

National Pharmaceutical Pricing Authority

**Subject: Minutes of the 40<sup>th</sup> meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 at 11:00 AM.**

40<sup>th</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 14.03.2022 at 11:00 A.M. under the convenorship of Shri Manmohan Sachdeva, Advisor (Cost), through video-conferencing. The following members attended the meeting through video conferencing:-

1. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
2. Dr. J. J. Cherian, Scientist-D, ICMR
3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli
4. Dr. Pooja Gupta, Associate Professor, Department of Pharmacology, AIIMS-New Delhi,
5. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoea Commission – Co-opted member

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing)
2. Shri Prasenjit Das, Deputy Director (Pricing), NPPA
3. Shri Mahaveer Saini, Deputy Director (Pricing), NPPA

**1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013-Each vial contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1%lg G3, 10% Ig G4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer)**

1.1 The Committee noted that M/s Intas Pharmaceuticals Ltd made a representation dated 04.03.2022 based on the decision taken by the Committee in its 37<sup>th</sup>, 38<sup>th</sup> and 39<sup>th</sup> meeting held on 25.11.2021, 24.01.2022 and 25.02.2022 respectively and examined the same. The Committee deliberated upon the matter in detail and reiterated its earlier decision taken in the 39<sup>th</sup> meeting held on 25.02.2022 that an additional 15% increase over the present applicable ceiling price of Normal Human Immunoglobulin 5% infusion be allowed to the subject formulation of M/s Intas Pharmaceuticals Ltd for incremental innovation.

1.2 Accordingly, the Committee recommended the retail price of each vial of Human Normal Immunoglobulin 5% solution (Ig M enriched) which contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1%lg G3, 10% Ig

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G4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer) at Rs. 177.85 per ml [Rs. 154.65 per + additional 15% increment] excluding GST.

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

2.1 The Committee noted that eight applications have been received for retail price fixation of three Fixed Dose Combinations (FDCs) of Linagliptin and Metformin tablets i.e. (i) Linagliptin 2.5 mg + Metformin 500 mg tablet, (ii) Linagliptin 2.5 mg + Metformin 850 mg tablet and (iii) Linagliptin 2.5 mg + Metformin 1000 mg tablet. The Committee further noted that the formulation 'Linagliptin' has become/ on the verge of becoming off-patent.

2.2. The Committee recalled the decision taken in its 33<sup>rd</sup> meeting dated 21.06.2021 and approved by the Authority in its 89<sup>th</sup> meeting dated 28.06.2021 regarding retail price fixation of FDCs of 'Saxagliptin and Metformin tablet' in which the formulation 'Saxagliptin' become off-patent on 05.03.2021 which are as follows:

*"...The Committee noted that the patent of formulation 'Saxagliptin' has expired on 05.03.2021. Accordingly, the retail price of the Fixed Dose Combinations (FDCs) of Metformin + Saxagliptin tablet, if calculated based on six month prior market data, the price of the patented period would be taken into consideration and hence the benefits of price rationalisation due to expiry of the patent would not be pass on to the patients."*

2.3 The Committee observed that the market data of the FDCs of Linagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Linagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price for the FDCs of Linagliptin and Metformin tablet in line with the decision taken in its 33<sup>rd</sup> 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.

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

2.4.1 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Natco Pharma Limited (Marketer) and M/s Optimus Pharma Private Limited (Manufacturer) at Rs. 8.04 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
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	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) - (f)		14.651
(h)	Claimed Retail Price		8.04
(i)	Retail Price as per Pharmatrac based on July 2021 data		23.93
(j)	Recommended Retail Price		8.04

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where:

P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles

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

2.4.2 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Emcure Pharmaceuticals Limited (Marketer) and M/s MSN Laboratories Private limited (Manufacturer) at Rs. 14.651 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) - (f)		14.651
(h)	Claimed Retail Price		23.93
(i)	Retail Price as per Pharmatrac based on July		23.93

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	2021 data		
(j)	Recommended Retail Price		14.651

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.3 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Eris Lifesciences Limited (Marketer) and M/s MSN Laboratories Private limited (Manufacturer) at Rs. 14.651 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) - (f)		14.651
(h)	Claimed Retail Price		17.86
(i)	Retail Price as per Pharmatrac based on July 2021 data		23.93
(j)	Recommended Retail Price		14.651

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.4 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg for M/s Micro Labs Limited (Marketer & Manufacturer) at Rs. 10.63 per tablet excluding GST as detailed below:

S.	Particulars	Source/Method	Amount
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No.			(Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 500mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 500 mg	Ceiling Price	1.51
(e)	Sub of (c) and (d)		14.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.302
(g)	Worked Out Retail Price (e) - (f)		14.651
(h)	Claimed Retail Price		10.63
(i)	Retail Price as per Pharmatrac based on July 2021 data		23.93
(j)	Recommended Retail Price		10.63

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.5 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Natco Pharma Limited (Marketer) and M/s Optimus Pharma Private Limited (Manufacturer) at Rs. 8.37 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg	Ceiling Price	3.61
(e)	Sub of (c) and (d)		17.053
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.722
(g)	Worked Out Retail Price (e) - (f)		16.331
(h)	Claimed Retail Price		8.37

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(i)	Retail Price as per Pharmatrac based on July 2021 data	24.88
(j)	Recommended Retail Price	8.37

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.6 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Emcure Pharmaceuticals Limited (Marketer) and M/s MSN Laboratories Private limited (Manufacturer) at Rs. 16.331 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg	Ceiling Price	3.61
(e)	Sub of (c) and (d)		17.053
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.722
(g)	Worked Out Retail Price (e) - (f)		16.331
(h)	Claimed Retail Price		24.91
(i)	Retail Price as per Pharmatrac based on July 2021 data		24.88
(j)	Recommended Retail Price		16.331

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.7 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg for M/s Micro Labs Limited (Marketer & Manufacturer) at Rs. 11.52 per tablet excluding GST as detailed below:

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S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 1000mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 1000 mg	Ceiling Price	3.61
(e)	Sub of (c) and (d)		17.053
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.722
(g)	Worked Out Retail Price (e) - (f)		16.331
(h)	Claimed Retail Price		11.52
(i)	Retail Price as per Pharmatrac based on July 2021 data		24.88
(j)	Recommended Retail Price		11.52

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where: P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles  
P(s) = 44.81 [1+0.8{2.5-5/5}] = 26.886

2.4.8 Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 850mg for M/s Emcure Pharmaceuticals Limited (Marketer) and M/s MSN Laboratories Private limited (Manufacturer) at Rs. 15.451 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Linagliptin 2.5mg + Metformin Hydrochloride IP 850mg		
(a)	Derived retail price of Linagliptin 5mg	Retail price (as per July 2021 data)	44.81
(b)	Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report (Note)		26.886
(c)	50% of (b)		13.443
(d)	Metformin 850 mg (July, 2021)	Retail Price	2.51
(e)	Sub of (c) and (d)		15.953
(f)	Less: 20% of the lowest of (c) and (d) as recommended in the Pronab Sen Committee report		0.502
(g)	Worked Out Retail Price (e) - (f)		15.451

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(h)	Claimed Retail Price	24.38
(i)	Retail Price as per Pharmatrac based on July 2021 data	24.36
(j)	Recommended Retail Price	15.451

Note: Derived retail price of Linagliptin 2.5mg as per Pronab Sen Committee Report

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

Where:

P(s) = Price of the strength s  
P\* = Price of the reference strength s\*  
S = Strength in terms of API content  
S\* = reference strength  
A = 0.8 for pack / capsule and 0.7 for injectibles

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

2.5 The committee also noted that the therapeutic category of all the above FDC of Linagliptin and Metformin is Antidiabetic. However, the same has been stated inadvertently as Antihypertensive.

### 3. Agenda No. 3 - Retail price fixation under Para 5 of DPCO, 2013 - Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablet.

3.1 The Committee noted that ten applications have been received for retail price fixation of three Fixed Dose Combinations (FDCs) of Sitagliptin and Metformin tablets i.e. (i) Sitagliptin 50 mg + Metformin 500 mg tablet, (ii) Sitagliptin 50 mg + Metformin 1000 mg tablet, (iii) Sitagliptin 100 mg + Metformin 500 mg (extended release) tablet and (iv) Sitagliptin 100 mg + Metformin 500 mg (extended release) tablet. The Committee further noted that the formulation 'Sitagliptin' is on the verge of becoming off-patent.

3.2. The Committee recalled the decision taken in its 33<sup>rd</sup> meeting dated 21.06.2021 and approved by the Authority in its 89<sup>th</sup> meeting dated 28.06.2021 regarding retail price fixation of FDCs of 'Saxagliptin and Metformin tablet' in which the formulation 'Saxagliptin' become off-patent on 05.03.2021 which are as follows:

*"...The Committee noted that the patent of formulation 'Saxagliptin' has expired on 05.03.2021. Accordingly, the retail price of the Fixed Dose Combinations (FDCs) of Metformin + Saxagliptin tablet, if calculated based on six month prior market data, the price of the patented period would be taken into consideration and hence the benefits of price rationalisation due to expiry of the patent would not be pass on to the patients."*

3.3 The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become/ is on the verge of becoming off-patent would not pass not on to the consumers. The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become/ on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price. Accordingly, the Committee recommended to allow retail price

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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.

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

3.4.1 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 20.025 per tablet excluding GST as detailed below:

S. No	Particulars	Source/Method	Amount (Rs.)
	Composition - 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 May, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price [b+c]		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		24.11
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000 mg tablet' as per Pharmatrac Data for May 2021		21.58
(i)	Recommended retail price		20.025

3.4.2 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP 64.25 mg eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 18.343 per tablet excluding GST as detailed below:

S.	Particulars	Source/Method	Amount
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No.			(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 May, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price [b+c]		18.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343
(g)	Claimed Retail price		22.32
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet' as per Pharmatrac Data for May 2021		21.67
(i)	Recommended retail price		18.343

3.4.3 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as an extended release form) for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 20.171 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 100 mg + Metformin Hydrochloride (ER) IP 500 mg		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per May, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.92
(d)	Retail Price		20.555
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee		0.384

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(f)	Worked out Retail Price (d)-(e)		20.171
(g)	Claimed Retail price		40.18
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 500mg tablet" as per Pharmatrac Data for May 2021		Data not available
(i)	Recommended retail price		20.171

3.4.4 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as an extended release form) for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 19.81 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 100 mg + Metformin Hydrochloride (ER) IP 1000 mg		
(a)	Derived retail price of Sitagliptin 100 mg tablet	Retail price (as per May, 2021 data)	37.27
(b)	50% of (a)		18.635
(c)	Metformin CR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.66
(d)	Retail Price		22.295
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.732
(f)	Worked out Retail Price (d)-(e)		21.563
(g)	Claimed Retail price		41.96
(h)	Retail price of FDC of 'Sitagliptin 100mg + Metformin 1000mg tablet" as per Pharmatrac Data for May 2021		19.81
(i)	Recommended retail price		19.81

3.4.5 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Emcure Pharmaceuticals Ltd. (marketer) at Rs. 18.343 per tablet excluding GST as detailed below:

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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 July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343
(g)	Claimed Retail price		25.98
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for July 2021		21.67
(i)	Recommended retail price		18.343

3.4.6 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Exemed Pharmaceuticals (manufacturer) and M/s Emcure Pharmaceuticals Ltd. (marketer) at Rs. 20.025 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee		0.72

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	report		
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		26.70
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for July 2021		21.58
(i)	Recommended retail price		20.025

3.4.7 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Zydus Healthcare Ltd. (manufacturer and marketer) at Rs. 18.343 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 July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343
(g)	Claimed Retail price		26.49
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for July 2021		21.67
(i)	Recommended retail price		18.343

3.4.8 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Zydus Healthcare Ltd. (manufacturer and marketer) at Rs. 20.025 per tablet excluding GST as detailed below:

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

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	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 July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Retail Price		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		28.15
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for July 2021		21.58
(i)	Recommended retail price		20.025

3.4.9 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 500 mg for M/s Morepan Laboratories Ltd. (manufacturer and marketer) at Rs. 18.343 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 July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 500 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	1.51
(d)	Retail Price		18.645
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.302
(f)	Worked out Retail Price (d)-(e)		18.343

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(g)	Claimed Retail price		22.77
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 500mg tablet" as per Pharmatrac Data for July 2021		21.67
(i)	Recommended retail price		18.343

3.4.10 Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg for M/s Morepan Laboratories Ltd. (manufacturer and marketer) at Rs. 20.025 per tablet excluding GST as detailed below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each film coated tablet containing Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg + Metformin Hydrochloride IP 1000 mg		
(a)	Derived retail price of Sitagliptin 50 mg tablet	Retail price (as per July, 2021 data)	34.27
(b)	50% of (a)		17.135
(c)	Metformin IR 1000 mg	Ceiling Price [SO. 1330(E) dated 25.03.2021]	3.61
(d)	Worked out Retail Price		20.745
(e)	Less 20% of the lower of (b) or (c) as recommended in the Pronab Sen Committee report		0.72
(f)	Worked out Retail Price (d)-(e)		20.025
(g)	Claimed Retail price		22.86
(h)	Retail price of FDC of 'Sitagliptin 50mg + Metformin 1000mg tablet" as per Pharmatrac Data for July 2021		21.58
(i)	Recommended retail price		20.025

**4. Agenda No. 4 - Retail price fixation under Para 5 of DPCO, 2013- Each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Serum Institute of India Ltd. (marketer).**

4.1 The Committee deliberated upon the matter in detail and recommended the retail price of each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Serum Institute of India Ltd. (marketer) at Rs. 14.04 per tablet excluding GST as detailed below:

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Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Derived retail price of Medroxyprogesterone Acetate Sustained Release Tablets 30 mg	Note 1	Rs. 14.04 per tablet excluding GST
Company Claimed Price excluding GST (per tablet)		Rs. 16.52
Recommended price excluding GST (per tablet)		Rs. 14.04

Note 1. Derived retail price as per recommendation of pronab sen committee:

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

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

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

s = strength in terms of API content

s\* = reference strength

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

#### Calculation of price Medroxyprogesterone Acetate Sustained Release Tablets 30 mg

Ceiling Price for Medroxyprogesterone Acetate tablet 10 mg = Rs. 5.40 per tablet [SO. 1330(E) dated 25.03.2021

Derived Retail price for Medroxyprogesterone Acetate tablet 30 mg in line with the formula as Pronab Sen Committee Report =  $5.40[1 + 0.80\{(30 - 10)/10\}] = \text{Rs. } 14.04$  per tablet.

#### **5. Agenda No. 5 - Retail price fixation under Para 5 of DPCO, 2013- Each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Torrent Pharmaceuticals Ltd. (marketer)**

5.1 The Committee deliberated upon the matter in detail and recommended the retail price of each uncoated sustained release tablet contains Medroxyprogesterone Acetate IP 30 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Torrent Pharmaceuticals Ltd. (marketer) at Rs. 14.04 per tablet excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Derived retail price of Medroxyprogesterone Acetate Sustained Release Tablets 30 mg	Note 1	Rs. 14.04 per tablet excluding GST
Company Claimed Price excluding GST (per tablet)		Rs. 20.50



Recommended price excluding GST (per tablet)	Rs. 14.04
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Note 1. Derived retail price as per recommendation of pronab sen committee:

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

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

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

s = strength in terms of API content

s\* = reference strength

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

Calculation of price Medroxyprogesterone Acetate Sustained Release Tablets 30 mg

Ceiling Price for Medroxyprogesterone Acetate tablet 10 mg = Rs. 5.40 per tablet [SO. 1330(E) dated 25.03.2021

Derived Retail price for Medroxyprogesterone Acetate tablet 30 mg in line with the formula as Pronab Sen Committee Report=  $5.40[1 + 0.80\{(30 - 10) / 10\}]$  = Rs. 14.04 per tablet.

**6. Agenda No. 6 - Retail price fixation under Para 5 of DPCO, 2013- Glycopyrrolate, Formoterol and Budesonide Metered Dose Inhaler in which each actuation delivers Glycopyrrolate IP 9 mcg + Formoterol Fumerate Dilhyderate IP eq. to Formoterol Fumerate 4.8 mcg + Budesonide IP 160 mcg for M/s Zydus Healthcare Ltd. (manufacturer and marketer)**

6.1 The Committee noted that Glycopyrrolate Injection 0.2mg/ml is a scheduled formulation. The Committee further noted that the data of Glucopyrrolate 25 mcg respule is available in Pharmatrac database. The Committee deliberated upon the matter in detail and decided that since the application is for inhalation, the data of Glucopyrrolate respules would be appropriate to calculate the price of formulation under consideration since inhaler and respules are similar type of formulations. Accordingly, the Committee recommended the retail price of Glycopyrrolate, Formoterol and Budesonide Metered Dose Inhaler in which each actuation delivers Glycopyrrolate IP 9 mcg + Formoterol Fumerate Dilhyderate IP eq. to Formoterol Fumerate 4.8 mcg + Budesonide IP 160 mcg for M/s Zydus Healthcare Ltd. (manufacturer and marketer) at Rs. 8.63 per MDI excluding GST as detailed below

Computation of Retail Price	Source/Method	Amount (Rs.)
Glycopyrrolate, Formoterol and Budesonide Metered Dose Inhaler Composition - Each actuation delivers Glycopyrrolate IP 9 mcg + Formoterol Fumerate Dilhyderate IP eq. to Formoterol Fumerate 4.8 mcg + Budesonide IP 160 mcg		
a. Glycopyrrolate IP 9 mcg	Note 1	12.13
b. Formoterol Fumerate Dilhyderate IP eq. to Formoterol Fumerate 4.8 mcg + Budesonide IP 160 mcg	Note 2	2.14

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Total (a) + (b)	14.27
c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report	0.43
Worked out Retail Price (a+b-c)	13.84 per MDI excluding GST
Company Claimed Price	8.63 per MDI excluding GST
Recommended price	8.63 per MDI excluding GST

Note 1. Derived Retail Price of Glycopyrrolate IP 9 mcg

Formula as per recommendation of pronab sen committee:

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

Where : P(s) = Price ceiling of the strength s  
P\* = price ceiling for reference strength s\*  
s = strength in terms of API content  
s\* = reference strength  
a = 0.8 for tablet / capsule and 0.7 for injectibles.

Retail price of Glycopyrrolate IP 25 mcg respules (based on Pharmatrac data of July, 2021) = Rs. 24.86 per 1 ml

Derived Retail price for Glycopyrrolate IP 9 mcg respules as per the Pronab Sen Committee formula =  $24.86[1 + 0.80\{(9-25)/25\}] = \text{Rs. } 12.13$

Note 2. Derived Retail Price of Budesonide 160 mcg + Formoterol 4.8 mcg MDI

Ceiling Price of Inhalation (MDI) Budesonide 200 mcg + Formoterol 6 mcg (Ceiling Price as per notification no. 1330(E) dated 25th March, 2021) = Rs. 2.68 per MDI

Derived Retail price for Inhalation (MDI) Budesonide 160 mcg + Formoterol 4.8 mcg =  $2.68 \times 0.80 = \text{Rs. } 2.14$  per MDI i.e price calculated on proportionate basis to that of strength. The strength of the formulation under consideration (Budesonide 160 mcg + Formoterol 4.8 mcg) is 80% of formulation for which ceiling price is fixed (Budesonide 200 mcg + Formoterol 6 mcg).

**7. Agenda No. 7 -Retail price fixation under Para 5 of DPCO, 2013- Each uncoated mouth dissolving tablet contains Folic Acid IP 5mg+ Pyridoxine Hydrochloride IP 3mg + Methylcobalamin IP 1500mcg +Vitamin D3 IP 1000 IU for M/s Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer)**

7.1 The Committee deliberated upon the matter in detail and recommended the retail price of Each uncoated mouth dissolving tablet contains Folic Acid IP 5mg+ Pyridoxine Hydrochloride IP 3mg + Methylcobalamin IP 1500mcg +Vitamin D3 IP 1000 IU for M/s

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Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. Rs.6.70 per tablet excluding GST (i. lower of calculated and claimed price)as detailed below:

Sl. No.	Company	Source/ Method	(Rs)
1	Each film coated tablet containing Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Vitamin D3 IP 1000 IU, Pyridoxine Hydrochloride IP 3mg, Folic Acid IP 1.5mg	As notified vide SO. 3400(E) dated 19.08.2021	10.97
2	Less:- Price of Alpha Lipoic Acid 100 mg	Note 1	3.32
3	Less:- Price of Folic Acid 1.5 mg	Note 2	0.62
4	Derived price of Methylcobalamin IP 1500mcg, Vitamin D3 IP 1000 IU, and Pyridoxine Hydrochloride IP 3mg [(1)-(2)-(3)]		7.03
5	Add: Folic Acid IP 5 mg	[Ceiling Price (as per notification no.1330(E) dated 25th March, 2021)]	1.40
6	Total[(4)+(5)]		8.43
7	Less:- 20% of the lower of (4) and (5)as recommended in the Pronab Sen Committee report		0.28
8	Net Retail Price [(6) - (7)]		Rs. 8.15 per tablet excluding GST
9.	Retail price claimed		Rs.6.70 per tablet excluding GST
10.	Recommended retail price		Rs.6.70 per tablet excluding GST

Note 1. As per S.O. 2458(E) dated 24.09.2009, for each 1 mg of Alpha Lipoic Acid Rs. 0.03321 shall be added/ subtracted. Accordingly, for 100 mg of Alpha Lipoic Acid it comes to Rs. 3.32 [0.03321x100 ]

Note 2. Derived retail price of Folic Acid 1.5 mg tablet as per recommendation of pronab sen committee:

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

Where : P(s) = Price ceiling of the strength s  
P\* = price ceiling for reference strength s\*  
s = strength in terms of API content  
s\* = reference strength  
a= 0.8 for tablet / capsule and 0.7 for injectibles.

Derived Retail Price of Folic Acid IP 1.5 mg

Ceiling price of Folic Acid IP 5 mg = Rs. 1.40 per tablet [SO. 1330(E) dated 25.03.2021]

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Derived Retail price for Folic Acid IP 1.5 mg =  $1.40[1+0.80\{(1.5-5)/5\}]$  = Rs. 0.616 per tablet

**8. Agenda No. 8 -Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin PR capsule contains Tacrolimus IP 3 mg for M/s Cadila Healthcare Ltd. (manufacturer and marketer)**

8.1 The Committee deliberated upon the matter in detail and noted that clarification as sought from Central Drugs Standard Control Organisation (CDSCO) is yet to be received. Accordingly, the Committee decided that the matter would be deliberated after receipt of clarification from CDSCO.

**9. Agenda No. 9 - Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015)**

9.1 The Committee deliberated upon the matter in detail and noted that clarification as sought from Central Drugs Standard Control Organisation (CDSCO) is yet to be received. Accordingly, the Committee decided that the matter would be deliberated after receipt of clarification from CDSCO.

The meeting ended with a vote of thanks to all.

*Rashmi Tahiliani*  
24/3/2022  
**(Rashmi Tahiliani)**  
Jt. Director (Pricing)

Copy to:  
All members of the Committee.













