92.14	4007289	0.09%	0.09%	N	9.21	
15	DAPAEASE 10 MG TABLET 10	DAPAEASE	JUBILANT GENERICS LIMITED	10 MG	10	TABLET	103.57	1011982	0.02%	0.02%	N	10.36	
16	DAPAGAIN 10 MG TABLET 15	DAPAGAIN	SYSTOPIC LABORATORIES LTD-MEM	10 MG	15	TABLET	63.22	9003729	0.21%	0.21%	N	4.21	
17	DAPAGLYN 10 MG TABLET 15	DAPAGLYN	ZYDUS CADILA - ZHL	10 MG	15	TABLET	200.36	252756460	5.85%	5.85%	Y	13.36	13.36
18	DAPAGREAT 10 MG TABLET 15	DAPAGREAT	SINSHAN PHARMACEUTICALS	10 MG	15	TABLET	142.14	5797322	0.13%	0.13%	N	9.48	
19	DAPAGZA 10 MG TABLET 15	DAPAGZA	EMCURE PHARMACEUTICALS LTD	10 MG	15	TABLET	159.64	116378	0.00%	0.00%	N	10.64	
20	DAPAHENZ 10 MG TABLET 15	DAPAHENZ	LA RENON	10 MG	15	TABLET	181.07	6963228	0.16%	0.16%	N	12.07	
21	DAPAKEY 10 MG TABLET 10	DAPAKEY	PRECIA PHARMA	10 MG	10	TABLET	103.57	7559989	0.17%	0.17%	N	10.36	
22	DAPALEX 10 MG TABLET 10	DAPALEX	AJANTA PHARMA LTD	10 MG	10	TABLET	110.71	36370894	0.84%	0.84%	N	11.07	
23	DAPAMAC 10 MG TABLET 10	DAPAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	143916626	3.33%	3.33%	Y	10.64	10.64
24	DAPANORM 10 MG TABLET 10	DAPANORM	ALKEM LABORATORIES LTD.	10 MG	10	TABLET	125.00	194902500	4.51%	4.51%	Y	12.50	12.50
25	DAPANOVA 10 MG TABLET 15	DAPANOVA	MEDLEY PHARMACEUTICALS	10 MG	15	TABLET	140.71	41790637	0.97%	0.97%	N	9.38	
26	DAPAOONE 10 MG TABLET 10	DAPAOONE	MSN LABORATORIES LTD	10 MG	10	TABLET	107.14	27338700	0.63%	0.63%	N	10.71	
27	DAPARAY 10 MG TABLET 10	DAPARAY	ICON LIFESCENCES	10 MG	10	TABLET	69.64	903858	0.02%	0.02%	N	6.96	
28	DAPARYL 10 MG TABLET 10	DAPARYL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	189216978	4.38%	4.38%	Y	9.29	9.29
29	DAPASIS 10 MG TABLET 10	DAPASIS	AKESSIS PHARMA (P) LTD	10 MG	10	TABLET	99.29	7152355	0.17%	0.17%	N	9.93	
30	DAPASPEC 10 MG TABLET 10	DAPASPEC	SPECTRA THERAPEUTICS PVT. LTD.	10 MG	10	TABLET	96.43	1602362	0.04%	0.04%	N	9.64	
31	DAPATEN 10 MG TABLET 15	DAPATEN	BAL PHARMA	10 MG	15	TABLET	117.54	219447	0.01%	0.01%	N	7.84	
32	DAPATREND 10 MG TABLET 14	DAPATREND	ANTHEM BIOPHARMA PVT LTD	10 MG	14	TABLET	165.00	5654715	0.13%	0.13%	N	11.79	
33	DAPATURN 10 MG TABLET 10	DAPATURN	LUPIN LTD	10 MG	10	TABLET	103.57	24174792	0.56%	0.56%	N	10.36	
34	DAPAVEL 10 MG TABLET 10	DAPAVEL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	236483033	5.47%	5.47%	Y	9.29	9.29
35	DAPAYES 10 MG TABLET 10	DAPAYES	ANAX LIFE SCIENCES PVT.LTD	10 MG	10	TABLET	103.57	81199	0.00%	0.00%	N	10.36	
36	DAPAZOL 10 MG TABLET 10	DAPAZOL	ALTEUS BIOGENICS PVT.LTD.	10 MG	10	TABLET	96.43	533903	0.01%	0.01%	N	9.64	
37	DAPEFY 10 MG TABLET 14	DAPEFY	SUN PHARMA LABORATORIES LTD.	10 MG	14	TABLET	129.00	10464885	0.24%	0.24%	N	9.21	
38	DAPGLIN 10 MG TABLET 10	DAPGLIN	VASU ORGANICS PVT.LTD	10 MG	10	TABLET	83.57	19890	0.00%	0.00%	N	8.36	
39	DAPIXA 10 MG TABLET 10	DAPIXA	TAS MED (INDIA) PRIVATE LTD.	10 MG	10	TABLET	100.00	588200	0.01%	0.01%	N	10.00	
40	DAPLO 10 MG TABLET 10	DAPLO	DR. REDDYS LABORATORIES LTD	10 MG	10	TABLET	117.86	75729993	1.75%	1.75%	Y	11.79	11.79

