

विषय : औषध (मूल्य नियंत्रण)आदेश, 2013के अंतर्गत दवा Composition:- Each film coated tablet contains: Empagliflozin 5mg + Metformin Hydrochloride IP 500mg for M/s Morepen Laboratories Ltd (Manufacturer) & (Marketer) की रिटेल कीमत निर्धारण (फाइल नंबर 4386).

Number of Companies consisting of Market Share of 1% & Above								1
Sum of MAT value considered for price calculation (in Lakhs)								356.97
Sum of PTR per unit considered for price calculation								27.30
Number of Packs considered								1
Average PTR								27.30
Add : 16% Retailer Margin								4.37
Retail Price (without local taxes)								31.67
% Reduction with compared to Highest Price								0.00%

Minimum Price (Rs.)			27.30
Maximum Price (Rs.)			27.30
Average of all considered (Rs.)			27.30
Retail Price (Rs.)			31.67

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औषध (मूल्य नियंत्रण) आदेश, 2013 के अंतर्गत दवा Each film coated tablets contains:  
Empagliflozin 12.5 mg + Metformin Hydrochloride IP 500 mg for M/s Exemed  
Pharmaceuticals (Manufacturer) & M/s USV Limited (Marketer) की रिटेल कीमत निर्धारण  
(फाइल नंबर 4400)

Minimum Price (Rs.)			31.20
Maximum Price (Rs.)			31.20
Average of all considered (Rs.)			31.20
Retail Price (Rs.)			36.19

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औषध (मूल्य नियंत्रण)आदेश, 2013के अंतर्गत दवा **Composition:- Each film coated tablet contains: Empagliflozin 12.5mg + Metformin Hydrochloride IP 850mg for M/s Morepen Laboratories Ltd (Manufacturer) & (Marketer) की रिटेल कीमत निर्धारण (फाइल नंबर 4382).**

1	<b>Manufacturer Name</b>	M/s Morepen Laboratories Ltd.
2	<b>Marketer Name</b>	M/s Morepen Laboratories Ltd.
3	<b>Date of Application</b>	28.12.2024
4	<b>Patented Component</b>	Empagliflozin
5	<b>Patent Holder</b>	M/s Boehringer Ingelheim
6	<b>License Holder</b>	M/s Lupin LTD, M/s Cipla and M/s Torrent
7	<b>Date of Patent Expiry</b>	10.03.2025
8	<b>Calculation of Retail price</b>	
A	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Empagliflozin 12.5 mg (Note 1)</b>	28.64
B	50% of Empagliflozin 12.5mg	14.32
C	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Metformin 850mg Tablet</b>	3.84
D	<b>Total</b>	<b>18.16</b>
E	Less: 20% of the lower of (B) and (C) based on inference drawn from the Pronab Sen Committee Report	0.77
F	<b>Worked out Retail Price (D-E)</b>	17.39
G	Claimed retail price excluding GST	12.94
H	Proposed retail price excluding GST	12.94

**Note 1:**

The retail price of Empagliflozin 12.5mg tablet has been attempted as per the formula recommended in the Pronab Sen Committee report. The calculation is as below:

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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.

The Retail Price of Empagliflozin 25mg Tablet = Rs. 47.73 per tablet (Excluding GST) based on MAT/PTR of May 2024 (Database month – Dec 2024)

Derived retail price of Empagliflozin 12.5mg tablet as on May 2024 after applying the formula of Pronab Sen Committee as per (c) above:

$$= 47.73[1+0.80\{(12.5-25)/25\}] = \text{Rs. } 28.64 \text{ per tablet (excluding GST)}$$

औषध (मूल्य नियंत्रण) आदेश, 2013 के अंतर्गत दवा **Each Film Coated Bilayered Tablet contains: Empagliflozin 5 mg + Metformin Hydrochloride IP 1000 mg (As Extended Release) for M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) & M/s Alkem Laboratories Limited (Marketer)** की रिटेल कीमत निर्धारण (फाइल नंबर 4413)

1	<b>Manufacturer Name</b>	M/s Pure and Cure Healthcare Pvt. Ltd.
2	<b>Marketer Name</b>	M/s Alkem Laboratories Limited (Applicant)
3	<b>Date of Application</b>	9.1.2025
4	<b>Patented Component</b>	Empagliflozin
5	<b>Patent Holder</b>	M/s Boehringer Ingelheim
6	<b>License Holder</b>	M/s Lupin LTD, M/s Cipla and M/s Torrent
7	<b>Date of Patent Expiry</b>	10.03.2025
8	<b>Calculation of Retail price</b>	
A	Price as on 6 months prior to application date i.e. MAT & PTR for June 2024 of <b>Empagliflozin 5mg (Note 1)</b>	17.18
B	50% of Empagliflozin 5mg	8.59
C	Ceiling Price for Metformin 1000mg Modified release as on June 2024 (S.O. 1547(E) dated 26.3.2024) (i.e price applicable for month ending 6 months prior to month of receipt of application)	4.05
D	<b>Total</b>	<b>12.64</b>
E	Less: 20% of the lower of (B) and (C) based on inference drawn from the Pronab Sen Committee Report	0.81
F	<b>Worked out Retail Price (D-E)</b>	11.83
G	Claimed Retail price	13.39
H	<b>Recommended Price (Lower of worked out and claimed price) per tablet</b>	<b>11.83</b>

**Note 1: Derived price of Empagliflozin 5mg based on retail price of Empagliflozin 25mg Tablet as per the formula recommended in the Pronab Sen Committee report**

The Retail Price of Empagliflozin 25mg Tablet = Rs. 47.73 per tablet (Excluding GST) based on MAT/PTR of June 2024 (Database month – Dec 2024)

The retail price of Empagliflozin 5mg tablet 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.

Derived price of Empagliflozin 5mg tablet as on June 2024 after applying the formula of Pronab Sen Committee:

$$= 47.73[1+0.80\{(5-25)/25\}] = \text{Rs. } 17.18 \text{ per tablet (excluding GST)}$$

औषध (मूल्य नियंत्रण)आदेश, 2013के अंतर्गत दवा **Composition:- Each film coated bilayered tablet contains: Empagliflozin 5mg + Metformin Hydrochloride IP 1000mg (in extended release form) for M/s Zydus Healthcare Ltd (Manufacturer & Marketer) की रिटेल कीमत निर्धारण (फाइल नंबर 4388).**

1	<b>Manufacturer Name</b>	M/s Zydus Healthcare Limited
2	<b>Marketer Name</b>	M/s Zydus Healthcare Limited
3	<b>Date of Application</b>	30.12.2024
4	<b>Patented Component</b>	Empagliflozin
5	<b>Patent Holder</b>	M/s Boehringer Ingelheim
6	<b>License Holder</b>	M/s Lupin LTD, M/s Cipla and M/s Torrent
7	<b>Date of Patent Expiry</b>	10.03.2025
8	<b>Calculation of Retail price</b>	
A	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Empagliflozin 5mg (Note 1)</b>	17.18
B	50% of Empagliflozin 5mg	8.59
C	Ceiling Price for Metformin 1000mg Modified release as on May 2024 (S.O. 1547(E) dated 26.3.2024) (i.e price applicable for month ending 6 months prior to month of receipt of application)	4.05
D	<b>Total</b>	<b>12.64</b>
E	Less: 20% of the lower of (B) and (C) based on inference drawn from the Pronab Sen Committee Report	0.81
F	<b>Worked out Retail Price (D-E)</b>	<b>11.83</b>
G	Claimed Retail Price	50.00
H	<b>Proposed Retail Price</b>	<b>11.83</b>

**Note 1: Derived price of Empagliflozin 5mg based on retail price of Empagliflozin 25mg Tablet as per the formula recommended in the Pronab Sen Committee report**

The Retail Price of Empagliflozin 25mg Tablet = Rs. 47.73 per tablet (Excluding GST) based on MAT/PTR of May 2024 (Database month – Dec 2024)

The retail price of Empagliflozin 5mg tablet 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.

Derived price of Empagliflozin 5mg tablet as on May 2024 after applying the formula of Pronab Sen Committee:

$$= 47.73[1+0.80\{(5-25)/25\}] = \text{Rs. } 17.18 \text{ per tablet (excluding GST)}$$

औषध (मूल्य नियंत्रण)आदेश, 2013के अंतर्गत दवा **Composition:- Each film coated tablet contains: Empagliflozin 5mg + Metformin Hydrochloride IP 1000mg for M/s Morepen Laboratories Ltd (Manufacturer) & (Marketer) की रिटेल कीमत निर्धारण (फाइल नंबर 4385).**

1	<b>Manufacturer Name</b>	M/s Morepen Laboratories Ltd.
2	<b>Marketer Name</b>	M/s Morepen Laboratories Ltd.
3	<b>Date of Application</b>	28.12.2024
4	<b>Patented Component</b>	Empagliflozin
5	<b>Patent Holder</b>	M/s Boehringer Ingelheim
6	<b>License Holder</b>	M/s Lupin LTD, M/s Cipla and M/s Torrent
7	<b>Date of Patent Expiry</b>	10.03.2025
8	<b>Calculation of Retail price</b>	
A	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Empagliflozin 5mg (Note 1)</b>	17.18
B	50% of Empagliflozin 5mg	8.59
C	Ceiling Price for Metformin 1000mg as on May 2024 (S.O. 1547(E) dated 26.3.2024) (i.e price applicable for month ending 6 months prior to month of receipt of application)	3.49
D	<b>Total</b>	<b>12.08</b>
E	Less: 20% of the lower of (B) and (C) based on inference drawn from the Pronab Sen Committee Report	0.70
F	<b>Worked out retail price (D-E)</b>	11.38
G	Claimed retail price	8.03
H	<b>Proposed retail price</b>	<b>8.03</b>

**Note 1: Derived price of Empagliflozin 5mg based on retail price of Empagliflozin 25mg Tablet as per the formula recommended in the Pronab Sen Committee report**

The Retail Price of Empagliflozin 25mg Tablet = Rs. 47.73 per tablet (Excluding GST) based on MAT/PTR of May 2024 (Database month – Dec 2024)

The retail price of Empagliflozin 5mg tablet based on formula recommended in the Pronab Sen Committee report is as below: -

Derived retail price as per recommendation of Pronab Sen committee:

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

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 injectables.

Derived price of Empagliflozin 5mg tablet as on May 2024 after applying the formula of Pronab Sen Committee:

$$= 47.73[1+0.80\{(5-25)/25\}] = \text{Rs. } 17.18 \text{ per tablet (excluding GST)}$$

औषध (मूल्य नियंत्रण)आदेश, 2013के अंतर्गत दवा **Composition:- Each film coated tablet contains: Empagliflozin 5mg + Metformin Hydrochloride IP 850mg for M/s Morepen Laboratories Ltd (Manufacturer) & (Marketer) की रिटेल कीमत निर्धारण (फाइल नंबर 4384).**

1	<b>Manufacturer Name</b>	M/s Morepen Laboratories Ltd.
2	<b>Marketer Name</b>	M/s Morepen Laboratories Ltd.
3	<b>Date of Application</b>	28.12.2024
4	<b>Patented Component</b>	Empagliflozin
5	<b>Patent Holder</b>	M/s Boehringer Ingelheim
6	<b>License Holder</b>	M/s Lupin LTD, M/s Cipla and M/s Torrent
7	<b>Date of Patent Expiry</b>	10.03.2025
8	<b>Calculation of Retail price</b>	
	Calculated Price	
A	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Empagliflozin 5mg (Note 1)</b>	17.18
B	50% of Empagliflozin 5mg	8.59
C	Price as on 6 months prior to application date i.e. MAT & PTR for May 2024 of <b>Metformin 850mg Tablet</b>	3.84
D	<b>Total</b>	<b>12.43</b>
E	Less: 20% of the lower of (B) and (C)	0.77
F	<b>Worked out Retail Price (D-E)</b>	<b>11.66</b>
G	Claimed retail price excluding GST	7.13
H	Proposed retail price excluding GST	7.13

**Note 1:**

The retail price of Empagliflozin 5mg tablet 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.

The Retail Price of Empagliflozin 25mg Tablet = Rs. 47.73 per tablet (Excluding GST) based on MAT/PTR of May 2024 (Database month – Dec 2024)

Derived retail price of Empagliflozin 5mg tablet as on May 2024 after applying the formula of Pronab Sen Committee as per (c) above:

$$= 47.73[1+0.80\{(5-25)/25\}] = \text{Rs. } 17.18 \text{ per tablet (excluding GST)}$$

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

Empagliflozin 25mg tablet		Number of Companies cosisting of Market Share of 1% & Above					5
		Sum of MAT value considered for price calculation (in Lakhs)					23,870.89
		Sum of PTR per unit considered for price calculation					205.74
		Number of Packs considered					5
		Average PTR					41.15
		Add : 16% Retailer Margin					6.58
		Retail Price (without local taxes)					47.73
		% Reduction 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

[illegible]



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

Empagliflozin IP 25mg	Number of Companies consisting of Market Share of 1% & Above							5
	Sum of MAT value considered for price calculation (in Lakhs)							23,969.05
	Sum of PTR per unit considered for price calculation							205.74
	Number of Packs considered							5
	Average PTR							41.15
	Add : 16% Retailer Margin							6.58
	Retail Price (without local taxes)							47.73
	% Reduction 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

[illegible]

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

Metformin 850mg		Number of Companies consisting of Market Share of 1% & Above					6
		Sum of MAT value considered for price calculation (in Lakhs)					3,007.31
		Sum of PTR per unit considered for price calculation					26.51
		Number of Packs considered					8
		Average PTR					3.31
		Add : 16% Retailer Margin					0.53
		Retail Price (without local taxes)					3.84
		% Reduction with compared to Highest Price					20.43%

Minimum Price (Rs.)			2.39
Maximum Price (Rs.)			4.16
Average of all considered (Rs.)			3.31
Retail Price (Rs.)			3.84

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