

National Pharmaceutical Pricing Authority

Subject: Minutes of the 49th meeting of the Multidisciplinary Committee of Experts held on 23.02.2023 at 11:00 AM.

49th meeting of the "Multidisciplinary Committee of Experts" was held on 23.02.2023 at 11:00AM under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting through video conferencing: -

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

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
2. Shri Mahaveer Saini, Deputy Director (Pricing), NPPA
3. Sh. Gaurav Gupta represented Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoea 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 Dapagliflozin + Sitagliptin + Metformin tablet.

1.1. The Committee noted that 2 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 were patented and the patent expired in October, 2020 and 5th/6th July, 2022 respectively.

1.2. 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

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consideration and hence the price rationalisation due to expiry of the patent may not pass on to the patients.

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

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

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

1.3. The Authority further approved the retail prices of FDCs as stated in above para 1.2 in its 97th, 99th, 100th, 101st, 102nd, 103rd, 106th and 109th meeting dated 06.05.2022, 28.06.2022, 05.08.2022, 07.09.2022, 27.09.2022, 10.11.2022, 30.12.2022 and 21.02.2023 based on the recommendation made by the Multidisciplinary Committee of Experts in its 41st, 42nd, 43rd, 44th, 45th, 46th, 47th and 48th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022, 13.09.2022, 19.10.2022, 02.12.2022 and 20.01.2023 as per the above mentioned methodology.

1.4. Accordingly, the retail price of these FDCs has been attempted in line with principles as adopted earlier i.e., reduction of 50% from the patented component i.e., Dapagliflozin [termed as (a)] and Sitagliptin [termed as (b)] and then adding the ceiling price of the scheduled components as applicable six month earlier from the date of application [termed as (e)]. From the total, a reduction of 20% of the lower of (b), (d) and (e) is provided drawing reference from para No. 3.2 of Pronab Sen Committee Report and also as per the precedent followed in the similar cases.

1.5. Accordingly, the draft price calculation as per methodology as mentioned in Para 5 was placed as Agenda Item No. 1 (i) to 1 (ii) for kind deliberations of the Committee. Further, the calculation as per Para 5 of DPCO 2013, based on the market data available in Pharmatrac, if any, is also calculated.

1.6 Accordingly, the Committee deliberated on the agenda item in detail and recommended the retail price of FDCs of Dapagliflozin + Sitagliptin + Metformin Hydrochloride IP tablet for various companies as detailed below:

1.6.1 Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 500mg (as Extended Release) for M/s Exemed Pharmaceuticals (manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 16.95 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Dapagliflozin 10 mg tablet	(as per June, 2022 data)	14.96
(b)	50% of Patent Component		7.48
(c)	Calculated retail price of Sitagliptin 100 mg tablet	(as per June, 2022 data)	35.50
(d)	50% of Patent Component		17.75
(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)		0.43
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		26.93
(h)	Claimed Retail price		16.95
(i)	Retail price as per Pharmatrac Data for June, 2022		NA
(j)	Recommended retail price		16.95

1.6.2. Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg + Metformin Hydrochloride IP 1000mg (as extended release) for M/s Exemed pharmaceuticals (manufacturer) and M/s Wockhardt Limited (marketer) at Rs. 17.84 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Dapagliflozin 10 mg tablet	Retail price (as per June, 2022 data)	14.96
(b)	50% of Patent Component		7.48
(c)	Calculated retail price of Sitagliptin 100	Retail price (as per	35.50

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S. No.	Particulars	Source/Method	Amount (Rs.)
	mg tablet	June, 2022 data)	
(d)	50% of Patent Component		17.75
(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)		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		28.47
(h)	Claimed Retail price		17.84
(i)	Retail price as per Pharmatrac Data for June, 2022		NA
(j)	Recommended retail price		17.84

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

2.1. The committee noted that total of 2 applications have been received for the FDC of Dapagliflozin + Vildagliptin (as sustained release) + Metformin(as sustained release) tablet. The committee further noted that the component Dapagliflozin and Vildagliptin of the FDCs were patented and the patent expired on 02.10.2020 and 09.12.2019 respectively.

2.2. In this connection, it may be mentioned that the Authority in its 103rd meeting dated 10.11.2022 (based on the recommendation of the Committee of Experts in its 46th meeting dated 19.10.2022) approved the retail price of the FDC of Dapagliflozin + Sitagliptin + Metformin in line with the methodology decided 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) for the calculation of retail price of the FDC of Sitagliptin + Metformin tablet in line with the 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 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 Authority further approved the retail prices of FDCs as stated in above para 2.2 in its 97th, 99th, 100th, 101st, 102nd, 103rd, 106th and 109th meeting dated 06.05.2022, 28.06.2022, 05.08.2022, 07.09.2022, 27.09.2022, 10.11.2022, 30.12.2022 and 21.02.2023 based on the recommendation made by the Multidisciplinary Committee of Experts in its 41st, 42nd, 43rd, 44th, 45th, 46th, 47th and 48th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022, 13.09.2022, 19.10.2022, 02.12.2022 and 20.01.2023 as per the above mentioned methodology.

2.4. Accordingly, the retail price of these FDCs was calculated in line with principles as adopted earlier i.e., reduction of 50% from the patented component i.e., Dapagliflozin [termed as (a)] and Vildagliptin [termed as (b)] and then adding the ceiling price of the scheduled components as applicable six month earlier from the date of application [termed as (e)]. From the total, a reduction of 20% of the lower of (b), (d) and (e) is provided drawing reference from para No. 3.2 of Pronab Sen Committee Report and also as per the precedent followed in the similar cases.

2.5. Accordingly, the Committee deliberated upon the same and recommended the retail price of FDCs of Dapagliflozin + Vildagliptin (as sustained release) + Metformin (as sustained release) tablet for various companies as detailed below:

2.6.1 Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Vildagliptin 100mg (as sustained release) + Metformin Hydrochloride IP 500mg (as sustained release) for M/s Alkem Laboratories Ltd. (marketer) and M/s Ravenbhel Healthcare Pvt. Ltd. (manufacturer) at Rs. 14.84 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Dapagliflozin 10 mg tablet	Retail price (as per June, 2022 data)	14.96
(b)	50% of Patent Component		7.48
(c)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32

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S. No.	Particulars	Source/Method	Amount (Rs.)
(d)	50% of Patent Component		5.66
(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)		0.43
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		14.84
(h)	Claimed Retail price		27.67
(i)	Retail price as per Pharmatrac Data for June, 2022		NA
(j)	Recommended retail price		14.84

2.6.2- Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Vildagliptin 100mg (as sustained release) + Metformin Hydrochloride IP 1000mg (as sustained release) for M/s Alkem Laboratories Ltd. (marketer) and M/s Ravenbhel Healthcare Pvt. Ltd. (manufacturer) at Rs. 16.38 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Dapagliflozin 10 mg tablet	Retail price (as per June, 2022 data)	14.96
(b)	50% of Patent Component		7.48
(c)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32
(d)	50% of Patent Component		5.66
(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)		0.81
(g)	Worked out Retail Price (b)+(d)+(e)-(f)		16.38
(h)	Claimed Retail price		29.46
(i)	Retail price as per Pharmatrac Data for June, 2022		NA
(j)	Recommended retail price		16.38

3. Agenda No. 3 - Retail price fixation under Para 5 of DPCO, 2013 - Fixed Dose Combinations (FDCs) of Vildagliptin (as sustained release) + Metformin (as sustained release) tablet.

3.1. The committee noted that total of 12 applications have been received for the FDC of Vildagliptin (as sustained release) + Metformin (as sustained release) tablet. The committee further noted that the component Vildagliptin of the FDCs was patented and the patent expired on 09.12.2019 respectively.

3.2. Further, NPPA has earlier fixed the retail prices of FDCs of Vildagliptin (IR)+ Metformin (IR/SR) based on the basis of decision taken in 72nd meeting of Authority

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held on 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest. It was decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form V- data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.

3.3. In this connection, it is stated that NPPA has earlier not fixed the retail price of FDCs of Vildagliptin (SR)+ Metformin (IR/SR), and the data for the same is also not available in the Pharmatrac database. Therefore, the retail price of FDCs of Vildagliptin (SR)+ Metformin (SR) are proposed to be fixed in line with the methodology decided 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) for the calculation of retail price of the FDC of Sitagliptin + Metformin tablet in line with the 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 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.

3.4. The Authority further approved the retail prices of FDCs as stated in above para 2.2 in its 97th, 99th, 100th, 101st, 102nd, 103rd, 106th and 109th meeting dated 06.05.2022, 28.06.2022, 05.08.2022, 07.09.2022, 27.09.2022, 10.11.2022, 30.12.2022 and 21.02.2023 based on the recommendation made by the Multidisciplinary Committee of Experts in its 41st, 42nd, 43rd, 44th, 45th, 46th, 47th and 48th meeting dated 08.04.2022, 02.06.2022, 04.07.2022, 04.08.2022, 13.09.2022, 19.10.2022, 02.12.2022 and 20.01.2023 as per the above mentioned methodology.

3.5. Accordingly, the retail price of these FDCs was calculated in line with principles as adopted earlier i.e., reduction of 50% from the patented component i.e., Vildagliptin SR [termed as (b)] and then adding the ceiling price of the scheduled components as applicable six month earlier from the date of application [termed as (c)]. From the total, a reduction of 20% of the lower of (b) and (c) is provided drawing reference from para No. 3.2 of Pronab Sen Committee Report and also as per the precedent followed in the similar cases.

3.6. Accordingly, the Committee deliberated upon the same and recommended the retail price of FDCs of Dapagliflozin + Vildagliptin (as sustained release) + Metformin (as sustained release) tablet for various companies as detailed below:

3.6.1- Each film coated bilayered tablet contains: Vildagliptin (as sustained release) 100mg + Metformin Hydrochloride IP (as sustained release) 500mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd (marketer) at Rs. 7.36 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32
(b)	50% of Patent Component		5.66
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.36
(f)	Claimed Retail price		12.50
(g)	Retail price as per Pharmatrac Data for June, 2022		NA
(h)	Recommended retail price		7.36

3.6.2- Each film coated bilayered tablet contains: Vildagliptin (as sustained release) 100mg + Metformin Hydrochloride IP (as sustained release) 500mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Torrent Pharmaceuticals Ltd (marketer) at Rs. 7.36 per tablet excluding GST as detailed below:

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32
(b)	50% of Patent Component		5.66
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.36
(f)	Claimed Retail price		13.50
(g)	Retail price as per Pharmatrac Data for June, 2022		NA
(h)	Recommended retail price		7.36

3.6.3- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 500mg (as Sustained Release) for M/s Synkem Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Zydus Healthcare Limited (marketer) at Rs. 7.43per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.43
(f)	Claimed Retail price		20.00
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		7.43

3.6.4- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 500mg (As Sustained Release) for M/s Synkem pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Lupin Limited (marketer) at Rs. 7.43per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13

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S. No.	Particulars	Source/Method	Amount (Rs.)
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.43
(f)	Claimed Retail price		13.39
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		7.43

3.6.5- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 500mg (As Sustained Release) for M/s Synokem pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Limited (marketer) at Rs. 7.43per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.43
(f)	Claimed Retail price		22.32
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		7.43

3.6.6- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 500mg (As Sustained Release) for M/s Synokem pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Cipla Limited (marketer) at Rs. 7.43per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	2.13
(d)	Less 20% of the lower of (b) and (c)		0.43
(e)	Worked out Retail Price (b)+(c)-(d)		7.43
(f)	Claimed Retail price		25.00
(g)	Retail price as per Pharmatrac Data for July, 2022		NA

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S. No.	Particulars	Source/Method	Amount (Rs.)
(h)	Recommended retail price		7.43

3.6.7- Each film coated bilayered tablet contains: Vildagliptin (as sustained release) 100mg + Metformin Hydrochloride IP (as sustained release) 1000mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Intas Pharmaceuticals Ltd (marketer) at Rs. 8.90 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32
(b)	50% of Patent Component		5.66
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.90
(f)	Claimed Retail price		15.00
(g)	Retail price as per Pharmatrac Data for June, 2022		NA
(h)	Recommended retail price		8.90

3.6.8- Each film coated bilayered tablet contains: Vildagliptin (as sustained release) 100mg + Metformin Hydrochloride IP (as sustained release) 1000mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Torrent Pharmaceuticals Ltd (marketer) at Rs. 8.90 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per June, 2022 data)	11.32
(b)	50% of Patent Component		5.66
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.90
(f)	Claimed Retail price		14.50
(g)	Retail price as per Pharmatrac Data for June, 2022		NA
(h)	Recommended retail price		8.90

3.6.9- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 1000mg (as Sustained Release) for M/s Synkem Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Lupin Limited (marketer) at Rs. 8.97 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
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	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.97
(f)	Claimed Retail price		15.17
(g)	Retail price" as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		8.97

3.6.10- Each film coated bilayered tablet contains: Vildagliptin (as sustained release) 100mg + Metformin Hydrochloride IP (as sustained release) 1000mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Zydus Healthcare Limited (marketer) at Rs. 8.97per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.97
(f)	Claimed Retail price		25.00
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		8.97

3.6.11- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 1000mg (as Sustained Release) for M/s Synokem Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Eris Lifesciences Limited (marketer) at Rs. 8.97per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05

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(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.97
(f)	Claimed Retail price		26.78
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		8.97

3.6.12- Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) + Metformin Hydrochloride IP 1000mg (as Sustained Release) for M/s Synokem Pharmaceuticals Pvt. Ltd. (manufacturer) and M/s Cipla Limited (marketer) at Rs. 8.97 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Patent Component		
(a)	Calculated retail price of Vildagliptin 100 mg (as sustained Release) tablet	Retail price (as per July, 2022 data)	11.46
(b)	50% of Patent Component		5.73
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1499(E) dated 30.03.2022]	4.05
(d)	Less 20% of the lower of (b) and (c)		0.81
(e)	Worked out Retail Price (b)+(c)-(d)		8.97
(f)	Claimed Retail price		30.00
(g)	Retail price as per Pharmatrac Data for July, 2022		NA
(h)	Recommended retail price		8.97

4. Agenda No. 4- Each Sachet of 4.38g contains: Zinc Sulphate Monohydrate IP 0.011g + Sodium Citrate IP 0.58g + Potassium Chloride IP 0.30g + Sodium Chloride IP 0.52g + Dextrose Anhydrous IP 2.70g for M/s FDC Ltd. (manufacturer) and M/s FDC Ltd. (marketer)

4.1 The committee deliberated on the matter and recommended the retail price for Each Sachet of 4.38g containing Zinc Sulphate Monohydrate IP 0.011g + Sodium Citrate IP 0.58g + Potassium Chloride IP 0.30g + Sodium Chloride IP 0.52g + Dextrose Anhydrous IP 2.70g for M/s FDC Ltd. (manufacturer) and M/s FDC Ltd. (marketer) of Rs. 6.12 per ml excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each Sachet of 4.38g contains: Zinc Sulphate Monohydrate IP 0.011g + Sodium Citrate IP 0.58g + Potassium Chloride IP 0.30g + Sodium Chloride IP 0.52g + Dextrose Anhydrous IP 2.70g		
(a)	Calculated retail price of Zinc Sulphate Monohydrate IP 0.011g	Note 1	2.23
(b)	Sodium Citrate IP 0.58g + Potassium Chloride IP 0.30g + Sodium Chloride IP 0.52g + Dextrose Anhydrous IP	Ceiling Prices of ORS Sachet (as per Notification)	4.33

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	2.70g (ORS Sachet)	No. 1499(E) dated 30.03.2022 (0.99 per GM *)	
(d)	Less 20% of the lower of (b) and (c)		0.44
(e)	Worked out Retail Price (b)+(c)-(d)		6.12
(f)	Claimed Retail price		10.00
(g)	Recommended retail price		6.12

Note 1 : Calculation of Retail Price of Zinc Sulphate Monohydrate IP 0.011g powder

(i) Present applicable ceiling price of Zinc Sulphate Dispersible Tablet 20 mg =

Rs 3.49 per tablet.

(ii) Therefore, the derived Retail Price for Zinc Sulphate Monohydrate IP 0.011 g or 11 mg =

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

P* = price ceiling for reference strength

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables

Accordingly, the committee recommended as below by applying the Pronab Sen formula to Zinc Sulphate Dispersible Tablet 20 mg:

$$= 3.49[1+0.8\{(11-20)/20\}] = \text{Rs. 2.23 (excluding GST)}$$

5. Agenda No. 5 - Retail price fixation under Para 5 of DPCO, 2013 - Each dose of 0.5ml containing Diphtheria Toxoid \geq 30IU, Tetanus Toxoid \geq 60IU, Inactivated w-B.pertussis \geq 4 IU Purified capsular polysaccharide of Haemophilus influenzae type b conjugated to 18-33 μ g of Tetanus Toxoid (carrier protein) 10 μ g, Inactivated Salk Poliovirus Type 1* 40 DU, Inactivated salk Poliovirus Type 2* 8 DU**, Inactivated Salk Poliovirus Type 3* 32 DU**, Aluminium content (Al+++)
(As Aluminium Phosphate gel NMT 1.25mg, 2-Phenoxyethanol 3.3mg and Physiological saline q.s. for M/s Panacea Biotech Ltd. (Manufacturer and marketer).**

5.1 The matter relates to retail price fixation of Vaccine for M/s Panacea Biotech Limited. The matter was deliberated in the 48th meeting of the MDC held on 20.01.2023, wherein the committee noted that other similar vaccines (Easy Four TT, Easy FIVE TT, Easy Six) of the applicant company (M/s Panacea Biotech Ltd.) are available at much lower prices. After deliberating the matter, the committee had directed as follows:

- To check whether the applicant company has applied for retail price fixation of their other vaccines i.e. Easy Four TT, Easy FIVE TT and Easy Six? If yes, retail prices calculated; if not necessary action may be taken.
- The applicant company may be asked to present their case in next MDC

5.2 The committee noted the reply of the company dated 10.02.2023 wherein the company had stated that it had inadvertently submitted form I for price approval to NPPA and that the applied vaccine (Easy four Pol) is covered under Patent bearing No. 272351 dated 30.03.2016. Hence, it requested to ignore Form I application and consider the same under the exemption of pre approval of price as per Para 32 of DPCO 2013.

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5.3 With respect to Easy Four TT, the company replied that it had obtained the price approval from NPPA and the price was notified by NPPA vide SO No. 6253 dated 21.12.2018.

5.4 With respect to Easy Five, it was informed by the company that this vaccine was non scheduled at the time of its launch and later when the ceiling price of the same was notified by NPPA in 2017, the same was implemented by the company

5.5 With respect to Easy Six, the company mentioned that it had filed an intimation regarding grant of patent no. 272351 corresponding to this product.

5.6 The committee deliberated upon the explanation of the company in detail and directed that:

- i. M/s Panacea Biotec Limited may apply a fresh under Para 32 if the exemption is to be sought in respect of the applied new drug. The exemption under para 32 is not self-invocable. After receiving the application for exemption under Para 32, NPPA shall examine the same for further deliberations by MDC.
- ii. Necessary action may be taken for the vaccine Easy Six in respect of which no exemption was sought by the company under para 32 from NPPA and the same was launched without price approval of NPPA.

6. Agenda No. 6-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.

6.1 The matter relates to the review order passed by DoP on 03.10.2022 w.r.t. review application dated 24.01.2020 against National Pharmaceutical Pricing Authority's ("NPPA" herein) notification SO. No. 2944(E) dated 14.08.2019 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 IP 100 mcg Inhaler (MDI).

6.2 The matter was deliberated in the 47th meeting of MDC held on 02.12.2022, wherein company representatives were also present. 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.

6.3 The committee noted that a letter was sent to M/s Cipla Limited on 27.12.2022 requesting to submit the inputs by 10.01.2023. M/s Cipla Limited vide letter dated 09.01.2023 requested to allow one month time to submit their response. The committee was appraised that even as on date of meeting (23.02.2023), the requisite details have not been received.

6.4 The committee deliberated on the matter and directed that a reminder may be issued to M/s Cipla Limited giving one week time to submit the requisite details and if the same are not received within the due time, the matter shall be treated as closed.



7. Agenda No. 7-Retail price fixation under DPCO, 2013- Each ml contains Ibuprofen IP 100mg for M/s Akums Drugs & Pharmaceuticals (manufacturer) and M/s Cipla Ltd. (marketer) (F.No. 3099)

7.1. The matter relates to the retail price fixation of Each ml contains Ibuprofen IP 100mg for M/s Akums Drugs & Pharmaceuticals (manufacturer) and M/s Cipla Ltd. (marketer). The matter was deliberated in the 48th meeting of MDC held on 20.01.2023, wherein committee recommended retail price of Rs. 5.05 per ml calculated taking the ceiling price of Diclofenac Injection 25 mg/ml as base as against the claim price of Rs.26.78 per ml (excluding taxes) by the company.

7.2 The committee noted that M/s Cipla Limited had filed representation dated 07.02.2023 stating that the drug with same dosage & strength is imported and sold by another company at prices almost double (i. e Rs. 74.375 per ML. Applicant has also stated that there are no other manufacturers of the said formulation and notifying retail price suggested by MDC will lead to discouragement of launches of innovative drugs in India. Therefore, applicant had requested to fix retail price in line with the market available formulation or as claimed by the company.

7.3 The committee deliberated on the matter and directed to collect the data from companies (suggested by M/s Cipla Limited and also identified from Websources) and Hospitals/Institutions in this respect and then resubmit the matter to MDC.

The meeting ended with a vote of thanks to all.

Rashmi
3/2/23
(Rashmi Tahiliani)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

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

Each film coated tablet containing Dapagliflozin Propionedial Monohydrate (eq. to Dapagliflozin 10mg)

Number of Companies consisting of Market Share of 1% & Above	14
Sum of MAT value considered for price calculation (in lakhs)	38,870.13
Sum of PTR per unit considered for price calculation	206.47
Number of Packs considered	16
Average PTR	12.90
Add : 16% Retailer Margin	2.06
Retail Price (without local taxes)	14.96
% Reduction with compared to Highest Price	68.51%

Minimum Price (Rs.)	7.74
Maximum Price (Rs.)	40.96
Average of all considered (Rs.)	12.90
Retail Price (Rs.)	14.96

S.No.	पैक विवरण Pack Description	ब्रैंड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	4,46,92,95,067	100%	M3			
								MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (V/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 LIFESCIENCE PVT LTD	10 MG	10	TABLET	85.00	774860	0.02%	0.02%	N	8.50	
2	4 DAPA M 10 MG TABLET 10	4 DAPA M	4 CARE LIFESCIENCE PVT LTD	10 MG	10	TABLET	100.00	4300	0.00%	0.00%	N	10.00	
3	BIOXIGA 10 MG TABLET 10	BIOXIGA	BIOS LAB PVT.LTD	10 MG	10	TABLET	102.85	698143	0.02%	0.02%	N	10.29	
4	DAGLIPACK 10 MG TABLET 10	DAGLIPACK	KOYE PHARMACEUTICALS PVT. LTD.	10 MG	10	TABLET	99.29	5053067	0.11%	0.11%	N	9.93	
5	DAJIO 10 MG TABLET 15	DAJIO	MICRO LABS LTD	10 MG	15	TABLET	126.43	41671202	0.93%	0.93%	N	8.43	
6	DAMITA 10 MG TABLET 10	DAMITA	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	96998896	2.17%	2.17%	Y	10.64	10.64
7	DAPA GOLD 10 MG TABLET 15	DAPA GOLD	HBC LIFESCENCES PVT LTD	10 MG	15	TABLET	150.00	15213495	0.34%	0.34%	N	10.00	
8	DAPABEST 10 MG TABLET 10	DAPABEST	PANACEA BIOTEC LTD	10 MG	10	TABLET	100.00	12009600	0.27%	0.27%	N	10.00	
9	DAPABITE 10 MG TABLET 10	DAPABITE	CORONA	10 MG	10	TABLET	117.07	106559125	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	459820	0.01%	0.01%	N	8.21	
11	DAPACARE 10 MG TABLET 10	DAPACARE	OC TALIFE PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	78.57	472441	0.01%	0.01%	N	7.86	
12	DAPACONIC 10 MG TABLET 15	DAPACONIC	LA RENON	10 MG	15	TABLET	181.07	3112774	0.07%	0.07%	N	12.07	
13	DAPACOSE 10 MG TABLET 10	DAPACOSE	JB CHEMICALS	10 MG	10	TABLET	94.25	36552896	0.82%	0.82%	N	9.43	
14	DAPADEL 10 MG TABLET 10	DAPADEL	CADELL HEALTH CARE PVT.LTD	10 MG	10	TABLET	92.14	4137752	0.09%	0.09%	N	9.21	
15	DAPAFASE 10 MG TABLET 10	DAPAFASE	JUBILANT GENERICS LIMITED	10 MG	10	TABLET	103.57	1263968	0.03%	0.03%	N	10.36	
16	DAPAFOR 10 MG TABLET 10	DAPAFOR	ZUVENTUS HEALTHCARE LTD	10 MG	10	TABLET	75.00	23400	0.00%	0.00%	N	7.50	
17	DAPAGAIN 10 MG TABLET 15	DAPAGAIN	SYSTOPIK LABORATORIES LTD-NEM	10 MG	15	TABLET	63.22	14273748	0.32%	0.32%	N	4.21	
18	DAPAGLYN 10 MG TABLET 15	DAPAGLYN	ZYDUS CADILA ZHL	10 MG	15	TABLET	200.36	264281592	5.91%	5.91%	Y	13.36	13.36
19	DAPAGREAT 10 MG TABLET 15	DAPAGREAT	SINSAN PHARMACEUTICALS	10 MG	15	TABLET	142.14	4690620	0.10%	0.10%	N	9.48	
20	DAPAGZA 10 MG TABLET 15	DAPAGZA	EMCURE PHARMACEUTICALS LTD	10 MG	15	TABLET	159.64	925273	0.02%	0.02%	N	10.64	
21	DAPAHENZ 10 MG TABLET 15	DAPAHENZ	LA RENON	10 MG	15	TABLET	181.07	9395541	0.21%	0.21%	N	12.07	
22	DAPAKEY 10 MG TABLET 10	DAPAKEY	PRECIA PHARMA	10 MG	10	TABLET	103.57	7689762	0.17%	0.17%	N	10.36	
23	DAPALEX 10 MG TABLET 10	DAPALEX	AJANTA PHARMA LTD	10 MG	10	TABLET	110.71	38055596	0.85%	0.85%	N	11.07	
24	DAPAMAC 10 MG TABLET 10	DAPAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	10 MG	10	TABLET	106.43	156124378	3.49%	3.49%	Y	10.64	10.64
25	DAPANORM 10 MG TABLET 10	DAPANORM	ALKE M LABORATORIES LTD.	10 MG	10	TABLET	125.00	218550500	4.89%	4.89%	Y	12.50	12.50
26	DAPANOVA 10 MG TABLET 15	DAPANOVA	MEDLEY PHARMACEUTICALS	10 MG	15	TABLET	140.71	44151339	0.99%	0.99%	N	9.38	
27	DAPAOONE 10 MG TABLET 10	DAPAOONE	MISN LABORATORIES LTD.	10 MG	10	TABLET	107.14	30543578	0.68%	0.68%	N	10.71	
28	DAPARAY 10 MG TABLET 10	DAPARAY	ICON LIFESCENCES	10 MG	10	TABLET	69.64	1092721	0.02%	0.02%	N	6.96	
29	DAPARYL 10 MG TABLET 10	DAPARYL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	209664637	4.69%	4.69%	Y	9.29	9.29
30	DAPASIS 10 MG TABLET 10	DAPASIS	AKESIS PHARMA (P) LTD	10 MG	10	TABLET	99.29	8350885	0.19%	0.19%	N	9.93	
31	DAPASPEC 10 MG TABLET 10	DAPASPEC	SPECTRA THERAPEUTICS PVT. LTD.	10 MG	10	TABLET	96.43	1868421	0.04%	0.04%	N	9.64	
32	DAPATEN 10 MG TABLET 15	DAPATEN	BAL PHARMA	10 MG	15	TABLET	117.54	327937	0.01%	0.01%	N	7.84	
33	DAPATEND 10 MG TABLET 14	DAPATEND	JANTHEMBOPHARMA PVT. LTD	10 MG	14	TABLET	117.86	6208185	0.14%	0.14%	N	8.42	
34	DAPATURN 10 MG TABLET 10	DAPATURN	ICON LTD	10 MG	10	TABLET	103.57	33750874	0.76%	0.76%	N	10.36	
35	DAPAVEL 10 MG TABLET 10	DAPAVEL	INTAS PHARMACEUTICALS LTD	10 MG	10	TABLET	92.86	259692316	5.81%	5.81%	Y	9.29	9.29

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

Each, uncoated bilayered tablet contains: Vildagliptin 100 mg (as sustained release)	Number of Companies consisting of Market Share of 1% & Above	18
	Sum of MAT value considered for price calculation (In Lakhs)	8,157.94
	Sum of PTR per unit considered for price calculation	214.69
	Number of Packs considered	22
	Average PTR	9.76
	Add : 16% Retailer Margin	1.56
	Retail Price (without local taxes)	11.32
	% Reduction with compared to Highest Price	64.04%

Minimum Price (Rs.)	7.07
Maximum Price (Rs.)	27.14
Average of all considered (Rs.)	9.76
Retail Price (Rs.)	11.32

S.No.	Pack Description	BRAND	Company	Strength	Pack Size	Unit	PTR	84,82,08,341	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	ABVIDA 100 MG TABLET SR 15	ABVIDA	ABBOTT HEALTHCARE PVT. LTD	100 MG	15	TABLET SR	139.29	12960238	1.53%	1.53%	Y	9.29	9.29
2	BIOVILDA 100 MG TABLET SR 10	BIOVILDA	BIO'S LAB PVT.LTD	100 MG	10	TABLET SR	90.00	439740	0.05%	0.05%	N	9.00	
3	ENCELIN OD 100 MG TABLET 10	ENCELIN	TORRENT PHARMACEUTICALS LTD.	100 MG	10	TABLET	78.57	39774884	4.69%	4.69%	Y	7.86	7.86
4	GALVUS OD 100 MG TABLET 15	GALVUS	NOVARTIS INDIA LTD	100 MG	15	TABLET	407.15	45654544	5.38%	5.38%	Y	27.14	27.14
5	GLIPACURE OD 100 MG TABLET 15	GLIPACURE	HBC LIFESCIENCES PVT LTD	100 MG	15	TABLET	117.86	220045	0.03%	0.03%	N	7.86	
6	GLIPTAGRE AT OD 100 MG TABLET 10	GLIPTAGRE AT	MANKIND PHARMACEUTICALS LTD.	100 MG	10	TABLET	70.71	36313545	4.28%	4.28%	Y	7.07	7.07
7	GLUPY OD 100 MG TABLET SR 15	GLUPY	ALEMBC LTD	100 MG	15	TABLET SR	128.57	11088905	1.31%	1.31%	Y	8.57	8.57
8	GLUVILDA OD 100 MG TABLET 15	GLUVILDA	ALKEM LABORATORIES LTD.	100 MG	15	TABLET	117.86	46010997	5.42%	5.42%	Y	7.86	7.86
9	IBVILDA OD 100 MG TABLET SR 10	IBVILDA	INDIAGULLS PHARMACEUTICALS LTD	100 MG	10	TABLET SR	89.29	522257	0.06%	0.06%	N	8.93	
10	INTAGLIP OD 100 MG TABLET 10	INTAGLIP	INTAS PHARMACEUTICALS LTD	100 MG	10	TABLET	107.07	28280827	3.33%	3.33%	Y	10.71	10.71
11	JALRA OD 100 MG TABLET 10	JALRA	USV PVT LTD	100 MG	10	TABLET	128.57	186252545	21.96%	21.96%	Y	12.86	12.86
12	JUBIVILDA 100 MG TABLET 15	JUBIVILDA	JUBILANT GENERICS LIMITED	100 MG	15	TABLET	107.14	2361044	0.28%	0.28%	N	7.14	
13	Q VILDALOG 100 MG TABLET 10	Q VILDALOG	IWOCKHARDT LTD	100 MG	10	TABLET	142.86	7152286	0.84%	0.84%	N	14.29	
14	TORGLIP OD 100 MG TABLET 10	TORGLIP	TORRENT PHARMACEUTICALS LTD.	100 MG	10	TABLET	78.57	23659391	2.79%	2.79%	Y	7.86	7.86
15	VERIFICA 100 MG TABLET SR 10	VERIFICA	LUPIN LTD	100 MG	10	TABLET SR	114.29	24800587	2.92%	2.92%	Y	11.43	11.43
16	VIBITE 100 MG TABLET SR 15	VIBITE	CORONA	100 MG	15	TABLET SR	116.68	8617292	1.02%	1.02%	Y	7.78	7.78
17	VIDAGLO OD 100 MG TABLET 10	VIDAGLO	MEDLEY PHARMACEUTICALS	100 MG	10	TABLET	92.86	2619488	0.31%	0.31%	N	9.29	
18	VILACT 100 MG TABLET SR 10	VILACT	MANKIND PHARMACEUTICALS LTD.	100 MG	10	TABLET SR	107.14	1302072	0.15%	0.15%	N	10.71	
19	VILAPIL SR 100 MG TABLET 10	VILAPIL SR	CADELL HEALTH CARE PVT.LTD	100 MG	10	TABLET	67.86	111019	0.01%	0.01%	N	6.79	
20	VILASON OD 100 MG TABLET 10	VILASON	UNISON PHARMACEUTICALS	100 MG	10	TABLET	42.86	794153	0.09%	0.09%	N	4.29	
21	VILATIN 100 MG TABLET SR 15	VILATIN	AVANTA PHARMA LTD	100 MG	15	TABLET SR	128.03	15584350	1.84%	1.84%	Y	8.60	8.60
22	VILDABLIS 100 MG TABLET SR 10	VILDABLIS	MED MANOR ORGANICS PVT LTD.	100 MG	10	TABLET SR	85.71	12321	0.00%	0.00%	N	8.57	
23	VILDAMAC OD 100 MG TABLET 15	VILDAMAC	MACLEOD'S PHARMACEUTICALS PVT.LTD	100 MG	15	TABLET	128.57	24494771	2.89%	2.89%	Y	8.57	8.57
24	VILDAMBIC OD 100 MG TABLET 10	VILDAMBIC	ALEMBC LTD	100 MG	10	TABLET	70.71	648764	0.08%	0.08%	N	7.07	
25	VILDANA 100 MG TABLET SR 10	VILDANA	AKESISS PHARMA (P) LTD	100 MG	10	TABLET SR	85.00	5428100	0.64%	0.64%	N	8.50	
26	VILDANIX SR 100 MG TABLET 10	VILDANIX SR	LYOYD HEALTHCARE PVT.LTD	100 MG	10	TABLET	78.58	4949754	0.58%	0.58%	N	7.86	
27	VILDAPRIDE OD 100 MG TABLET 10	VILDAPRIDE	MICRO LABS LTD	100 MG	10	TABLET	85.71	23647646	2.79%	2.79%	Y	8.57	8.57
28	VILDAPRIME 100 MG TABLET SR 15	VILDAPRIME	PRIMUS REMEDIES PVT LTD	100 MG	15	TABLET SR	117.86	1393695	0.16%	0.16%	N	7.86	
29	VILDARAY SR 100 MG TABLET 10	VILDARAY SR	LYOYD HEALTHCARE PVT.LTD	100 MG	10	TABLET	78.58	13051431	1.54%	1.54%	Y	7.86	7.86
30	VILDASPC C 100 MG TABLET SR 10	VILDASPC C	SPECTRA THERAPEUTICS PVT. LTD.	100 MG	10	TABLET SR	67.86	643041	0.08%	0.08%	N	6.79	
31	VILMUR OD 100 MG TABLET 15	VILMUR	OPISICARE LIFESCIENCE PVT LTD	100 MG	15	TABLET	106.07	199199	0.02%	0.02%	N	7.07	
32	VILPOWER OD 100 MG TABLET 15	VILPOWER	MICRO LABS LTD	100 MG	15	TABLET	128.57	11313703	1.34%	1.34%	Y	8.57	8.57
33	VILSURE 100 MG TABLET SR 15	VILSURE	SINSON PHARMACEUTICALS	100 MG	15	TABLET SR	160.71	622751	0.07%	0.07%	N	10.71	
34	VILTAD 100 MG TABLET SR 15	VILTAD	ALTUS BIOGENICS PVT.LTD.	100 MG	15	TABLET SR	96.43	74059	0.01%	0.01%	N	6.43	
35	VINGLYN 100 MG TABLET SR 10	VINGLYN	ZYDUS CADILA - ZHL	100 MG	10	TABLET SR	86.04	17002984	2.00%	2.00%	Y	8.60	8.60
36	VISMALI OD 100 MG TABLET 10	VISMALI	DR. REDDYS LABORATORIES LTD	100 MG	10	TABLET	71.43	2920558	0.34%	0.34%	N	7.14	
37	VYLDIA OD 100 MG TABLET 15	VYLDIA	EMCURE PHARMACEUTICALS LTD	100 MG	15	TABLET	159.64	85245365	10.05%	10.05%	Y	10.64	10.64
38	VYSOV 100 MG TABLET SR 15	VYSOV	CIPLA LTD.	100 MG	15	TABLET SR	138.21	45645511	5.38%	5.38%	Y	9.21	9.21
39	ZAVA OD 100 MG TABLET 10	ZAVA	INTAS PHARMACEUTICALS LTD	100 MG	10	TABLET	107.07	56779649	6.69%	6.69%	Y	10.71	10.71
40	ZOMILIS 100 MG TABLET SR 10	ZOMILIS	IRIS LIFESCIENCES LTD	100 MG	10	TABLET SR	78.57	41845910.58	4.93%	4.93%	Y	7.86	7.86

41	ZUKANORM 100 MG TABLET SR 10	ZUKANORM	MANKIND PHARMACEUTICALS LTD.	100 MG	10	TABLET SR	70.71	17748917.1	2.09%	2.09%	Y	7.07	7.07
		Rs. Per Tablet											
	Worked out Retail Price	11.32	Excluding GST										

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

Each uncoated bilayered tablet contains Vildagliptin 100 mg (as sustained release)	Number of Companies: consisting of Market Share of 1% & Above	18
	Sum of MAT value considered for price calculation (in Lakhs)	8,805.80
	Sum of PTR per unit considered for price calculation	217.45
	Number of Packs considered	22
	Average PTR	9.88
	Add: 16% Retailer Margin	1.58
	Retail Price (without local taxes)	11.46
% Reduction with compared to Highest Price	63.60%	

Minimum Price (Rs.)	7.07
Maximum Price (Rs.)	27.14
Average of all considered (Rs.)	9.88
Retail Price (Rs.)	11.46

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR	91,60,17,884		100%		Qualify (Y/N) Y=Yes N=No	M3	
								MAT (Rs.)	SKU wise MAT %	Brand wise MAT (Ignoring 0% MAT)	Price per unit (Rs.)		Price per unit (Rs.) Considered	
1	ABVIDA 100 MG TABLET SR 15	ABVIDA	ABBOTT HEALTHCARE PVT. LTD	100 MG	15	TABLET SR	139.29	14950414	1.63%	1.63%	Y	9.29	9.29	
2	BIOVILDA 100 MG TABLET SR 10	BIOVILDA	BIO S LAB PVT.LTD	100 MG	10	TABLET SR	90.00	455040	0.05%	0.05%	N	9.00	9.00	
3	ENCELIN OD 100 MG TABLET 10	ENCELIN	TORRENT PHARMACEUTICALS LTD.	100 MG	10	TABLET	78.57	41801361	4.56%	4.56%	Y	7.86	7.86	
4	GALVUS OD 100 MG TABLET 15	GALVUS	NOVARTIS INDIA LTD	100 MG	15	TABLET	407.15	51393730	5.61%	5.61%	Y	27.14	27.14	
5	GLIPACURE OD 100 MG TABLET 15	GLIPACURE	HBC LIFE SCIENCES PVT LTD	100 MG	15	TABLET	2721.39	272139	0.03%	0.03%	N	7.86	7.86	
6	GLIPTAGREAT OD 100 MG TABLET 10	GLIPTAGREAT	MANKIND PHARMACEUTICALS LTD.	100 MG	10	TABLET	70.71	40022567	4.37%	4.37%	Y	7.07	7.07	
7	GLIPY OD 100 MG TABLET SR 15	GLIPY	ALEMBC LTD	100 MG	15	TABLET SR	120.57	13885431	1.52%	1.52%	Y	8.57	8.57	
8	GLUVILDA OD 100 MG TABLET 15	GLUVILDA	ALKEM LABORATORIES LTD.	100 MG	15	TABLET	117.86	48593451	5.30%	5.30%	Y	7.86	7.86	
9	IBVILDA OD 100 MG TABLET SR 10	IBVILDA	INDIABULLS PHARMACEUTICALS LTD	100 MG	10	TABLET SR	89.29	578063	0.06%	0.06%	N	8.93	8.93	
10	INTAGLIP OD 100 MG TABLET 10	INTAGLIP	INTAS PHARMACEUTICALS LTD	100 MG	10	TABLET	107.07	29689119	3.24%	3.24%	Y	10.71	10.71	
11	JALRA OD 100 MG TABLET 10	JALRA	USV PVT LTD	100 MG	10	TABLET	128.57	198951147	21.72%	21.72%	Y	12.86	12.86	
12	JUBVILDA 100 MG TABLET 15	JUBVILDA	JUBILANT GENERICS LIMITED	100 MG	15	TABLET	107.14	2681500	0.29%	0.29%	N	7.14	7.14	
13	O VILDALOG 100 MG TABLET 10	O VILDALOG	WOCKHARDT LTD	100 MG	10	TABLET	142.86	6549702	0.72%	0.72%	N	14.29	14.29	
14	TORGLIP OD 100 MG TABLET 10	TORGLIP	TORRENT PHARMACEUTICALS LTD.	100 MG	10	TABLET	78.57	25488029	2.78%	2.78%	Y	7.86	7.86	
15	VERIFICA 100 MG TABLET SR 15	VERIFICA	LUPIN LTD	100 MG	15	TABLET SR	114.29	26813920	2.93%	2.93%	Y	11.43	11.43	
16	VIBITE 100 MG TABLET SR 15	VIBITE	CORONA	100 MG	15	TABLET SR	116.68	9642863	1.05%	1.05%	Y	7.78	7.78	
17	VIDAGLO OD 100 MG TABLET 10	VIDAGLO	MEDLEY PHARMACEUTICALS	100 MG	10	TABLET	92.86	3250286	0.35%	0.35%	N	9.29	9.29	
18	VILACT 100 MG TABLET XR 10	VILACT	MANKIND PHARMACEUTICALS LTD.	100 MG	10	TABLET XR	107.14	1404177	0.15%	0.15%	N	10.71	10.71	
19	VILAPIL SR 100 MG TABLET 10	VILAPIL SR	CADELL HEALTH CARE PVT.LTD	100 MG	10	TABLET	67.86	192180	0.02%	0.02%	N	6.79	6.79	
20	VILASON OD 100 MG TABLET 10	VILASON	UNISON PHARMACEUTICALS	100 MG	10	TABLET	42.86	1008282	0.11%	0.11%	N	4.29	4.29	
21	VILATIN 100 MG TABLET SR 15	VILATIN	AJANTA PHARMA LTD	100 MG	15	TABLET SR	128.93	15933383	1.74%	1.74%	Y	8.60	8.60	
22	VILDABUS 100 MG TABLET SR 10	VILDABUS	MED MANOR ORGANICS PVT LTD.	100 MG	10	TABLET SR	85.71	15235	0.00%	0.00%	N	8.57	8.57	
23	VILDAMAC OD 100 MG TABLET 15	VILDAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	100 MG	15	TABLET	128.57	27104999	2.96%	2.96%	Y	8.57	8.57	
24	VILDAMBIC OD 100 MG TABLET 10	VILDAMBIC	ALEMBC LTD	100 MG	10	TABLET	70.71	846116	0.09%	0.09%	N	7.07	7.07	
25	VILDANA 100 MG TABLET SR 10	VILDANA	AKESSIS PHARMA (P) LTD	100 MG	10	TABLET SR	85.00	5820800	0.64%	0.64%	N	8.50	8.50	
26	VILDANEX SR 100 MG TABLET 10	VILDANEX SR	LLOYD HEALTHCARE PVT.LTD	100 MG	10	TABLET	78.58	5381001	0.59%	0.59%	N	7.86	7.86	
27	VILDAPRIDE OD 100 MG TABLET 10	VILDAPRIDE	MICRO LABS LTD	100 MG	10	TABLET	85.71	25029977	2.73%	2.73%	Y	8.57	8.57	
28	VILDAPRIME 100 MG TABLET SR 15	VILDAPRIME	PRIMUS REMEDIES PVT LTD	100 MG	15	TABLET SR	117.86	1741028	0.19%	0.19%	N	7.86	7.86	
29	VILDARAY SR 100 MG TABLET 10	VILDARAY SR	LLOYD HEALTHCARE PVT.LTD	100 MG	10	TABLET	78.58	14385012	1.57%	1.57%	Y	7.86	7.86	
30	VILDASPEC 100 MG TABLET SR 10	VILDASPEC	SPECTRA THERAPEUTICS PVT. LTD.	100 MG	10	TABLET SR	74.65	694667	0.08%	0.08%	N	7.47	7.47	
31	VILMUR OD 100 MG TABLET 15	VILMUR	OPISICARE LIFE SCIENCES PVT LTD	100 MG	15	TABLET	106.07	284480	0.34%	0.34%	N	7.07	7.07	
32	VILPOWER OD 100 MG TABLET 15	VILPOWER	MICRO LABS LTD	100 MG	15	TABLET	128.57	12343749	1.35%	1.35%	Y	8.57	8.57	
33	VILSURE 100 MG TABLET SR 15	VILSURE	SINSAN PHARMACEUTICALS	100 MG	15	TABLET SR	160.71	582092	0.06%	0.06%	N	10.71	10.71	
34	VILTAB 100 MG TABLET SR 15	VILTAB	ALTEUS BIOGENICS PVT.LTD.	100 MG	15	TABLET SR	96.43	88523	0.01%	0.01%	N	6.43	6.43	
35	VINGLYN 100 MG TABLET SR 10	VINGLYN	ZYDUS CADILA - ZHL	100 MG	10	TABLET SR	86.04	18207301	1.99%	1.99%	Y	8.60	8.60	
36	VINSORIN OD 100 MG TABLET 10	VINSORIN	FUSION HEALTHCARE PVT LTD	100 MG	10	TABLET	89.29	254387	0.03%	0.03%	N	8.93	8.93	
37	VSMALL OD 100 MG TABLET 10	VSMALL	DR. REDDYS LABORATORIES LTD	100 MG	10	TABLET	71.43	3338567	0.36%	0.36%	N	7.14	7.14	
38	VYLD A OD 100 MG TABLET 15	VYLD A	EMCURE PHARMACEUTICALS LTD	100 MG	15	TABLET	175.43	91545883	9.99%	9.99%	Y	11.70	11.70	
39	VYSOV 100 MG TABLET XR 15	VYSOV	CIPLA LTD.	100 MG	15	TABLET XR	138.21	50346586	5.50%	5.50%	Y	9.21	9.21	
40	ZAVA OD 100 MG TABLET 10	ZAVA	INTAS PHARMACEUTICALS LTD	100 MG	10	TABLET	117.14	60560882	6.61%	6.61%	Y	11.71	11.71	

