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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 67th meeting of the Multidisciplinary Committee of Experts held on 2.4.2025 at 2:00 PM.

67th meeting of the Multidisciplinary Committee of Experts was held on 2.4.2025 at 2:00 PM under the convenorship of Shri Sanjay Kumar, Advisor (Cost). The following members attended the meeting: -

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO through Video Conferencing
2. Dr. J. J. Cherian, Scientist-E (Med), ICMR
3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli, through Video Conferencing
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. Jai Prakash, Indian Pharmacopoeia Commission – Co-opted member

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

1. Ms. Rashmi Tahiliani, Director (Pricing)
2. Shri Mahaveer Saini, Deputy Director (Pricing)
3. Ms. Yuvika Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Application by M/s Intas Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (ii & iii) for the formulation "Clozapine Extended Release 12.5 mg/ 25 mg/ 50 mg/ 100 mg/200 mg capsule.

1. The matter was earlier placed in 64th meeting of MDC held on 6.12.2024, wherein the agenda was deferred and the committee directed that the matter may be pursued with DPIIT for nomination of suitable officer. Further, the representative of office of DPIIT attended the 66th meeting of MDC held on 3.3.2025 and informed that the subject application as forwarded by NPPA is at an advanced stage of examination. The Committee requested that the comments may be shared with NPPA by 15th March 2025 so that the matter may be deliberated in next meeting for early disposal.

2. The meeting notice and the agenda for the 67th meeting held on 2.4.2025 was sent to nominee of DPIIT on 26.3.2025 with request to attend the meeting and provide the comments in the matter. However, neither any comments have been received nor the meeting was attended by representative of DPIIT. Accordingly, the Committee deferred the agenda and directed to pursue the matter with DPIIT for early inputs in the matter.

Agenda Item No. 2: Application from M/s Biological E Limited for exemption under Para 32 (i, ii & iii) of the DPCO, 2013 for the formulation Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14)

1. The matter was earlier placed in 64th meeting of MDC held on 6.12.2024, wherein the agenda was deferred and the committee directed that the matter may be pursued with DPIIT for nomination of suitable officer. Further, the representative of office of DPIIT attended the 66th meeting of MDC held on 3.3.2025 and informed that the subject application as forwarded by NPPA is at an advanced stage of examination. The Committee requested that the comments may be shared with NPPA by 15th March 2025 so that the matter may be deliberated in next meeting for early disposal.

2. The meeting notice and the agenda for the 67th meeting held on 2.4.2025 was sent to nominee of DPIIT on 26.3.2025 with request to attend the meeting and provide the comments in the matter. However, neither any comments have been received nor the meeting was attended by representative of DPIIT. Accordingly, the Committee deferred the agenda and directed to pursue the matter with DPIIT for early inputs in the matter.

Agenda Item No. 3: Retail price fixation of each Vaginal Film Contains: Clotrimazole IP 50 mg M/s Hetero Healthcare Ltd. (Manufacturer & Marketer) (F. No. 4471)

1. The Committee noted that the data for the applied formulation is not available in the market data base. The Committee deliberated and observed that the applied formulation is an anti-fungal drug. It was also noted that pessary form of the said drug has the same route of administration for which ceiling price has been notified at Rs. 10.01 for 100mg / pessary. Therefore, the Committee recommended the retail price of Rs. 6.01(excluding GST) per film on the basis of Clotrimazole Pessary 100mg using formula given in Pronab Sen Committee Report. The details are as follows:

(i) The Ceiling price of Clotrimazole Pessary 100mg applicable in June 2024 i.e. 6 months prior to application - Rs. 10.01 / Pessary (S.O. 1547(E) dated 26.3.2024)

The retail price of Clotrimazole Pessary 50mg based on formula recommended in the Pronab Sen Committee report is as below: -

Derived retail price as per recommendation of Pronab Sen committee:

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

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

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

s = strength in terms of API content

s^* = reference strength

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

= 10.01[1+0.80{(50-100)/100)] = Rs. 6.01(excluding GST) per 50mg Pessary or 50mg Vaginal Film

(ii) Claimed Price is Rs. 21.25 (excluding GST) per pouch of 2 film i.e. 10.63 per film

(iii) Recommended Price (lower of worked out and claimed price) i.e. Rs. 6.01 (excluding GST) per film

Agenda Item No. 4(a): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 10 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Lupin Ltd. (Marketer) (F. No. 4540)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Lupin Ltd. (Applicant)
3	Date of Application	13.3.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	Aug 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	Aug 24	10.31 (Linagliptin 5mg)	19.72 (Empagliflozin 10mg)
C.	Total		NA	31.42
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	29.08
F.	Claimed Price		22.32	22.32
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			22.32

Agenda Item No. 4(b): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 10 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketer) (F.No. 4534)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Mankind Pharma Ltd. (Applicant)
3	Date of Application	11.3.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	Aug 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	Aug 24	10.31 (Linagliptin 5mg)	19.72 (Empagliflozin 10mg)
C.	Total		NA	31.42
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	29.08
F.	Claimed Price		34.00	34.00
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			29.08

Agenda Item No. 4(c): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 10 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Eris Lifesciences Ltd. (Marketer) (F.No. 4499)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Eris Lifesciences Ltd. (Applicant)
3	Date of Application	10.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	19.72 (Empagliflozin 10mg)
C.	Total		NA	31.42
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	29.08
F.	Claimed Price		42.41	42.41
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			29.08

Agenda Item No. 4(d): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 10 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Cipla Ltd. (Marketer) (F.No. 4496)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Cipla Ltd. (Applicant)
3	Date of Application	7.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 10 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	19.72 (Empagliflozin 10mg)
C.	Total		NA	31.42
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	29.08
F.	Claimed Price		25.00	25.00
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			25.00

Agenda Item No. 5(a): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Lupin Ltd. (Marketer) (F.No. 4541)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Lupin Ltd.
3	Date of Application	13.3.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	Aug 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	Aug 24	10.31 (Linagliptin 5mg)	23.07 (Empagliflozin 25mg)
C.	Total		NA	34.77
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	32.43
F.	Claimed Price		23.21	23.21
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			23.21

Agenda Item No. 5(b): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Mankind Pharma Ltd. (Marketer) (F.No. 4511)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Mankind Pharma Ltd.
3	Date of Application	11.3.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	Aug 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	Aug 24	10.31 (Linagliptin 5mg)	23.07 (Empagliflozin 25mg)
C.	Total		NA	34.77
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	32.43
F.	Claimed Price		38.00	38.00
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			32.43

Agenda Item No. 5(c): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Micro Labs Ltd. (Marketer) (F.No. 4511)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Micro Labs Ltd. (Applicant)
3	Date of Application	20.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	23.87 (Empagliflozin 25mg)
C.	Total		NA	35.57
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	33.23
F.	Claimed Price		35.71	35.71
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			33.23

Agenda Item No. 5(d): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Eris Lifesciences Ltd. (Marketer) (F.No. 4500)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Eris Lifesciences Ltd. (Applicant)
3	Date of Application	10.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	23.87 (Empagliflozin 25mg)
C.	Total		NA	35.57
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	33.23
F.	Claimed Price		44.64	44.64
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			33.23

Agenda Item No. 5(e): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Intas Pharmaceuticals Ltd. (Marketer) (F.No. 4498)

The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Intas Pharmaceuticals Ltd.(Applicant)
3	Date of Application	7.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Component i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	23.87 (Empagliflozin 25mg)
C.	Total		NA	35.57
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	33.23
F.	Claimed Price		15.00	15.00
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			15.00

Agenda Item No. 5(f): Retail price fixation of each Film Coated Tablet Contains: Empagliflozin 25 mg + Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Cipla Ltd. (Marketer) (F.No. 4497)

1. The Committee deliberated on the matter and recommended retail price on the lines of DPCO amendment vide S.O. No. 2165(E) dated 11.05.2023 as below:

S.N.	Particulars	Details
1	Manufacturer Name	M/s Pure and Cure Healthcare Pvt. Ltd.
2	Marketer Name	M/s Cipla Ltd.(Applicant)
3	Date of Application	7.2.2025
4	Patented Component - I	Empagliflozin
5	Patent Holder	M/s Boehringer
6	License Holder	M/s Lupin, M/s Cipla, M/s Torrent
7	Date of Patent Expiry	March 2025
8	Patented Component - II	Linagliptin
9	Patent Holder	M/s Boehringer
10	License Holder	M/s Lupin
11	Date of Patent Expiry	February 2022

Calculation of Retail Price

S.N.	Particulars	Data Month	Option-I Empagliflozin 25 mg + Metformin Hydrochloride IP 1000 mg (ER)	Option-II Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)
A.	Retail price of FDC excluding Patent & License Holder under Option II	July 24	NA	11.70
B.	Other Components i.e. Linagliptin excluding Patent & License Holder and Empagliflozin at 50% of price	July 24	10.27 (Linagliptin 5mg)	23.87 (Empagliflozin 25mg)
C.	Total		NA	35.57
D.	Less: 20% of lower of A&B taking inference from the Pronab Sen Committee Report		NA	2.34
E.	Calculated Price of applied FDC		NA	33.23
F.	Claimed Price		29.00	29.00
G.	**Recommended Price (Lower of worked out and claimed price) per tablet**			29.00

Agenda Item No. 6: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd.

1. The Committee noted that the matter was earlier deliberated in 60th to 64th meeting of MDC. The Committee in its 64th meeting held on 6.12.2024 recommended the following price:

Details	Price (for packing with special features)
(i) Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml)	9.12
(ii) Ceiling Price of Each 100ml contains: Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg OR **Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B)** Pack Size - 500ml	85.52 (S.O. 4663(E) dated 25.10.2023)
Total (i+ii)	94.64
Less: 20% of Lower of i and ii based on inference drawn from the Pronab Sen Committee Report	1.82
Worked Out Price	92.82
Claimed Price	284.83
Recommended Price (Lower of the Claimed & Worked out retail price)	92.82

2. The committee noted submissions made by the applicant in their representations dated 13.1.2025, 21.1.2025 and 07.03.2025 requested to review the retail price determination of the subject formulation. The Committee deliberated upon the same and reiterated its earlier recommendation as given in 64th meeting i.e. retail price of Rs. 92.82 for pack of 500ml of MDC may be placed before the Authority for approval.

Agenda Item No. 7: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd.

1. The Committee recalled that the matter was earlier deliberated in 60th meeting to 64th meeting of MDC. The Committee in its 64th meeting held on 6.12.2024 recommended retail price of Rs.68.30 as below:

Details	Price (for packing with special features)
(i) Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml)	9.12
(ii) Retail Price of Each 100ml contains: Dextrose Monohydrate IP 5000mg OR Glucose Injection 5% Pack Size – 500ml	2.52
(iii) Derived Price of Each 100ml contains: Sodium Chloride IP 450mg OR Sodium Chloride Injection 0.45% Pack Size – 500ml –	57.16
Total (i+ii+iii)	68.80
Less: 20% of Lower of (i), (ii) and (iii) based on inference drawn from the Pronab Sen Committee Report	0.50
Worked Out Price	68.30
Claimed Price	267.00
Recommended Price (Lower of worked out and claimed price)	**68.30**

2. The applicant vide letters dated 13.1.2025 requested to review the retail price of the subject formulation. Further, the applicant vide emails dated 21.01.2025 & 07.3.2025 informed that the price of Dextrose Monohydrate IP 5000mg OR Glucose Injection 5% has been considered at Rs.2.52 for a pack of 100 ml, whereas the applied pack size is of 500 ml.

3. The Committee deliberated up on the representation of the company and observed that the required API quantity of Dextrose in 500ml pack is 25 grams whereas while working out the recommended price, price of 5 grams of API was considered. Accordingly, the Committee recommended the revised price as follows:

Details	Price (for packing with special features)
(i) Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml)	9.12
(ii) Retail Price of Each 100ml contains: Dextrose Monohydrate IP 5000mg OR Glucose Injection 5% Pack Size – 500ml	**11.21 (Note-1)**
(iii) Derived Price of Each 100ml contains: Sodium Chloride IP 450mg OR Sodium Chloride Injection 0.45% Pack Size – 500ml	57.16
Total (i+ii+iii)	77.49
Less: 20% of Lower of (i), (ii) and (iii) based on inference drawn from the Pronab Sen Committee Report	1.82
Worked Out Price	75.67
Claimed Price	267.00
Recommended Price (Lower of worked out and claimed price)	**75.67**

Note-1: The retail price of Glucose 5gm has been attempted as per the formula recommended in the Pronab Sen Committee report. The calculation is as below: -

Derived retail price as per recommendation of Pronab Sen committee:

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

where, P(s) =Price ceiling of the strength s

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

s = strength in terms of API content

s^* = reference strength

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

Calculated Retail price of Glucose 1gm powder as per para 5 of DPCO from Pharmatrac Data for January, 2024 = Rs. 0.63

Derived retail price of Glucose 5% in 100ml or 25gm in 500ml = 0.63 [1+0.7{(25-1)/1}] =Rs. 11.21

Agenda item No. 8: Request for consideration of Price fixation for Multiple electrolytes and 5% Dextrose injection Type I USP for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature under Para 11(3) of DPCO, 2013 as applied by M/s Otsuka Pharmaceuticals India Pvt. Ltd. (Manufacturer & Marketer).

1. The Committee noted that the matter was earlier deliberated in 62nd to 64th meeting of MDC. The Committee in its 64thmeeting held on 6.12.2024 recommended the following price

S. No.	Particulars	Source/Method	Amount (Rs.)
(a)	Derived retail price of Sodium Chloride IP 526mg	Ceiling Price (S.O. No. 4663(E) dated 25.10.2023)	62.36
(b)	Derived retail price of Sodium Gluconate USP 502mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data	1.54
(c)	Derived retail price of Sodium Acetate Trihydrate IP 368mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data	1.19
(d)	Derived retail price of Potassium Chloride IP 37mg	Ceiling Price (S.O. No. 4663(E) dated 25.10.2023)	2.79
(e)	Derived retail price of Magnesium Chloride Hexahydrate IP 30mg	Ceiling Price (S.O. 4663(E) dated 25.10.2023)	2.71
(f)	Derived retail price of Dextrose Monohydrate IP 5000mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data	11.21
(g)	Less 20% of the lower of (a) to (f) based on inference drawn from the Pronab Sen Committee Report		0.24
(h)	Worked out Retail Price (sum of (a) to (f) less (g))		81.56
(i)	Claimed Retail price		379.47
(j)	Recommended retail price (Lower of worked out & claimed)		81.56

2. The applicant vide letters dated 13.1.2025 and 21.1.2025 requested to review the retail price of the subject formulation. Applicant informed that their current application is for Multiple Electrolyte and 5% Dextrose Injection Type I USP pack and they are selling Multiple Electrolyte at Rs. 350 for pack of 500ML. The MRP of Multiple Electrolyte of M/s Fresenius Kabi is Rs. 343 for pack of 500ml. Further, the applicant vide email dated 7.3.2025 again mentioned that retail price application is for subject formulation in a non-glass container in a plastic bottle with a euro head and in non-PVC bag and requested that the retail price of the Multiple Electrolyte US Pharmacopeia composition be reconsidered after taking into account the literature provided on subject formulation.

3. The Committee noted that data for the "**Multiple electrolytes** is available in the IPDMS. Accordingly, the committee deliberated that since the exact composition of subject formulation excluding **5% Dextrose injection is** available, the retail price of the subject formulation may be calculated based on price of Multiple Electrolyte in plastic bottle plus 15% for innovation on account of special packaging as per the current practice and price of **5% Dextrose injection** may be added to the same. Accordingly, the Committee recommended the revised retail price for the subject formulation for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature as follows:

S. No.	Particulars	Source/Method	Amount (Rs.)
(a)	Derived retail price of Multiple Electrolyte **Type 1 USP**	(**Note 1**) based on January, 2024 data	142.92
(b)	Derived retail price of Dextrose Monohydrate IP 5000mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data **(Note-2)**	11.21
(c)	Less 20% of the lower of (a) to (b) based on inference drawn from the Pronab Sen Committee Report		2.24
(d)	Worked out Retail Price (sum of a+b-c)		151.89
(e)	Claimed Retail price		379.47
(f)	Recommended retail price (Lower of worked out & claimed)		151.89

Note-1: Retail price of Multiple Electrolyte Type 1 USP in 500ml packing

PTR of Multiple Electrolyte **Type 1 USP** in Non-PVC packaging as per data available in IPDMS (Form-V filed on 20.7.2023)	107.14
Add: Retailer's margin @16%	17.14
Total	124.28
Add: 15% on account of special packaging i.e. Euro Head Bottle and Non-PVC bags	18.64
Total	142.92

Note-2: Retail price of Glucose 5gm as per the formula recommended in the Pronab Sen Committee Report

Calculated Retail price of Glucose 1gm powder as per para 5 of DPCO from Pharmatrac Data for January, 2024 = Rs. 0.63

Derived retail price as per recommendation of Pronab Sen committee:

$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$
where, $P(s)$ =Price ceiling of the strength s
P^* = price ceiling for reference strength s^*
s = strength in terms of API content
s^* = reference strength
a= 0.8 for tablet / capsule and 0.7 for injectables.
Derived retail price of Glucose 5000mg or 5gm in 100ml or 25gm for a pack of 500ml = 0.63 [1+0.7{(25-1)/1}]

=Rs. 11.21 per 500ml pack

Agenda Item No. 9: Application for approval of separate ceiling prices of IV fluids in special feature packaging by M/s Cartel Lifescience Pvt Ltd

1. The Committee noted that M/s Cartel Lifescience Pvt Ltd vide letter dated 20.2.2025 applied for approval of separate ceiling prices of IV fluids in special feature packaging (Special feature product in PP granules, where dual port cap is the special feature) for the following formulations:

Sr. No.	Name of Product	Pack Size	MRP including GST Claimed
1.	Sodium Chloride Inj 0.9% w/v	100ml	47.10
2.	Sodium Chloride Inj 0.9% w/v	500ml	98.45
3.	Compound Sodium Lactate Injection	500ml	72.75
4.	Dextrose Injection IP 5% w/v	500ml	92.11
5.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	95.75
6.	Dextrose Injection IP 10% w/v	500ml	39.15
7.	Multiple Electrolytes and Dextrose Injection IP Type I (P)	500ml	299.00
8.	Multiple Electrolytes and Dextrose Injection IP Type III (M)	500ml	299.00

2. The Committee deliberated upon the application of the company and directed that the applicant may be asked to appear before the committee in next meeting to present their case and demonstrate the product for additional benefits claimed in the application.

Agenda Item No. 10: Application for separate pricing for paracetamol infusion as per Para 11 (3) of the Drugs Price control order (DPCO), 2013.

1. The Committee noted that M/s Themis Medicare Limited applied for special price approval of Paracetamol 1000MG/100ML pack in FFS bottle, which is a non-schedule formulation under Para 11(3) of the DPCO, 2013. In its application, applicant has mentioned that they are already marketing the formulation in FFS Bottle. Now, they are intending to launch the same formulation in new package i.e. Non-PVC pack with special feature offering advantages of closed system of infusion like no air embolism, no contamination during admixing, No error of mixing, totally collapsible and optimize design for easy handling. Applicant has requested for special price of Rs. 850/100ml pack.

2. The applicant has claimed the following additional benefits for here new packages:

- No microbiological/chemical contamination during admixing
    - Closed system of infusion
    - Drains without needle prick (least chances of infection)
- No air embolism
- No medication error during admixing
    - Two ports for infusion and injection
    - Self-sealable ports to prevent leakage
- Totally collapsible – easy to store
- Optimize design for easy handling

3. The Committee deliberated upon the application of the company and directed that the applicant may be asked to appear before the committee in next meeting to present their case and demonstrate the product for additional benefits claimed in the application.

The meeting ended with a vote of thanks to all.

4/4/2025

(Rashmi Tahiliani)
Director (Pricing)

Copy to:
All members of the Committee.

Computation of Retail Price based on Aug, 2024 Data under Para 5 of DPCO, 2013

Linagliptin 5mg	Number of Companies existing of Market Share of 1% & Above	16
	Sum of MAT value considered for price calculation (in Lakhs)	6,102,71
	Sum of PTR per unit considered for price calculation	160.02
	Number of Packs considered	10
	Average PTR	8.89
	Add : 10% Retailer Margin	1.42
	Total Price (without local taxes)	10.31
	% Reduction with compared to Highest Price	37.70%

Minimum Price (Rs.)	5.56
Maximum Price (Rs.)	14.23
Average of all considered (Rs.)	8.89
Retail Price (Rs.)	10.31

TOTAL MAT 63,21,68,709 100% N.A

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwise MAT (ignoring 0% MAT)	Quality (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	LINGLIPTIN 5 MG TABLET 10	LINGRETIN	ABBOTT HEALTHCARE PVT. LTD	5 MG	10	TABLET	107.14	8260566.86	1.31%	1.31%	Y	10.71	10.71
2	LINATIN 5 MG TABLET 10	LINATIN	AJANTA PHARMA LTD	5 MG	10	TABLET	70.71	9979797.27	1.58%	1.58%	Y	7.07	7.07
3	LINAPAZ 5 MG TABLET 10	LINAPAZ	AKESIS PHARMA (P) LTD	5 MG	10	TABLET	64.43	2584720.04	0.40%	0.40%	N	6.44	
4	LINAPIL 5 MG TABLET 10	LINAPIL	ALKEM LABORATORIES LTD.	5 MG	10	TABLET	67.86	66606532.90	10.52%	10.52%	Y	8.70	8.70
5	LINTAB 5 MG TABLET 15	LINTAB	ALTCUS BIOGENICS PVT.LTD.	5 MG	15	TABLET	96.43	2543437.68	0.40%	0.40%	N	6.43	
6	TRAJENTA 5 MG TABLET 10	TRAJENTA	BOEHRINGER INGELHEIM	5 MG	10	TABLET	154.25						
7	LINACIP 5 MG TABLET 15	LINACIP	CIPLA LTD.	5 MG	15	TABLET	96.43	11561107.94	1.83%	1.83%	Y	6.43	6.43
8	LINASITE 5 MG TABLET 10	LINASITE	CORONA	5 MG	10	TABLET	70.71	17635298.28	2.79%	2.79%	Y	7.07	7.07
9	LINAGET 5 MG TABLET 10	LINAGET	DICG LIFESCIENCES PRIVATE LIMITED	5 MG	10	TABLET	67.14	593380.42	0.00%	0.00%	N	6.71	
10	EMLINZ 5 MG TABLET 10	EMLINZ	EMCURE PHARMACEUTICALS LTD	5 MG	10	TABLET	85	15719560.00	2.49%	2.49%	Y	8.50	8.50
11	LINADEL 5 MG TABLET 10	LINADEL	FRIDOS LIFESCIENCES	5 MG	10	TABLET	70.71	7159968.64	0.11%	0.11%	N	7.07	
12	LINARES 5 MG TABLET 10	LINARES	ERIS LIFESCIENCES LTD	5 MG	10	TABLET	117.75	143468943.51	22.70%	22.70%	Y	11.78	11.78
13	LINAGRIN 5 MG TABLET 10	LINAGRIN	FUSION HEALTHCARE PVT LTD	5 MG	10	TABLET	85.71	388523.43	0.06%	0.06%	N	8.57	
14	KATLIN 5 MG TABLET 10	KATLIN	FUSION HEALTHCARE PVT LTD	5 MG	10	TABLET	85.71	5260872.58	0.08%	0.08%	N	8.57	
15	LINERO 5 MG TABLET 10	LINERO	INTAS PHARMACEUTICALS LTD	5 MG	10	TABLET	93.39	20048198.69	3.17%	3.17%	Y	9.34	9.34
16	LINAHLNZ 5 MG TABLET 10	LINAHLNZ	LA HLNON HEALTHCARE PVT LTD	5 MG	10	TABLET	132.14	22446225.38	3.55%	3.55%	Y	13.21	13.21
17	LINA DKD 5 MG TABLET 10	LINA DKD	LA HLNON HEALTHCARE PVT LTD	5 MG	10	TABLET	132.14	5895693.38	0.93%	0.93%	N	13.21	
18	GLYPANTA 5 MG TABLET 10	GLYPANTA	LINDOLN PHARMACEUTICALS LTD	5 MG	10	TABLET	71.43	538667.34	0.08%	0.08%	N	7.14	
19	ONDERO 5 MG TABLET 10	ONDERO	LUPIN LTD	5 MG	10	TABLET	131.18						
20	LINAMAC 5 MG TABLET 10	LINAMAC	MACLEODS PHARMACEUTICALS PVT LTD	5 MG	10	TABLET	95	13154930.00	2.08%	2.08%	Y	9.50	9.50
21	LINADINE 5 MG TABLET 10	LINADINE	MACLEODS PHARMACEUTICALS PVT LTD	5 MG	10	TABLET	95	8265095.00	1.31%	1.31%	Y	9.50	9.50

22	JUSUNA 5 MG TABLET 10	JUSUNA	MANKIND PHARMACEUTICALS LTD	5 MG	10	TABLET	53.57	23002888.27	0.73%	0.73%	Y	5.36	5.36
23	DYNAGLIPT 5 MG TABLET 10	DYNAGLIPT	MANKIND PHARMACEUTICALS LTD.	5 MG	10	TABLET	53.57	4667136.754	7.38%	7.38%	Y	5.36	5.36
24	LINAPRIDE 5 MG TABLET 10	LINAPRIDE	MICRO LABS LTD	5 MG	10	TABLET	84.29	7203852.53	11.54%	11.54%	Y	8.43	8.43
25	LINAMIT 5 MG TABLET 10	LINAMIT	MILLOCH PHARMA PVT LTD	5 MG	10	TABLET	89.29	666010.14	0.11%	0.11%	N	8.93	
26	LINANEXT 5 MG TABLET 10	LINANEXT	MSN LABORATORIES LTD	5 MG	10	TABLET	124.71	27509181.58	4.35%	4.35%	Y	12.47	12.47
27	LINANAT 5 MG TABLET 10	LINANAT	NATCO PHARMA LTD	5 MG	10	TABLET	107.14	12790871.84	2.02%	2.02%	Y	10.71	10.71
28	DIABLIN 5 MG TABLET 15	DIABLIN	PRIMUS REMEDIES PVT LTD	5 MG	15	TABLET	117.86	5015265.14	0.82%	0.82%	N	7.85	
29	LINAPERK 5 MG TABLET 10	LINAPERK	SPECTRA THERAPEUTICS PVT LTD.	5 MG	10	TABLET	45	270085.00	0.03%	0.03%	N	4.50	
30	LINALENT 5 MG TABLET 10	LINALENT	TALENT INDIA	5 MG	10	TABLET	65.72	503957.84	0.10%	0.10%	N	5.57	
31	LINAXA 5 MG TABLET 10	LINAXA	TORRENT PHARMACEUTICALS LTD	5 MG	10	TABLET	92.85	7855315.46	12.43%	12.43%	Y	8.28	9.28
32	LGLIP 5 MG TABLET 10	LGLIP	UNION PHARMACEUTICALS	5 MG	10	TABLET	19.23	992713.08	0.16%	0.16%	N	1.93	
33	LIRATIN 5 MG TABLET 10	LIRATIN	USV PVT LTD	5 MG	10	TABLET	85	11043850.00	1.69%	1.69%	Y	8.50	8.50
		Rs. Per tablet											
	Worked out Retail Price	10.71	Excluding GST										

Note: In view of DPCO Amendment Vide S.O. No. 2160(E) dated 11.05.2023, Patent Holder of Linagliptin i.e. M/s Boehringer & License holder i.e. M/s Lupin are not considered for price fixation.

Computation of Retail Price based on Aug, 2024 Data under Para 5 of DPCO, 2013

Empaglifozin 10mg

Number of Companies consisting of Market Share of 1% & Above	5
Sum of MAT value considered for price calculation (in Lakhs)	10 606.75
Sum of PTR per unit considered for price calculation	169.05
Number of Packs considered	5
Average PTR	34.00
Add : 16% Retailer Margin	5.44
Retail Price (without local taxes)	39.44
% Reduction with compared to Highest Price	16.11%

Minimum Price (Rs.)	11.36
Maximum Price (Rs.)	40.05
Average of all considered (Rs.)	34.00
Retail Price (Rs.)	39.44

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	TOTAL MAT MAT(Rs.) 1,06,06,98,313	SKU wise MAT % 100%	Brandwise MAT (ignoring 0% MAT)	Quality (Y/N) Y=Yes N=No	MS Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	JARDIANCE 10 MG TABLET 10	JARDIANCE	BOEHRINGER INGELHEIM	10 MG	10	TABLET	40.05	[illegible]	77.43%	77.43%	Y	40.05	40.05
2	GRITULIN 10 MG TABLET 10	GRITULIN	LUPIN LTD	10 MG	10	TABLET	40.05	20,674,055.50	19.49%	19.49%	Y	40.05	40.05
3	DIBRAVO 10 MG TABLET 10	DIBRAVO	DIPLA LTD.	10 MG	10	TABLET	384.75	1,403,103.50	1.32%	1.32%	Y	38.48	38.48
4	VIGRA 10 MG TABLET 30	VIGRA	CHL BLOOMS LABORATORIES LTD	10 MG	10	TABLET	107.14	322,901.04	0.30%	0.30%	N	10.71	
5	EMPADYNE 10 MG TABLET 10	EMPADYNE	MANKIND PHARMA LTD	10 MG	10	TABLET	113.57	2,405,264.09	2.27%	2.27%	Y	11.36	11.36
6	COSFIAO 10 MG TABLET 10	COSFIAO	TORRENT PHARMACEUTICALS LTD.	10 MG	10	TABLET	400.5	3,675,941.00	3.46%	3.46%	Y	40.05	40.05
		Rs. Per Tablet											
	Worked out Retail Price	39.44	Excluding GST										
	50% of Worked out Retail Price	19.72	Excluding GST										

Note: In view of DPCO Amendment vide S.O. No. 2965(E) dated 18.06.2023, Patent holder of Linagliptin i.e. M/s Boehringer & Licensee holder i.e. M/s Lupin, M/s Dipla, M/s Torrent are not considered for price fixation.

Computation of Retail Price based on Aug. 2024 Data under Para 5 of DPCO, 2013

Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (ER)	Number of Companies covering of Market Share of 95 % Above	7
	Sum of MAT value considered for price calculation (in Lakhs)	220.92
	Sum of PTR per unit considered for price calculation	70.64
	Number of Packs considered	7
	Average PTR	10.09
	Add : 16% Retailer Margin	1.61
	Retail Price (without local taxes)	11.70
	% Reduction with considered to highest Price	27.57%

Minimum Price (Rs.)	7.14
Maximum Price (Rs.)	13.91
Average of all considered (Rs.)	10.09
Retail Price (Rs.)	11.7

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	TOTAL MAT MAT(Rs.) 2,22,64,534	SKU wise MAT % 100%	Brandwise MAT (ignoring 0% MAT)	Quality [Y/N] Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	LINACIP M 5/1000 MG TABLET X	LINACIP M	CIPLA LTD	5/1000 MG	15	TABLET XR	107.14	936479.56	4.39%	4.39%	Y	7.14	7.14
2	LINAUTE M 5/1000 MG TAB.ET	LINAB.TE M	CORONA	5/1000 MG	30	TABLET	70.71	86116.43	0.39%	0.39%	N	7.07	
3	LINAGET M DD 5/1000 MG TAB	LINAGLA T M CD	DCS LIFESCIENCES PRIVATE LIMITED	5/1000 MG	30	TABLET	92.85	92591.42	0.42%	0.42%	N	9.29	
4	EMLINZ M 5/1000 MG TABLET L	EMLINZ M	EMCURE PHARMACEUTICALS LTD	5/1000 MG	30	TABLET	106.43	995104.07	4.47%	4.47%	Y	10.64	10.64
5	LINARES M ER TB 5/1000 MG L	LINARES M FOR	ERS LIFESCIENCES LTD	5/1000 MG	30	TABLET	100	990100.00	4.45%	4.45%	Y	10.00	10.00
6	LINERO M ER 5/1000 MG TABLE	LINERO M	INTAS PHARMACEUTICALS LTD	5/1000 MG	30	TABLET	99.39	2267635.43	10.19%	10.19%	Y	9.93	9.93
7	LINAHENZ M CD 5/1000 MG TA	LINAHENZ M CD	LA RESON HEALTHCARE PVT LTD	5/1000 MG	30	TABLET	139.29	3631958.24	16.43%	16.43%	Y	13.93	13.93
8	ONDERO MET DD 5/1000 MG T	ONDERO MET D	CLIPIN LTD	5/1000 MG	30	TABLET	116.93						
9	LINANEXT M 5/1000 MG TABLET	LINANEXT M	MSN LABORATORIES LTD	5/1000 MG	30	TABLET ER	97.38	695197.64	3.12%	3.12%	Y	9.74	9.74
10	LINAKA M XR 5/1000 MG TABLE	LINAKA M	TORRENT PHARMACEUTICALS LTD	5/1000 MG	30	TABLET	92.14	12517038.70	56.22%	56.22%	Y	9.21	9.21
		Rs. Per Tablet											
	Worked out Retail Price	11.70	Excluding GST										

Note: In view of DPCO Amendment vide S.O. No. 2365(E) dated 11.05.2023, Patent Holder of Linagliptin i.e. M/s Boehringer & License holder i.e. M/s Lupin are not considered for price fixation. M/s Boehringer is not available in the database for the subject formulation.

Computation of Retail Price based on July, 2024 Data under Para 5 of DPCO, 2013

Linagliptin 5 mg	Number of Companies existing of Market Share of 1% & Above	16
	Sum of MAT value considered for price calculation (in Lakhs)	5,803.01
	Sum of PTR per unit considered for price calculation	159.38
	Number of Packs considered	18
	Average PTR	8.85
	Add . 16% Retailer Margin	1.42
	Retail Price (with out local taxes)	10.27
	% Reduction with compared to Highest Price	33.01%

Minimum Price (Rs.)		5.34
Maximum Price (Rs.)		13.23
Average of all considered (Rs.)		8.85
Retail Price (Rs.)		10.27

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	TOTAL MAT MAT (Rs.) 60,07,02,848	SKU wise MAT % 100%	Brandwise MAT (ignoring 0% MAT)	Quality (Y/N) Y=Yes N=No	MT Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	LINGRETIN 5 MG TABLET 10	LINGRETIN	ABBOTT HEALTHCARE PVT. LTD	5 MG	10	TABLET	107.14	7651091.68	1.27%	1.27%	Y	10.71	10.71
2	LINATIN 5 MG TABLET 10	LINATIN	ALANTA PHARMA LTD	5 MG	10	TABLET	70.71	9051328.52	1.51%	1.51%	Y	7.07	7.07
3	LINAPAZ 5 MG TABLET 10	LINAPAZ	ABES SK PHARMA (P) LTD	5 MG	10	TABLET	56.43	2535222.03	0.42%	0.42%	N	5.64	
4	LINAFIL 5 MG TABLET 10	LINAFIL	ALKEM LABORATORIES LTD.	5 MG	10	TABLET	67.05	64245912.33	10.70%	10.70%	Y	6.70	6.70
5	LINTAN 5 MG TABLET 15	LINTAN	ALTIUS ROGONICS PVT.LTD	5 MG	15	TABLET	96.43	2587401.76	0.43%	0.43%	N	6.43	
6	TRAJENTA 5 MG TABLET 10	TRAJENTA	BOEHRINGER INGELHEIM	5 MG	10	TABLET	254.25						
7	LINACIP 5 MG TABLET 15	LINACIP	CIPLA LTD.	5 MG	15	TABLET	96.41	10185900.90	1.70%	1.70%	Y	6.43	6.43
8	LINABITE 5 MG TABLET 10	LINABITE	CONCINA	5 MG	10	TABLET	64.29	16650909.49	2.77%	2.77%	Y	6.43	6.43
9	LINAGET 5 MG TABLET 10	LINAGET	DIGS LIFESCIENCES PRIVATE LIMITED	5 MG	10	TABLET	67.14	539047.64	0.09%	0.09%	N	6.71	
10	EMLINZ 5 MG TABLET 30	EMLINZ	EMCURE PHARMACEUTICALS LTD	5 MG	10	TABLET	85	15652580.00	2.61%	2.61%	Y	8.00	8.00
11	LINADEL 5 MG TABLET 30	LINADEL	[illegible]	5 MG	10	TABLET	70.71	614664.87	0.10%	0.10%	N	7.07	
12	LINAREX 5 MG TABLET 10	LINAREX	ERIS LIFESCIENCES LTD	5 MG	10	TABLET	117.75	13846850.25	23.05%	23.05%	Y	11.78	11.78
13	LINASORIN 5 MG TABLET 10	LINASORIN	FUSION HEALTHCARE PVT LTD	5 MG	10	TABLET	70.71	294407.37	0.05%	0.05%	N	8.07	
14	LINATIN 5 MG TABLET 30	LINATIN	FUSION HEALTHCARE PVT LTD	5 MG	10	TABLET	85.71	409005.12	0.07%	0.07%	N	8.57	
15	LINERO 5 MG TABLET 30	LINERO	INTAS PHARMACEUTICALS LTD	5 MG	10	TABLET	93.39	18885751.14	3.14%	3.14%	Y	9.34	9.34
16	LINAHENZ 5 MG TABLET 30	LINAHENZ	LA FENON HEALTHCARE PVT.LTD	5 MG	10	TABLET	132.14	31240447.38	5.54%	5.54%	Y	13.21	13.21
17	LINAOKD 5 MG TABLET 10	LINAOKD	LA FENON HEALTHCARE PVT.LTD	5 MG	10	TABLET	132.14	5400756.26	0.90%	0.90%	N	13.21	
18	GLYPANTA 5 MG TABLET 10	GLYPANTA	LINCOLN PHARMACEUTICALS LTD	5 MG	10	TABLET	71.43	530633.19	0.09%	0.09%	N	7.14	
19	LINDERO 5 MG TABLET 10	LINDERO	LUPIN LTD	5 MG	10	TABLET	189.29						
20	LINAMAC 5 MG TABLET 10	LINAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	5 MG	10	TABLET	95	11804115.00	1.97%	1.97%	Y	9.50	9.50
21	LINALINE 5 MG TABLET 10	LINALINE	MACLEODS PHARMACEUTICALS PVT.LTD	5 MG	10	TABLET	95	7548415.00	1.26%	1.26%	Y	9.50	9.50

22	JUSUNA 5 MG TABLET 10	JUSUNA	MANKIND PHARMACEUTICALS LTD.	5 MG	10	TABLET	53.53	22497096.43	9.79%	8.75%	Y	5.36	5.95
23	DYNAGLIPT 5 MG TABLET 10	DYNAGLIPT	MANKIND PHARMACEUTICALS LTD.	5 MG	10	TABLET	53.57	41517242.13	6.91%	6.91%	Y	5.98	5.98
24	LNAPRIDE 5 MG TABLET 10	LNAPRIDE	MICRO LABS LTD	5 MG	10	TABLET	81.29	7210081.93	12.00%	12.00%	Y	8.40	8.40
25	LINAMIT 5 MG TABLET 10	LINAMIT	MITCH PHARMA PVT LTD	5 MG	10	TABLET	80.29	637825.07	0.11%	0.11%	N	8.90	
26	LINANEXT 5 MG TABLET 10	LINANEXT	MSN LABORATORIES LTD	5 MG	10	TABLET	124.71	25909146.30	4.31%	4.31%	Y	12.47	12.47
27	LINANAT 5 MG TABLET 10	LINANAT	NATCO PHARMA LTD	5 MG	10	TABLET	107.14	12892547.70	2.15%	2.15%	Y	10.71	10.71
28	LINALIN 5 MG TABLET 35	LINALIN	PRIMUS REMEDIES PVT LTD	5 MG	35	TABLET	117.86	4482038.50	0.75%	0.75%	N	7.06	
29	LINAPERE 5 MG TABLET 10	LINAPERE	SPECTRA THERAPEUTICS PVT. LTD.	5 MG	10	TABLET	45	140680.20	0.02%	0.02%	N	4.50	
30	LINALENT 5 MG TABLET 10	LINALENT	TALENT INDIA	5 MG	10	TABLET	65.22	840083.04	0.14%	0.14%	N	6.07	
31	LINAXA 5 MG TABLET 10	LINAXA	TORRENT PHARMACEUTICALS LTD.	5 MG	10	TABLET	92.86	7304962.30	12.30%	12.30%	Y	9.29	9.29
32	LGLP 5 MG TABLET 10	LGLP	UNISON PHARMACEUTICALS	5 MG	10	TABLET	10.10	830200.47	0.14%	0.14%	N	1.83	
33	URALIN 5 MG TABLET 10	URALIN	USV PVT LTD	5 MG	10	TABLET	85	10140160.10	1.68%	1.68%	Y	8.50	8.50
			Rs. Per tablet										
	Worked out Retail Price	10.27	Excluding GST										

Note. In view of DPCO Amendment Vide S.O. No. 2365(E) dated 11.05.2023, Patent Holder of Linagliptin i.e. M/s Boehringer & License holder i.e. M/s Lupin are not considered for price fixation.

Computation of Retail Price based on July, 2024 Data under Para 5 of DPCO, 2013

Linagliptin 5 mg + Metformin Hydrochloride IP 1000 mg (PR)	Number of Companies existing of Market Share of 1% & Above	7
	Sum of MAT value considered for price calculation (in Lakhs)	186.23
	Sum of PTR per unit considered for price calculation	70.64
	Number of Packs considered	7
	Average PTR	10.09
	Add : 16% Retailer Margin	1.61
	Retail Price (without local taxes)	11.70
	% Reduction with compared to Highest Price	27.67%

Minimum Price (Rs.)	7.14
Maximum Price (Rs.)	13.93
Average of all considered (Rs.)	10.09
Retail Price (Rs.)	11.7

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT (Rs.)	SKU wise MAT %	Brandwise MAT (Ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
							10 M MAT	1,87,50,376	100%			MS	
1	LINACIP M 5/1000 MG TABLET X	LINAC P M	CIPLA LTD.	5/1000 MG	15	TABLET XR	107.14	845237.46	4.51%	4.51%	Y	7.14	7.14
2	LINABITE M 5/1000 MG TABLET	LINAB.TE M	CORONA	5/1000 MG	10	TABLET	70.71	52153.96	0.28%	0.28%	N	7.07	
3	LINAGET M OD 5/1000 MG TAB	LINAGET M OD	IKOS LIFESCIENCES PRIVATE LIMITED	5/1000 MG	10	TABLET	92.86	75216.50	0.40%	0.40%	N	8.29	
4	ENLINZ M 5/1000 MG TABLET 1	ENLINZ M	ENCURE PHARMACEUTICALS LTD	5/1000 MG	30	TABLET	106.43	874037.4	4.66%	4.66%	Y	10.64	10.64
5	LINARES M FORTE 5/1000 MG T	LINARES M FORTE	ERIS LIFESCIENCES LTD	5/1000 MG	10	TABLET	100	859830.30	4.59%	4.59%	Y	10.00	10.00
6	LINERO M ER 5/1000 MG TABLE	LINERO M	INTAS PHARMACEUTICALS LTD	5/1000 MG	10	TABLET	89.29	2019635.69	10.78%	10.78%	Y	8.93	8.93
7	LINAHENZ M OD 5/1000 MG TA	LINAHENZ M OD	LA RENON HEALTHCARE PVT LTD	5/1000 MG	10	TABLET	139.29	3433131.93	18.31%	18.31%	Y	13.93	13.93
8	ONDERO MET OD 5/1000 MG T	ONDERO MET OD	LUPIN LTD	5/1000 MG	30	TABLET	114.93						
9	LINANEXT M 5/1000 MG TABLE	LINANEXT M	MANKIND PHARMACEUTICALS LTD	5/1000 MG	30	TABLET ER	97.95	516853.72	2.77%	2.77%	Y	9.79	9.79
10	LINAXA M XR 5/1000 MG TABLE	LINAXA M	TORRENT PHARMACEUTICALS LTD.	5/1000 MG	10	TABLET	92.14	10172124.13	54.27%	55.32%	Y	9.21	9.21
		Rs. Per tablet											
	Worked out Retail Price	11.70	Excluding GST										

Note: In view of DPCO Amendment Vide S.O. No. 2159(E) dated 11.05.2023, Patent Holder of Linagliptin i.e. M/s Boehringer & Licence holder i.e. M/s Lupin are not considered for price fixation. M/s Ucer Ranger is not available in the database for the subject formulation.

Computation of Retail Price based on July, 2024 Data under Para 5 of DPCO, 2013

Empagliflozin 10 mg

Number of Companies possessing of Market Share of 1% & Above	5
Sum of MAT value considered for price calculation (in Lakhs)	10,504.32
Sum of PTR per unit considered for price calculation	189.99
Number of Prices considered	5
Average PTR	34.00
Add. 16% Retailer Margin	5.44
Retail Price (without local taxes)	39.44
% Reduction with compared to Highest Price	16.11%

Minimum Price (Rs.)	11.36
Maximum Price (Rs.)	40.05
Average of all considered (Rs.)	34.00
Retail Price (Rs.)	39.44

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	Skuwise MAT %	Brandwise MAT (Ignoring 0% MAT)	Quality (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
							TOTAL MAT	1,06,53,33,855	100%				
1	JARDIANCE 10 MG TABLET 30	JARDIANCE	BOEHRINGER INGELHEIM	10 MG	30	TABLET	400.5	722563768.50	73.42%	73.42%	Y	40.05	40.05
2	GINTUJID 10 MG TABLET 30	GINTUJID	LUPIN LTD	10 MG	30	TABLET	400.5	205885848.50	19.32%	19.32%	Y	40.05	40.05
3	OZORAVO 10 MG TABLET 30	OZORAVO	CIPLA LTD.	10 MG	30	TABLET	394.75	16004426.75	1.50%	1.50%	Y	38.48	38.48
4	VICRA 10 MG TABLET 30	VICRA	DR. REDDYS LABORATORIES LTD	10 MG	30	TABLET	107.14	402077.50	0.04%	0.04%	N	10.71	
5	EMPACINE 10 MG TABLET 30	EMPACINE	MSN LABORATORIES LTD	10 MG	30	TABLET	113.57	3517236.15	0.33%	0.33%	Y	11.36	11.36
6	COSPAVO 10 MG TABLET 30	COSPAVO	TORRENT PHARMACEUTICALS LTD.	10 MG	30	TABLET	400.5	3580650.00	0.33%	0.33%	Y	40.05	40.05
		Rs. Per tablet											
	Worked out Retail Price	39.44 Excluding GST											
	50% of Worked out Retail Price	19.72 Excluding GST											

Note: In view of DPCO Amendment Vide S.O. No. 2105(E) dated 11.05.2021, Patent Holder of Empagliflozin i.e. M/s Boehringer & Licence holder i.e. M/s Lupin, M/s Cipla, M/s Torrent are not considered for price fixation.

Computation of Retail Price based on Aug. 2023 Data under Para 3 of DPCO, 2013

Empagliflozin 25mg

Number of Companies cosisting of Market Share of 1% & Above	4
Sum of MAT value considered for price calculation (in Lakhs)	23,527.39
Sum of PTR per unit considered for price calculation	197.19
Number of Packs considered	4
Average PTR	39.77
Add: 16% Retailer Margin	6.36
Retail Price (without local taxes)	46.13
% Reduction w.r.t compared to Highest Price	18.15%

Minimum Price (Rs.)	2.50
Maximum Price (Rs.)	49.57
Average of all considered (Rs.)	39.77
Recd Price (Rs.)	46.13

							TOTAL VAT	2,37,43,10,910	100%					
S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT (Rs.)	SKU Wise MAT %	Brandwise MAT (ignoring 0% MAT)	Qualify (Y/N) Y=Yes N=No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
1	JARDIANCE 25 MG TABLET 10	JARDIANCE	BOEHRINGER INGELHEIM	25 mG	10	TABLET	485.25	1553074160.25	65.41%	65.41%	Y	48.53	48.53
2	GIBTULIO 25 MG TABLET 10	GIBTULIO	LUPIN LTD	25 MG	10	TABLET	485.25	647277880.50	27.26%	27.26%	Y	48.53	48.53
3	OSIGLIFLO 25 MG TABLET 10	OSIGLIFLO	CIPLA LTD	25 MG	10	TABLET	485.25	210660730.00	8.87%	8.87%	N	48.65	
4	VICRA 25 MG TABLET 10	VICRA	DR. REDDY'S LABORATORIES LTD	25 MG	10	TABLET	128.57	45938061	0.02%	0.02%	N	12.86	
5	EMPACOVE 25 MG TABLET 10	EMPACOVE	MSN LABORATORIES LTD	25 MG	10	TABLET	116	86216130.00	3.63%	3.63%	Y	13.50	13.50
6	COMPAGLIFLO 25 MG TABLET 10	COMPAGLIFLO	TORRENT PHARMACEUTICALS LTD.	25 MG	10	TABLET	485.25	66215230.00	2.79%	2.79%	Y	48.53	48.53
		Rs. Per tablet											
	Worked out Retail Price	46.13	Excluding GST										
	50% of Worked out Retail Price	23.07	Excluding GST										

Note: In view of DPCO Amendment Vide S.O. No. 2165(E) dated 18.06.2023, Patent Holder of Empagliflozin i.e. M/s Boehringer & License holder i.e. M/s Lupin, M/s Cipla, M/s Torrent are not considered for price fixation.

Computation of Retail Price based on July, 2024 Data under Para 5 of DPCO, 2013

Empagliflozin 25mg

Number of Companies contributing at Market Share of 1% & Above	5
Sum of MAT value considered for price calculation (in Lakhs)	23,940.53
Sum of PTR per unit considered for price calculation	205.74
Number of Packs considered	5
Average PTR	41.16
Add : 16% Retailer Margin	6.58
Retail Price (ex-factory local taxes)	47.73
% Deviation with compared to highest Price	15.21%

Minimum Price (Rs.)		13.50
Maximum Price (Rs.)		48.53
Average of all considered (Rs.)		41.15
Retail Price (Rs.)		47.73

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	PTR (Rs.)	MAT(Rs.)	SKU wise MAT %	Brand wise MAT (Ignoring O% MAT)	Quality (Y/N) Y-Yes N-No	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
							TOTAL MAT	2,39,45,80,235	100%				
1	JARDIANCE 25 MG TABLET 10	JARDIANCE	BOEHRINGER INGELHEIM	25 MG	10	TABLET	455.25	1367251230.25	65.45%	65.45%	Y	45.53	45.53
2	GLYNITO 25 MG TABLET 10	GLYNITO	LUPIN LTD	25 MG	10	TABLET	455.25	649068459.00	27.11%	27.11%	Y	45.53	45.53
3	DBORANO 25 MG TABLET 10	DBORANO	CIPLA LTD.	25 MG	10	TABLET	466.5	23944978.50	1.00%	1.00%	Y	46.65	46.65
4	VIGRA 25 MG TABLET 10	VIGRA	DR. REDDY'S LABORATORIES LTD	25 MG	10	TABLET	136.37	327354.14	0.02%	0.02%	N	13.46	
5	EMPAONE 25 MG TABLET 10	EMPAONE	MSN LABORATORIES LTD	25 MG	10	TABLET	135	8986130.00	0.38%	0.38%	Y	13.50	13.50
6	COSPAG 25 MG TABLET 10	COSPAG	TORRENT PHARMACEUTICALS LTD.	25 MG	10	TABLET	485.25	69826473.50	2.97%	2.97%	Y	48.53	48.53
		Rs. Per tablet											
	Worked out Retail Price	47.73	Excluding GST										
	50% of Worked out Retail Price	23.87	Excluding GST										

Note: In view of DPCO Amendment Vide S.O. No. 2365(E) dated 21.05.2021, Patent Holder of Empagliflozin i.e. M/s Boehringer & Licence holder i.e. M/s Lupin, M/s Cipla, M/s Torrent are not considered for price fixation.