

**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 34<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 26.07.2021 at 11:00 AM in NPPA**

34<sup>th</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 26.07.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi
2. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
4. Dr. Gaurav Pratap Singh Jadaun, Sr. Scientific Officer, Indian Pharmacopoeia Commission
5. Dr. Pooja Gupta, Asso. Prof. Pharmacology, AIIMS, New Delhi
6. Dr. J.J. Cherian, Scientist D, IMCR, New Delhi

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

1. Ms. Rashmi Tahiliani, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Deputy Director (Pricing), NPPA

**1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013- Each pack of 200 ml oral solution containing Zinc Sulphate Monohydrate IP 0.0110g+ Sodium Citrate IP 0.5800g + Potassium Chloride IP 0.3000g + Sodium Chloride IP 0.5200g + Dextrose Anhydrous IP 2.7000g for M/s Halewood Laboratories Pvt. Ltd. (manufacturer) and M/s FDC Ltd. (marketer)**

1.1 The Committee deliberated upon the matter in detail and recommended the retail price of each pack of 200 ml oral solution containing Zinc Sulphate Monohydrate IP 0.0110g+ Sodium Citrate IP 0.5800g + Potassium Chloride IP 0.3000g + Sodium Chloride IP 0.5200g + Dextrose Anhydrous IP 2.7000g for M/s Halewood Laboratories Pvt. Ltd. (manufacturer) and M/s FDC Ltd. (marketer) at Rs. 0.15 per ml excluding GST as detailed below:

Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Each pack of 200 ml oral solution containing Zinc Sulphate Monohydrate IP 0.0110g + Sodium Citrate IP 0.5800g + Potassium Chloride IP 0.3000g + Sodium Chloride IP 0.5200g + Dextrose Anhydrous IP 2.7000g		
a. Zinc Sulphate Monohydrate IP 0.055 mg	Derived retail price (as per Pronab Sen Committee)	0.01

b. Sodium Citrate IP 0.5800g + Potassium Chloride IP 0.3000g + Sodium Chloride IP 0.5200g + Dextrose Anhydrous IP 2.7000g (assuming ceiling price of ORS liquid)	Ceiling Price of ORS Liquid (as per notification no.1330(E) dated 25.03.2021)	0.14
Worked out Retail Price		0.15
c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report		0.00
Worked out Retail Price (a+b-c)		0.15 per ml
Company Claimed Price		0.18 per ml
Recommended price		0.15 per ml

Note1. Derived Retail Price of Zinc Sulphate Monohydrate IP 0.0110 g in 200 ml pack

(i) 200 ml solution contains 0.0110g (i.e. 11mg) Zinc sulphate monohydrate in 200 ml pack. Therefore, in 1 ml pack it will contain 0.055 mg of Zinc Sulphate Monohydrate

(ii) Present applicable ceiling Price of Zinc Sulphate Dispersible Tablet 20 mg = Rs. 3.15 per tablet.

(iii) Therefore, the derived Retail price for Zinc Sulphate Monohydrate IP 0.055mg = Rs. 0.0087 i.e Re. 0.01 [Rs. 3.15/20 X 0.055]

Note 2. For calculation of the price of (b) in the table, the present ceiling price of ORS in solution i.e Rs. 0.14 per ml has been taken into consideration

**2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each enteric coated tablet containing Rabeprazole Sodium IP 20 mg+ Ondansetron Hydrochloride IP eq. to Ondansetron 4 mg for M/s Dallas Drugs Pvt. Ltd. (manufacturer) and M/s Alkem Laboratories Ltd. (marketer)**

2.1 The Committee noted that the Fixed Dose Combination (FDC) of enteric coated tablet containing Rabeprazole Sodium IP 20 mg+ Ondansetron Hydrochloride IP eq. to Ondansetron 4 mg is within the list of the formulations as per Central Drugs Standard Control Organisation (CDSCO) letter dated 08.01.2020 regarding the 'Procedure to be followed for subsequent applicant in respect of FDCs declared as rational by Prof. Kokate Committee and approval by DCG(I).'

2.2 The Committee deliberated upon the matter in detail and recommended the retail price of each enteric coated tablet containing Rabeprazole Sodium IP 20 mg+ Ondansetron Hydrochloride IP eq. to Ondansetron 4 mg for M/s Dallas Drugs Pvt. Ltd. (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 10.00 per tablet excluding GST as detailed below:-



Computation of Retail Price per Tablet	Source/Method	Amount (Rs.)
Composition – Each enteric coated tab containing Rabeprazole Sodium IP 20 mg Ondansetron Hydrochloride IP eq. Ondansetron 4 mg		
a. Rabeprazole Sodium IP 20 mg	Retail price (as per November 2020 data)	6.66
b. Ondansetron 4 mg	Ceiling Price (as per notification no.1330(E) dated 25.03.2021)	4.72
Worked out Retail Price		11.38
c. Less 20% of the lowest of (a) and (b) as recommended in the Pronab Sen Committee report		0.94
Net Retail Price (a+b-c)		10.44
Company Claimed Price		10.00
Recommended price		Rs. 10.00

**3. Agenda No. 3 – Retail price fixation under Para 5 of DPCO, 2013 - Each 5 ml syrup contains Paracetamol IP 125 mg + Phenylephrine Hydrochloride IP 5 mg + Chlorpheniramine Maleate IP 0.5 mg + Sodium Citrate IP 60 mg + Menthol IP 1 mg for M/s Shiv Industries (manufacturer) and M/s Profic Organic Ltd. (marketers)**

3.1 The Committee noted the retail price of subject new drug was earlier approved for various companies. Some of the companies have launched the formulations and have submitted Form-V. The Committee deliberated upon the matter in detail and decided to calculate the retail price by adding 16 percent to the average of the Price To Retailer (PTR) based on the latest Form-V submitted by the companies to whom the retail price were approved earlier. Accordingly, the Committee recommended the retail price of each 5 ml syrup contains Paracetamol IP 125 mg + Phenylephrine Hydrochloride IP 5 mg + Chlorpheniramine Maleate IP 0.5 mg + Sodium Citrate IP 60 mg + Menthol IP 1 mg for M/s Shiv Industries (manufacturer) and M/s Profic Organic Ltd. (marketers) at Rs. 0.64 per ml excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per ml
1	Group Pharmaceuticals Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide	60 ml	35.36	0.59

9

	SO. 2732(E) dated 17.08.2016)			
2	Magnet Labs Pvt. Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 3915(E) dated 18.12.2017)	60 ml	30.09	0.50
3.	Average PTR (Av of sl. No. 1 to 2)			0.55
4.	Add: Retailer margin @16% (16% of sl. No. 3)			0.09
5.	Calculated Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 3+ sl. No. 4)			0.64(Retail price per ml ex. GST)
6.	Retail price claimed			Rs. 1.25 per ml excluding GST
7.	Recommended retail price			Rs. 0.64 per ml

**4. Agenda No. 4 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)**

4.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*“(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were*

*earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets.*

*(iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

4.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> Authority meeting held on 28.06.2021. The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 6.25 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 5 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet were earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 7.00 per tablet excluding GST.

4.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 6.25 per tablet excluding GST.

**5. Agenda No. 5 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)**

5.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further*

*noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

5.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> Authority meeting held on 28.06.2021. The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 7.54 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 5 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 9.50 per tablet.

5.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 1000 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 7.54 per tablet excluding GST.

**6. Agenda No. 6 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (extended release) 500 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)**

6.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

6.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP (in extended release form) 500 mg at Rs. 9.65 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 11.00 per tablet.

6.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP 500 mg (extended release) for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 9.65 per tablet excluding GST.

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**7. Agenda No. 7 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)**

7.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

7.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP (in extended release form) 1000 mg at Rs. 11.17 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 13.50 per tablet excluding GST.

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7.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP 1000 mg (extended release) for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 11.17 per tablet excluding GST.

**8. Agenda No. 8 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Methylcobalamin IP 1500 mcg + Alpha lipoic Acid USP 100 mg+ Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3 mg+ Folic Acid IP 1.5 mg for M/s Akums Drugs and Pharmaceuticals Ltd. (manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (marketer)**

8.1. The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Methylcobalamin IP 1500 mcg + Alpha lipoic Acid USP 100 mg+ Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3 mg+ Folic Acid IP 1.5 mg for M/s Akums Drugs and Pharmaceuticals Ltd. (manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (marketer) at Rs. 10.97 per tablet excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per tablet
1	Zydus Healthcare Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 2398(E) dated 12.06.2018)	10 tablets	82.48	8.25
2	Cadila Pharmaceuticals Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 1674(E) dated 28.05.2020)	10 tablets	106.64	10.66
3.	Average PTR (Av of sl. No. 1 to 2)			9.46
4.	Add: Retailer margin @16% (16% of sl. No. 3)			1.51
5.	Calculated Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 3+ sl. No. 4)			10.97 (Retail price per tablet ex. GST)
6.	Retail price claimed			Rs. 16.07 per tablet excluding GST
7.	Recommended retail price			Rs. 10.97 per tablet

**9. Agenda No. 9 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Methylcobalamin IP 1500 mcg + Alpha lipoic Acid USP 100 mg+ Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3 mg+ Folic Acid IP 1.5 mg for M/s Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer)**

9.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Methylcobalamin IP 1500 mcg + Alpha lipoic Acid USP 100 mg+ Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3 mg+ Folic Acid IP 1.5 mg for M/s Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. 10.97 per tablet excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per tablet
1	Zydus Healthcare Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 2398(E) dated 12.06.2018)	10 tablets	82.48	8.25
2	Cadila Pharmaceuticals Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 1674(E) dated 28.05.2020)	10 tablets	106.64	10.66
3.	Average PTR (Av of sl. No. 1 to 2)			9.46
4.	Add: Retailer margin @16% (16% of sl. No. 3)			1.51
5.	Calculated Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 3+ sl. No. 4)			10.97 (Retail price per tablet ex. GST)
6.	Retail price claimed			Rs. 13.33 per tablet excluding GST
7.	Recommended retail price			Rs. 10.97 per tablet

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**10. Agenda No. 10 - Retail price fixation under Para 5 of DPCO, 2013- Gel containing Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac sodium 1.0% w/w +Methyl Salicyclate IP 10% w/w + Capsaicin USP 0.025% w/w + Menthol IP 5.0% w/w + Linseed Oil BP 3.0% w/w for M/s Hetero Healthcare Ltd. (manufacturer and marketer)**

10.1 The Committee deliberated upon the matter in detail and recommended the retail price of Gel containing Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac sodium 1.0% w/w +Methyl Salicyclate IP 10% w/w + Capsaicin USP 0.025% w/w + Menthol IP 5.0% w/w + Linseed Oil BP 3.0% w/w for M/s Hetero Healthcare Ltd. (manufacturer and marketer) at Rs. 2.70 per gm excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per gm
1	M/s Abbott Healthcare Pvt. Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 5638 (E) dated 02.11.2018)	30 gm	69.97	2.33
2	Add: Retailer margin @16% (16% of sl. No. 1)			0.37
3.	Proposed Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 1+ sl. No. 2)			2.70(Retail price per gm ex. GST)
4.	Retail price claimed			Rs. 3.57 per gm excluding GST
5.	Recommended retail price			Rs. 2.70 per gm

**11. Agenda No. 11 - Retail price fixation under Para 5 of DPCO, 2013- Each uncoated Orodispersible tablet containing Lorazepam IP 1mg & 2 mg for M/s La Pharma (Guj.) Pvt. Ltd. (manufacturer) and M/s Manas Pharma Mfg. (marketer)**

11.1 The Committee noted the application for retail price fixation of each uncoated Orodispersible tablet containing Lorazepam IP 1mg & 2 mg for M/s La Pharma (Guj.) Pvt. Ltd. (manufacturer) and M/s Manas Pharma Mfg.(marketer). The Committee further noted that Lorazepam 1mg & 2 mg tablet are scheduled formulations under DPCO 2013 and its ceiling price has been notified. The Committee deliberated upon the matter in detail and observed that there is no significant therapeutic advantage of

'orodispersible' variants of Lorazepam from the conventional variants. Accordingly, the Committee decided to close the application of M/s La Pharma (Guj.) Pvt. Ltd. (manufacturer) and M/s Manas Pharma Mfg (marketer) for retail price fixation of uncoated Orodispersible tablets containing Lorazepam IP 1mg & 2 mg. The Committee also decided that the ceiling price of Lorazepam 1mg & 2 mg tablet are applicable for Orodispersible tablets containing Lorazepam IP 1mg & 2 mg.

**12. Agenda No. 12 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 500 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer)**

12.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

12.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> Authority meeting held on 28.06.2021.

The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg at Rs. 6.25 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 5 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 6.74 per tablet.

12.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer) at Rs. 6.25 per tablet excluding GST.

**13. Agenda No. 13 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (extended release) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer)**

13.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets.*

*(iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by*

*adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

13.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP (in extended release form) 500 mg at Rs. 9.65 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 9.98 per tablet excluding GST.

13.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride 500 mg (extended release) for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer) at Rs. 9.65 per tablet excluding GST.

**14. Agenda No. 14 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer)**

14.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride*

*(Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers.”*

14.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.17 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 11.53 per tablet excluding GST.

14.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer) at Rs. 11.17 per tablet excluding GST.

**15. Agenda No. 15 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (extended release) 500 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Indoco Remedies Ltd. (marketer)**

15.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*“(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to*

*fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

15.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP (in extended release form) 500 mg at Rs. 9.65 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 11.87 per tablet excluding GST.

15.3 Accordingly, the Committee recommended the retail price of each film coated tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP/USP 500 mg (extended release) for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Indoco Remedies Ltd. (marketer) at Rs. 9.65 per tablet excluding GST.

**16. Agenda No. 16 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Indoco Remedies Ltd. (marketer)**

16.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*



*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

16.2 The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 11.17 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 13.73 per tablet.

16.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Indoco Remedies Ltd. (marketer) at Rs. 11.17 per tablet excluding GST.

**17. Agenda No. 17 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 1000 mg for M/s Synkem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. (marketer)**

17.1 The Committee noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug. The Committee further noted that the Authority in its 82nd meeting dated 23.12.2020 approved the retail price of Fixed Dose Combinations (FDCs) of Dapagliflozin 10 mg and Metformin Hydrochloride (Extended Release) 500/1000 mg tablet as per the methodology described below:

*"(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin has expired on 02.10.2020 making it an off-patent drug.*

*(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.*

*(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets. (iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiry to the consumers."*

17.2 The Committee also noted that in the similar methodology, the retail price of FDCs of Dapagliflozin 5mg and Metformin Hydrochloride 500mg/ 1000 mg tablet has been fixed for various companies in the 89<sup>th</sup> Authority meeting held on 28.06.2021. The Committee deliberated upon the matter in detail and decided to derive the retail price of each film coated bilayered tablet containing Dapagliflozin 5 mg + Metformin Hydrochloride IP (in extended release form) 1000 mg at Rs. 7.54 per tablet, in line with the decisions taken by the Authority in its 82nd meeting dated 23.12.2020, by taking data as per Form-V submitted by the companies to which the retail price for the Fixed Dose Combinations (FDCs) of Dapagliflozin 5 mg and Metformin Hydrochloride (Extended Release) 1000 mg tablet was earlier approved. The Committee also noted that the applicant company has claimed price of Rs. 8.04 per tablet.

17.3 Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg + Metformin Hydrochloride IP (extended release) 1000 mg for M/s Synokem Pharmaceuticals Ltd. (manufacturer) and M/s Primus Remedies Pvt. Ltd. Ltd. (marketer) at Rs. 7.54 per tablet excluding GST.

**18. Agenda No. 18 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Calcium Carbonate IP 1250 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + Calcium L-5-Methyltetrahydrofolate**

**(L- Methylfolate Calcium ) USP 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer)**

18.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + Calcium L-5-Methyltetrahydrofolate (L- Methylfolate Calcium) USP 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Unison Pharmaceuticals Pvt. Ltd. (manufacturer and marketer) at Rs. 17.12 per tablet excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per tablet
1	Torrent Pharmaceuticals Ltd (as per Form-V submitted by the company to which retail price approved earlier vide SO. 4062(E) dated 08.11.2019)	15 tablets	245.11	16.34
2	Cadila Pharmaceuticals Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 1674(E) dated 27.05.2020)	15 tablets	211.07	14.07
3.	Cipla Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 3973(E) dated 03 <sup>rd</sup> November, 2020)	15 tablets	213.32	14.22
4	Intas Pharmaceuticals Ltd. (as per Form-V submitted by the company to which retail price approved earlier vide SO. 1328(E) dated 25 <sup>th</sup> March, 2021)	10 tablets	144.14	14.41
5.	Average PTR (Av of sl. No. 1 to 4)			14.76
6.	Add: Retailer margin @16% (16% of sl. No. 5)			2.36
5.	Calculated Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 5+ sl. No. 6)			17.12 (Retail price per tablet ex. GST)
6.	Retail price claimed			Rs. 18.02 per

				tablet excluding GST
7.	Recommended retail price			Rs. 17.12 per tablet

**19. Agenda No. 19 - Application filed by M/s Cipla Ltd for grant of separate price / special price for 'Ciphaler Inhaler Device" under the provisions of para 11(3) of DPCO 2013**

19.1 The agenda item was deferred.

**20. Agenda No. 20 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features**

20.1 The agenda item was deferred.

**21. Agenda No. 21 – Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Mannitol Injection 20% in Non-glass pack having Special features.**

21.1 The agenda item was deferred.

**22. Agenda No. 22 – Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Dextrose Injection (25% w/v) 100 ml in Non-glass pack having Special features.**

22.1 The agenda item was deferred.

**23. Agenda No. 23 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.**

23.1 The Committee deliberated upon the matter in detail and noted that M/s Rusoma Laboratories Pvt. Ltd had applied for separate ceiling price for IV fluids with packaging in non-glass with special features i.e Eurohead bottles with brand name 'Dewdrip' in line with S.O. 1332(E) dated 25.03.2021. M/s Rusoma Laboratories Pvt. Ltd made demonstration before the members. The Committee also noted the copy of the license submitted by M/s Rusoma Laboratories Pvt. Ltd. The Committee observed that the non-glass packages of I.V. fluids of M/s Rusoma Laboratories Pvt. Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1332(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd for I.V. fluids in packages in non-glass with special features.

**24. Agenda No. 24 - Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature.**

24.1 The Committee deliberated upon the matter in detail and noted M/s Rusoma Laboratories Pvt. Ltd had applied for separate ceiling price for ringer lactate injection in packages with special features i.e Eurohead bottles with brand name 'Dewdrip' in line with S.O. 1333(E) dated 25.03.2021. M/s Rusoma Laboratories Pvt. Ltd made demonstration before the members. The Committee also noted the copy of the license submitted by M/s Rusoma Laboratories Pvt. Ltd and noted that the license for Ringer Lactate injection in 100 ml pack is not available. The Committee observed that the packages of ringer lactate injection of M/s Rusoma Laboratories Pvt. Ltd have special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in SO. 1333(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd [for product mentioned in Sl. No. 2, 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection for packages with special features.

The meeting ended with a vote of thanks to all.

*Rashmi*  
28/7/21  
(Rashmi Tahiliani)  
Jt. Director (Pricing)

Copy to:  
All members of the Committee.

Each film coated tablet containing Rabeprazole Sodium IP 20 mg for for M/s Dallas Drugs Pvt. Ltd. (manufacturer) and M/s Alkem Laboratories Ltd. (marketer)	Number of Companies consisting of Market Share of 1% & Above	19
	Sum of MAT value considered for price calculation (in Lakhs)	25,899.89
	Sum of PTR per unit considered for price calculation	114.77
	Number of Packs considered	20
	Average PTR	5.74
	Add : 16% Retailer Margin	0.92
	Retail Price (without local taxes)	6.66
% Reduction with compared to Highest Price	42.02%	

Minimum Price (Rs.)	0.79
Maximum Price (Rs.)	9.90
Average of all considered (Rs.)	5.74
Retail Price (Rs.)	6.66

S.No.	पैक विवरण Pack Description	ब्रांड BRAND	कंपनी Company	Strength	Pack Size	Unit	TOTAL MAT	2,856,464,088	100%	M3			
							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	ABOVE 5 20 MG TABLET 7	ABOVE 5	PFIZER LTD	20 MG	7	TABLET	29.36	30211.44	0.00%	0.00%	N	4.19	
2	ACERA 20 MG TABLET 10	ACERA	IPCA LABORATORIES PVT LTD.	20 MG	10	TABLET	53.57	9378778.63	0.33%	0.33%	N	5.36	
3	ACERA FAST 20 MG TABLET 10	ACERA FAST	IPCA LABORATORIES PVT LTD.	20 MG	10	TABLET	44.95	25351.8	0.00%	0.00%	N	4.50	
4	ACICHECK 20 MG TABLET 10	ACICHECK	IMACKENZIE PHARMACEUTICALS PVT.LTD	20 MG	10	TABLET	35	63630	0.00%	0.00%	N	3.50	
5	ANSUPER 20 MG TABLET 10	ANSUPER	AN PHARMACEUTICALS PVT.LTD.	20 MG	10	TABLET	67.63	123271.7	0.00%	0.00%	N	6.76	
6	ASCEND 20 MG TABLET 10	ASCEND	INDIAN DRUG & PHARMACEUTICALS LTD (IDPL)	20 MG	10	TABLET	55.36	166.08	0.00%	0.00%	N	5.54	
7	ASIDROP 20 MG TABLET 10	ASIDROP	INDIAN DRUG & PHARMACEUTICALS LTD (IDPL)	20 MG	10	TABLET	52.14	165283.8	0.01%	0.01%	N	5.21	
8	BEEPRAZ 20 MG TABLET 10	BEEPRAZ	GALPHA LABORATORIES LTD	20 MG	10	TABLET	25.66	144659.64	0.01%	0.01%	N	2.57	
9	BIPRA 20 MG TABLET 10	BIPRA	SINSAN PHARMACEUTICALS	20 MG	10	TABLET	58.93	2258945.83	0.08%	0.08%	N	5.89	
10	BRAVIA 20 MG TABLET 10	BRAVIA	GRANDCURE HEALTHCARE PVT. LTD.	20 MG	10	TABLET	47.14	6230258.1	0.22%	0.22%	N	4.71	
11	CHILKUL 20 MG TABLET 10	CHILKUL	RANBAXY LABORATORIES LTD	20 MG	10	TABLET	29.93	298910.91	0.01%	0.01%	N	2.99	
12	CYRA 20 MG TABLET 10	CYRA	SYSTOPIC LABORATORIES LTD-MEM	20 MG	10	TABLET	15.71	200894716.1	7.03%	7.03%	Y	1.57	1.57
13	DEREK 20 MG TABLET 10	DENEK	ALBERT DAVID	20 MG	10	TABLET	47.14	11120608.84	0.39%	0.39%	N	4.71	
14	DIALOZ 20 MG TABLET 10	DIALOZ	DIAL PHARMACEUTICALS PVT. LTD.	20 MG	10	TABLET	32.14	672136.12	0.02%	0.02%	N	3.21	
15	DIOROB 20 MG TABLET 10	DIOROB	DIVINE LIFECARE PVT LTD	20 MG	10	TABLET	29.29	179576.99	0.01%	0.01%	N	2.93	
16	EC RAB 20 MG TABLET 10	EC RAB	ICON LIFESCIENCES	20 MG	10	TABLET	44.64	365076.48	0.01%	0.01%	N	4.46	
17	ECORAB 20 MG TABLET 10	ECORAB	INDIABULLS PHARMACEUTICALS LTD	20 MG	10	TABLET	7.85	29690348.5	1.04%	1.04%	Y	0.79	0.79
18	ELRAB 20 MG TABLET 10	ELRAB	CAPTAB BIOTECH	20 MG	10	TABLET	41.9	635204	0.02%	0.02%	N	4.19	
19	ERB 20 MG TABLET 10	ERB	LYPHOMED REMEDIES P LTD	20 MG	10	TABLET	40.15	720652.35	0.03%	0.03%	N	4.02	
20	ERZOL 20 MG TABLET 10	ERZOL	ERGOS LIFE SCIENCES	20 MG	10	TABLET	62.07	4513606.28	0.16%	0.16%	N	6.21	
21	FAITHRAB 20 MG TABLET 10	FAITHRAB	FAITH-BUILD PHARMACEUTICALS	20 MG	10	TABLET	22.86	2354.58	0.00%	0.00%	N	2.29	
22	FAST(APPLE) 20 MG TABLET 10	FAST(APPLE)	APPLE LIFESCIENCE	20 MG	10	TABLET	45.71	260251.46	0.01%	0.01%	N	4.57	
23	FIRAZOL 20 MG TABLET 10	FIRAZOL	FIDELITY LIFESCIENCE	20 MG	10	TABLET	34.29	14127.48	0.00%	0.00%	N	3.43	
24	GRAB 20 MG TABLET 10	GRAB	KANAD LABS	20 MG	10	TABLET	45	1511.42	0.00%	0.00%	N	4.50	
25	HAPPI 20 MG TABLET 10	HAPPI	ZYDUS CADILA - ZHL	20 MG	10	TABLET	99	134829387	4.72%	4.72%	Y	9.90	9.90
26	HELIRAB 20 MG TABLET 10	HELIRAB	MICRO LABS LTD	20 MG	10	TABLET	65.71	5358002.53	0.19%	0.19%	N	6.57	
27	HINRAB 20 MG TABLET 10	HINRAB	PERK PHARMA	20 MG	10	TABLET	16.76	3184.4	0.00%	0.00%	N	1.68	
28	HYHEAL 20 MG TABLET 10	HYHEAL	GROUP PHARMACEUTICALS LTD.	20 MG	10	TABLET	26.43	1493439.29	0.05%	0.05%	N	2.64	
29	INRAB 20 MG TABLET 10	INRAB	VERITAZ HEALTHCARE LTD	20 MG	10	TABLET	38.5	3811.5	0.00%	0.00%	N	3.85	
30	LOCKER 20 MG TABLET 10	LOCKER	LEO LIFE SCIENCE PVT LTD	20 MG	10	TABLET	28.51	178468.74	0.01%	0.01%	N	2.85	
31	LRABI 20 MG TABLET 10	LRABI	LLOYD HEALTHCARE PVT.LTD	20 MG	10	TABLET	34.02	12281.22	0.00%	0.00%	N	3.40	
32	MAC 20 MG TABLET 10	MAC	CORONA	20 MG	10	TABLET	43.73	3805813.65	0.13%	0.13%	N	4.37	
33	MINIRAB 20 MG TABLET 10	MINIRAB	FORGEN HEALTHCARE LTD.	20 MG	10	TABLET	58.93	66722.89	0.00%	0.00%	N	5.89	
34	MYRAB 20 MG TABLET 10	MYRAB	MOREPEN LABORATORIES LIMITED	20 MG	10	TABLET	17.86	648335.86	0.02%	0.02%	N	1.79	
35	NUCID 20 MG TABLET 10	NUCID	HELIOS PHARMACEUTICALS	20 MG	10	TABLET	17.86	76905.16	0.00%	0.00%	N	1.79	
36	NULOC 20 MG TABLET 10	NULOC	ALKEM LABORATORIES LTD.	20 MG	10	TABLET	50	10208435.75	0.36%	0.36%	N	5.00	
37	NXTFLO 20 MG TABLET 10	NXTFLO	HAMPS INDIA PVT LTD	20 MG	10	TABLET	34.3	205.8	0.00%	0.00%	N	3.43	
38	ODIRAB 20 MG TABLET 10	ODIRAB	ZYDUS CADILA - ZHL	20 MG	10	TABLET	33.64	5514669.56	0.19%	0.19%	N	3.36	
39	ORG 20 MG TABLET 10	ORG	ORGANIC LABORATORIES	20 MG	10	TABLET	36.35	11086.75	0.00%	0.00%	N	3.64	
40	ORPRO 20 20 MG TABLET 10	ORPRO 20	EXELTIS	20 MG	10	TABLET	39.86	996.5	0.00%	0.00%	N	3.99	
41	PARIT 20 MG TABLET 10	PARIT	BIOCON LTD	20 MG	10	TABLET	72.22	13047192.98	0.46%	0.46%	N	7.22	
42	PEPCIA 20 MG TABLET 10	PEPCIA	FDC LTD.	20 MG	10	TABLET	28.5	31953733.37	1.12%	1.12%	Y	2.85	2.85
43	PEPRAZ 20 MG TABLET 10	PEPRAZ	EAST WEST PHARMA	20 MG	10	TABLET	55	12650	0.00%	0.00%	N	5.50	
44	PEPTARD 20 MG TABLET 15	PEPTARD	(INDO)EMIE HEALTH SPECIALITIES PVT. LTD.	20 MG	15	TABLET	125.94	29412128.5	1.03%	1.03%	Y	8.39	8.39
45	PRERABE 20 MG TABLET 10	PRERABE	CNX HEALTHCARE PVT LTD	20 MG	10	TABLET	50	528000	0.02%	0.02%	N	5.00	
46	PREREB 20 MG TABLET 10	PREREB	SUNFLOWER PHAMACEUTICALS	20 MG	10	TABLET	32.14	66404.62	0.00%	0.00%	N	3.21	
47	PRORAB 20 MG TABLET 10	PRORAB	DR. REDDYS LABORATORIES LTD	20 MG	10	TABLET	50.64	1946044.56	0.07%	0.07%	N	5.06	
48	R 20 20 MG TABLET 10	R 20	GNEXT LAB PVT LTD	20 MG	10	TABLET	51.79	636084.78	0.02%	0.02%	N	5.18	
49	R PPI 20 MG TABLET 10	R PPI	BLUE CROSS LABORATORIES LTD	20 MG	10	TABLET	24.64	21566603.52	0.79%	0.79%	N	2.46	
50	RAB (CIPLA) 20 MG TABLET 10	RAB (CIPLA)	CIPLA LTD.	20 MG	10	TABLET	60.12	92945.52	0.00%	0.00%	N	6.01	



