

मिसिलस.- 8(136)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(136)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 268/136/2025/F

Proceeding No: 268/136/2025/F

Minutes of the 268th (overall) and 136th meeting of the Authority under DPCO, 2013 held on 28.08.2025 at 12.00 noon.

The 268th meeting of the Authority (overall), which is the 136th meeting under the DPCO, 2013 was held on 28th August, 2025 at 12.00 noon under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Ms. Sai Ahlladini Panda, Member Secretary, NPPA
- (ii) Shri Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Dr. Rose Mary K. Abraham, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare.

The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri Sanjay Kumar, Advisor (Cost)
- (ii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)
- (v) Shri Mayur Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes of the 135th Meeting held on 30.07.2025.

1.1 The Authority confirmed the minutes of the meeting without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 135th Meeting held on 30.07.2025.

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority deliberated on 43 (Forty Three) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (43) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 42 (Forty Two) new drugs under Para 5 and 15 of the DPCO 2013 as given in **Table 1 below.**

Table No. 1: Retail price fixation of new drugs

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1	Amoxycillin & Potassium Clavulanate Oral suspension	Each 5 ml of constituted suspension contains: Amoxycillin Trihydrate IP Equivalent to Amoxycillin 400 mg Potassium Clavulanate Diluted IP Equivalent to Clavulanic Acid 57 mg	1 ml	M/s Copmed Pharmaceuticals Pvt. Ltd./ M/s Zydus Healthcare Ltd.	4.69
2	Amoxycillin & Potassium Clavulanate Oral suspension	Each ml of the reconstituted suspension contains: Amoxycillin Trihydrate IP equivalent to Amoxycillin 80 mg Potassium Clavulanate Diluted IP equivalent to Clavulanic Acid 11.4 mg	.1 ml	M/s Malik LifeSciences Pvt. Ltd./ M/s Aurobindo Pharma Ltd.	7.14
3	Amoxycillin & Potassium Clavulanate Tablets	Each film coated tablet contains: Amoxycillin Trihydrate IP Equivalent to Amoxycillin 875 mg Potassium Clavulanate Diluted IP Equivalent to Clavulanic Acid 125 mg	1 Tablet	M/s Alps Communication Pvt. Ltd./ M/s Indoco Remedies Ltd.	Deferred (Note 1)
4	Bilastine & Montelukast Tablets	Each film coated tablet contains: Bilastine IP 20 mg Montelukast Sodium IP equivalent to Montelukast 10 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.97
5	Bisoprolol Fumarate &	Each film coated tablet contains:	1 Tablet	M/s Swiss Garnier Life sciences/	8.72

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	Amlodipine tablets	Bisoprolol Fumarate IP 5 mg Amlodipine Besylate equivalent to Amlodipine IP 5 mg		M/s Cadila Pharmaceuticals Ltd.	
6	Calcium & Vitamin D3 tablets	Each film coated tablet contains: Calcium Citrate Malate IP eq. to Elemental Calcium 250 mg Vitamin D3 IP 1000 IU	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	12.09
7	Cefixime & Ofloxacin (SR) Tablets	Each film coated Sustained Release tablet contains: Cefixime IP as Trihydrate Eq. to Anhydrous Cefixime 400mg Ofloxacin IP 400mg	1 Tablet	M/s Malik Lifesciences Pvt. Ltd./ M/s Alkem Laboratories Ltd.	30.79
8	Cefixime & Ofloxacin oral suspension	Each 5ml reconstituted suspension contains: Cefixime IP as Trihydrate Eq. to Anhydrous Cefixime 50mg Ofloxacin IP 50mg	1 ml	M/s Innova Captab Ltd. /M/s FDC Ltd.	2.00
9	Cefixime Dispersible Tablets	Each Uncoated Dispersible Tablet Contains: Cefixime IP Eq. to Anhydrous Cefixime 100 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	7.56
10	Cefpodoxime & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefpodoxime Proxetil IP eq. to Cefpodoxime 200 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Malik Lifesciences Pvt. Ltd./ M/s Akumentis Healthcare Ltd.	30.72
11	Cholecalciferol (Vitamin D3) Oral Solution	Each 5 ml contains: Cholecalciferol IP (In Nano Droplet Form) 60,000 IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Zydus Healthcare Ltd.	15.17
12	Cilnidipine & Telmisartan Tablets	Each Film Coated Tablet Contains: Cilnidipine IP 10 mg Telmisartan IP 80 mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	17.37
13	Dapagliflozin, Glimepiride & Metformin Hydrochloride	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP Eq. to Dapagliflozin	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Dr. Reddy's Laboratories Ltd.	11.02

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(Extended Release) Tablets	10mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500mg (As Extended Release Form)			
14	Dapagliflozin, Glimepiride & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP Eq. to Dapagliflozin 10mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500mg (As Extended Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Dr. Reddy's Laboratories Ltd.	11.81
15	Empagliflozin & Metformin Hydrochloride Tablets	Each film-coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Systopic Laboratories Pvt Ltd	18.10
16	Empagliflozin, Linagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each Film coated bilayer tablet contains: Linagliptin 5 mg Empagliflozin 25 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Natco Pharma Ltd.	25.00
17	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg Metformin Hydrochloride (As Extended Release) IP 1000mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cadila Pharmaceuticals Ltd.	31.75
18	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000mg Empagliflozin 25 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cadila Pharmaceuticals Ltd.	35.29
19	Empagliflozin, Sitagliptin & Metformin	Each film coated bilayer tablet contains: Empagliflozin 10 mg	1 Tablet	M/s Exemed Pharmaceuticals/	22.90

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	Hydrochloride (Extended Release) Tablets	Metformin Hydrochloride (As Extended Release) IP 1000 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg		M/s MSN Laboratories Pvt. Ltd.	
20	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000mg Empagliflozin 25 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s MSN Laboratories Pvt. Ltd.	23.90
21	Indomethacin & Paracetamol Capsules	Each hard gelatin capsule contains: Indomethacin IP (enteric coated) 25mg Paracetamol IP 325 mg	1 Capsule	M/s Windlas Biotech Ltd./ M/s Micro Labs Ltd.	6.22
22	Meropenem & Sulbactam for Injection	Each vial contains: Meropenem Trihydrate IP Eq. to Anhydrous Meropenem 1000 mg Sodium (as Sodium Carbonate IP) 90.2 mg Sulbactam Sodium IP equivalent to Sulbactam 500 mg	1 Vial	M/s GMH Organics / M/s Zydus Healthcare Ltd.	1938.5 9
23	Mycophenolate Mofetil Tablets	Each film coated tablet contains: Mycophenolate Mofetil IP 750 mg	1 Tablet	M/s Ipca Laboratories Ltd.	131.58
24	Ofloxacin & Metronidazole Oral Suspension	Each 5ml contains: Ofloxacin IP 100mg Metronidazole Benzoate IP Eq. to Metronidazole 200mg	1 ml	M/s Aryatech Pharma Pvt. Ltd./ M/s Alkem Laboratories Ltd.	1.04
25	Ofloxacin & Metronidazole Suspension	Each 5 ml contains: Ofloxacin IP 100 mg Metronidazole Benzoate IP Equivalent to Metronidazole 200 mg	1 ml	M/s Hema Laboratories Pvt. Ltd./ M/s Abbott Healthcare Pvt. Ltd.	1.04
26	Olmesartan Medoxomil, Amlodipine &	Each film coated tablet contains: Olmesartan Medoxomil IP 40 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Laboratories Ltd.	20.98

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	Hydrochlorothiazide Tablets	Amlodipine Besilate IP Eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg			
27	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablets	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besilate IP Eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Laboratories Ltd.	15.82
28	Paracetamol Infusion	Each ml contains: Paracetamol IP 10 mg	1 ml	M/s Appasamy Ocular Devices Pvt. Ltd./ M/s Tyykem Pvt. Ltd.	3.41
29	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine Hydrochloride Tablets	Each film coated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 5 mg Caffeine (anhydrous) IP 30 mg Diphenhydramine Hydrochloride IP 25 mg	1 Tablet	M/s Prosperity Drugs Pvt. Ltd./ M/s Intas Pharmaceuticals Ltd.	4.49
30	Povidone-Iodine & Metronidazole Ointment	Povidone-Iodine IP 5 % w/w (Available Iodine 0.5% w/w) Metronidazole IP 1% w/w	1 gm	M/s Nanz Med Science Pharma (P) Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	3.77
31	Ramipril & Extended Release Metoprolol Succinate Tablets	Each film coated bilayered tablet contains: Ramipril IP 5 mg Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50 mg (as Extended Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./M/s Dr. Reddy's Laboratories Ltd.	25.78
32	Rosuvastatin, Aspirin & Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP Equivalent to Rosuvastatin 10 mg (As granules) Aspirin IP 75 mg (As enteric coated tablets) Clopidogrel Bisulphate IP Equivalent to Clopidogrel 75 mg (as two film coated tablets)	1 Capsule	M/s Windlas Biotech Ltd./ M/s Merck Specialities Pvt Ltd.	15.61

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
33	Rosuvastatin, Aspirin & Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP equivalent to Rosuvastatin 20 mg (As granules) Aspirin IP 75 mg (As enteric coated tablets) Clopidogrel Bisulphate IP Equivalent to Clopidogrel 75 mg (as two film coated tablets)	1 Capsule	M/s Windlas Biotech Ltd./ M/s Merck Specialities Pvt Ltd.	22.76
34	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 50 mg Metformin Hydrochloride IP 500 mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Corona Remedies Pvt. Ltd.	13.27
35	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Corona Remedies Pvt. Ltd.	14.95
36	Telmisartan & Amlodipine Tablets	Each film coated tablet contains: Telmisartan IP 80 mg Amlodipine Besilate IP Eq. to Amlodipine 5 mg	1 Tablet	M/s Lifecare Formulations Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	20.15
37	Telmisartan & Amlodipine Tablets	Each uncoated Tablet contains: Telmisartan IP 80 mg Amlodipine Besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s Workcell Solutions Pvt. Ltd.	16.00
38	Voglibose & Metformin HCl (SR) Tablets	Each uncoated bilayered tablet contains: Voglibose IP 0.3 mg Metformin Hydrochloride IP 500 mg (as sustained release form)	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s Workcell Solutions Pvt. Ltd.	11.61

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
39	Cefixime & Ofloxacin oral suspension	Each 5 ml reconstituted suspension contains: Cefixime Trihydrate IP equivalent to Cefixime anhydrous 50 mg Ofloxacin IP 50 mg	1 ml	M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd.	1.93
40	Ceftriaxone and Tazobactam injection	Each vial contains: Ceftriaxone Sodium IP equivalent to anhydrous Ceftriaxone 1000 mg Tazobactam Sodium IP equivalent to anhydrous Tazobactam 125mg	1 vial	M/s East African (India) Overseas / M/s FDC Limited	199.26
41	Amlodipine & Bisoprolol Fumarate Tablets	Each film coated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg Bisoprolol Fumarate IP 5 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Torrent Pharmaceuticals Ltd.	9.47
42	Amlodipine & Bisoprolol Fumarate Tablets	Each film coated tablet contains: Amlodipine Besylate IP eq. to Amlodipine 2.5 mg Bisoprolol Fumarate IP 2.5 mg	1 Tablet	M/s Exemed Pharmaceuticals/M/s Torrent Pharmaceuticals Ltd	7.39
43	Clarithromycin Extended Release Tablets	Each Extended Release film coated tablet contains: Clarithromycin IP 1000 mg	1 Tablet	M/s Abbott Healthcare Pvt. Ltd.	71.71

Note 1: The applicant company M/s Indoco Remedies Ltd. filed representation on 23.08.2025. Since the same is under examination, the Authority directed to defer the same.

5. Agenda item no. 5: Minutes of 70th meeting of Multidisciplinary Committee of Experts held on 05.08.2025.

5.1 Noted.

6. Agenda item no. 6: Application for approval of separate ceiling price for formulations in EURO Head packaging by M/s BML Parenteral Drugs.

6.1 The Authority noted that M/s BML Parenteral Drugs vide email dated 10.03.2025 and 8.05.2025 applied for extension of separate ceiling price under Para 11(3) for following I.V. fluids in Euro Head Packaging:

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Sr. No.	Name of Product	Pack Size	MRP including GST Claimed
1.	Sodium Chloride Inj 0.9% w/v	100ml	44.00
2.	Sodium Chloride Inj 0.9% w/v	250ml	65.00
3.	Sodium Chloride Inj 0.9% w/v	500ml	90.00
4.	Compound Sodium Lactate Injection	500ml	70.00
5.	Compound Sodium Lactate Injection	250ml	55.00
6.	Dextrose Injection IP 5% w/v	500ml	90.00
7.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	90.00

6.2 The Authority noted that the matter was deliberated by the MDC in its 69th meeting held on 03.07.2025 and 70th meeting held on 05.08.2025, wherein the applicant demonstrated their product for the features of self-sealability, self-collapsibility and Euro head to prevent contamination.

6.3 It was noted that the applicant had filed an application in March 2025 and at that time the ceiling price applicable for these formulations were notified in March 2024. The applicant claimed prices lower than the notified ceiling prices. Now, these prices have been revised based on WPI in March 2025, which are effective from 01.04.2025. The applicant requested to extend the separate ceiling prices for the applied formulations as applicable w.e.f. 01.04.2025 before the MDC. Accordingly, MDC recommended to extend the present applicable ceiling separate ceiling in respect of the formulations to the applicant.

6.4 The Authority deliberated upon the matter and approved the recommendation of MDC to extend the present applicable separate ceiling prices to M/s BML Parenteral Drugs under the provision of Para 11 (3) of DPCO 2013 as below:

Sr. No.	Name of Product	Pack Size	Notification No.	Approved Ceiling price / pack (Rs.)
1.	Sodium Chloride Inj 0.9% w/v	100ml	1485(E) Dated 27.03.2025	42.79
2.	Sodium Chloride Inj 0.9% w/v	250ml	1485(E) Dated 27.03.2025	63.18
3.	Sodium Chloride Inj 0.9% w/v	500ml	1485(E) Dated 27.03.2025	89.47
4.	Ringer Lactate Inj.	250ml	1474(E) Dated 27.03.2025	51.88
5.	Ringer Lactate Inj.	500ml	1474(E) Dated 27.03.2025	66.09
6.	Glucose Injection 5% (w/v)	500ml	1485(E) Dated 27.03.2025	83.70
7.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	500ml	1485(E) Dated 27.03.2025	87.01

7. Agenda item no. 7: Application for approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head /LDPE Bottles with special features by M/s Hindustan Polyfab.

7.1 The Authority noted that M/s Hindustan Polyfab vide email dated 30.06.2025 applied for separate ceiling prices under Para 11(3) of the DPCO, 2013 for the following IV Fluids:

Sr. No.	Name of Product	Pack Size	MRP including GST Claimed
1.	Sodium Chloride Inj 0.9% w/v	100ml	47.92
2.	Sodium Chloride Inj 0.9% w/v	500ml	100.21
3.	Dextrose Injection IP 5% w/v	500ml	93.74
4.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	97.45
5.	Dextrose Injection IP 25% w/v	100ml	26.88
6.	Compound Sodium Lactate Injection	500ml	74.02
7.	Ciprofloxacin Injection 200mg/100ml	100ml	25.76
8.	Metronidazole Injection 500mg/100ml	100ml	28.00
9.	Dextrose Injection IP 10% w/v	500ml	41.25

7.2 The Authority noted that the matter was deliberated by the MDC in its 69th meeting held on 03.07.2025 and 70th meeting held on 05.08.2025, wherein the applicant demonstrated their product for the features of self-sealability, self-collapsibility and has Euro head to prevent the contamination. The applicant also requested to withdraw the application for two formulations listed at S. No. 5 and 9 of above table i.e., Dextrose Injection IP 25% w/v in 100ml and Dextrose Injection IP 10% w/v in 500ml.

7.3 It was noted that MDC recommended to extend the present applicable separate ceiling in respect of the 7 applied formulations to the applicant.

7.4 The Authority deliberated upon the matter and approved the recommendation of MDC to extend the present applicable separate ceiling prices to M/s Hindustan Polyfab under the provision of Para 11 (3) of DPCO 2013 as below:

Sr. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date) (Rs.)	Claimed MRP/pack including GST	Claimed MRP/pack excluding GST	Approved Ceiling price (Rs.)
1.	Sodium Chloride Inj 0.9% w/v	100ml	42.79/pack (1485(E) dt.27.03.2025)	47.92	42.79	42.79 / pack
2.	Sodium Chloride Inj 0.9% w/v	500ml	89.47/pack (1485(E) dt.27.03.2025)	100.21	89.47	89.47 / pack

Sr. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date) (Rs.)	Claimed MRP/pack including GST	Claimed MRP/pack excluding GST	Approved Ceiling price (Rs.)
3.	Dextrose Injection IP 5% w/v	500ml	83.70/pack (1485(E) dt.27.03.2025)	93.74	83.70	83.70/pack
4.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	87.01/pack (1485(E) dt.27.03.2025)	97.45	87.01	87.01/pack
5.	Compound Sodium Lactate Injection	500ml	66.09/pack (1474(E) dt.27.03.2025)	74.02	66.09	66.09/pack
6.	Ciprofloxacin Injection 200mg/100ml	100ml	0.23/ml (1486(E) dt.27.03.2025)	25.76	23.00	0.23/ml
7.	Metronidazole Injection 500mg/100ml	100ml	0.25/ml (1486(E) dt.27.03.2025)	28.00	25.00	0.25/ml

8. Agenda item no. 8: Application for extension of ceiling price of L.V. Fluids with Packaging in non-glass with special feature by M/s Pharma Impex Laboratories Pvt. Ltd.

8.1 The Authority noted that M/s Pharma Impex Laboratories Pvt. Ltd. vide emails dated 7.11.2024 & 10.1.2025 applied for extension of ceiling price of following I.V. with packaging in non-glass with special feature for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification No. as mentioned in application
1.	Sodium Chloride Inj 0.9% w/v	100ml, 500 ml & 1000 ml	1552(E) Dated 26.03.2024
2.	Dextrose (Glucose) Injection 25% (w/v)	100ml pack	2289(E) Dated 14.06.2024
3.	Metronidazole Inj. (0.5% w/v)/500mg/100ml	100ml	1555(E) Dated 26.03.2024
4.	Ciprofloxacin Inj. 200 mg. per 100 ml	100ml	2286(E) Dated 14.06.2024
5.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	500 ml & 1000 ml	1552(E) Dated 26.03.2024
6.	Glucose Injection 5% (w/v)	500 ml & 1000 ml	1552(E) Dated 26.03.2024
7.	Mannitol Inj. 20%	100ml	1556(E) Dated 26.03.2024
8.	Ringer Lactate Inj.	500 ml & 1000 ml	1553(E) Dated 26.03.2024

8.2 The Authority noted the matter was deliberated by the MDC in its 69th meeting held on 03.07.2025 and 70th meeting held on 05.08.2025, wherein the applicant demonstrated their products for the features of no chances of contamination during manufacture/ infusion/admixing level, self-sealability, self-collapsibility and not having air vent. Further, the applicant also submitted before the MDC that at the time of submission of their application ceiling prices for these formulations were applicable based on WPI notification issued w.e.f. April 2024, however, the present applicable ceiling price of the applied formulations having special features to the eligible applicant companies have been revised w.e.f. 01.04.2025.

8.3 Accordingly, the Committee recommended the present applicable separate ceiling prices as below:

Sr. No.	Name of Product	Pack Size	Notification No. as mentioned in application	Recommended Ceiling price (Rs.)
1.	Sodium Chloride Inj 0.9% w/v	100ml	1485(E) Dated 27.03.2025	42.79/pack
2.	Sodium Chloride Inj 0.9% w/v	500ml	1485(E) Dated 27.03.2025	89.47/pack
3.	Sodium Chloride Inj 0.9% w/v	1000ml	1485(E) Dated 27.03.2025	100.22/pack
4.	Dextrose (Glucose) Injection, 25% (w/v)	100ml pack	1486(E) Dated 27.03.2025	0.24/ml
5.	Metronidazole Inj. (0.5% w/v)/500mg/100ml	100ml	1486(E) Dated 27.03.2025	0.25/ml
6.	Ciprofloxacin Inj. 200 mg. per 100 ml	100ml	1486(E) Dated 27.03.2025	0.23/ml
7.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	500ml	1485(E) Dated 27.03.2025	87.01/pack
8.	Glucose (Dextrose) 5% + Sodium Chloride 0.9% Inj.	1000ml	1485(E) Dated 27.03.2025	101.68/pack
9.	Glucose Injection 5% (w/v)	500ml	1485(E) Dated 27.03.2025	83.70/pack
10.	Glucose Injection 5% (w/v)	1000ml	1485(E) Dated 27.03.2025	96.77/pack
11.	Mannitol Inj. 20%	100ml	1486(E) Dated 27.03.2025	0.41/ml
12.	Ringer Lactate Inj.	500ml	1474(E) Dated 27.03.2025	66.09/pack
13.	Ringer Lactate Inj.	1000ml	1474(E) Dated 27.03.2025	116.20/pack

8.4 The Authority deliberated upon the matter in detail and approved the recommendation of the MDC by extending the ceiling price as per the table above under the provision of Para 11 (3) of DPCO 2013 to M/s Pharma Impex Laboratories Pvt. Ltd.

9. Agenda item no. 9: Application for separate ceiling price for "special feature" scheduled product under para 11(3) by M/s Gufic Biosciences Limited Meropenem injection in DCB (Dual Chamber Bags)

9.1 The Authority noted that M/s Gufic Biosciences Limited vide letter dated 10.06.2025 has requested for 'Special Feature rate' of scheduled formulation 'Meropenem injection' in DCB (Dual Chamber Bags) under para 11(3) of DPCO, 2013 as detailed below:

SI. No.	Product Name	Composition	Proposed Ceiling Price	Existing Ceiling Price	Proposed % increase
1	Merofic DCB 500 MG Injection	Meropenem Sterile 500 MG	Rs. 1000	Rs. 735.60	35.94 %
2	Merofic DCB 1 GM Injection	Meropenem Sterile 1 GM	Rs. 1300	Rs. 969.32	34.11 %

9.2 The Authority noted that the application was deliberated by the MDC in its 69th meeting held on 03.07.2025 and 70th meeting held on 05.08.2025, wherein the Committee deliberated on the submissions of the applicant and dual chamber bags have special feature (i) self-collapsibility and self-sealability (ii) not having air-vent; and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels in their dual chamber bags. Accordingly, the Committee recommended the separate ceiling price for Meropenem injection 500mg and 1000mg in DCB (Dual Chamber Bags) under para 11(3) of DPCO, 2013 at present applicable ceiling prices + 15% in line with increase considered earlier for this type of packaging, as detailed below:

SI. No.	Name of the Scheduled Formulation	Claimed Price	Existing Ceiling Price w.e.f. 01.04.2025	Approved separate Ceiling price i.e., ceiling price + 15%
1	Meropenem Powder for Injection 500 mg (as trihydrate) in Dual chamber bags	Rs. 1000	Rs. 735.60	Rs. 845.94 per Dual Chamber Bag
2	Meropenem Powder for Injection 1000 mg (as trihydrate) in Dual chamber bags	Rs. 1300	Rs. 969.32	Rs.1114.72 per Dual Chamber Bag

9.3 The Authority deliberated upon the matter in detail and approved the recommendation of the MDC by extending the ceiling price as per the table above under the provision of Para 11 (3) of DPCO 2013 M/s Gufic Biosciences Limited.

10. Agenda item no. 10: Application for separate pricing for paracetamol infusion as per Para 11 (3) of the Drugs Price control order (DPCO), 2013 in Non PVC bag with special features

10.1 The Authority noted that M/s Themis Medicare Limited on 17.10.2024 applied for separate price for Paracetamol 1000MG/100ML pack in Non-PVC bag with special features under Para 11(3) of the DPCO, 2013. 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. The applicant requested for separate price of Rs. 850/100ml pack. The applicant has mentioned that they are already marketing the formulation at Rs. 577.57/100ml pack in FFS Bottle. Now, they are intending to launch the same formulation in new package.

10.2 It was noted that the matter was deliberated by the MDC in 67th, 68th and 70th meeting. The Committee in the discussions held in the 67th and 68th meetings held on 2.4.2025 & 3.06.2025 respectively, observed that the company had already launched the formulation with special features. However, the MRP was same as product without special features (FFS bottle). The company has now sought separate price at RS. 850 per pack. The Committee in the 68th meeting requested additional information i.e., the launch date and price of the product, as well as certified quantity data. The applicant submitted the launch details and pricing history on 02.07.2025. However, the company vide email dated 31.07.2025, withdrew the application and decided to continue marketing the product at the existing MRP. The committee accepted the withdrawal and recommended to close the matter.

10.3 The Authority deliberated upon the matter in detail and approved the recommendation of the MDC to close the matter by accepting the withdrawal of the application by the company.

The meeting ended with a vote of thanks to the Chair and the participants.


(Sai Ahladini Panda)
Member Secretary