

मिसिलस.- 8(128)/2024/डी.पी/एनपीपीए-डीवी-II

F. No. 8(128)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 260/128/2024/F

Proceeding No: 260/128/2024/F

Minutes of the 260th (overall) and 128th meeting of the Authority under DPCO, 2013 held on 12.12.2024 at 11:30 a.m.

The 260th meeting of the Authority (overall), which is the 128th meeting under the DPCO, 2013 was held on 12th December, 2024 at 11:30 a.m. under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), O/o Chief Adviser (Cost), Department of Expenditure

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, Adviser (Cost)
- (ii) Shri G. L. Gupta, Director (M&E)
- (iii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)
- (v) Shri Rajesh K.T., Deputy Director, (M&E)
- (vi) Ms. Yuvika Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes and Record Note of Discussion of the 127th Meeting held on 08.10.2024.

1.1 The Authority confirmed the Minutes and Record Note of Discussions without any change.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 127th Meeting held on 08.10.2024.

2.1 Noted.

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

3.1 The Authority noted the status of Form I applications and it was informed that fifteen Form I applications have been rejected on account of different reasons viz., incomplete documents, non-compliance of licensing requirement as per NDCT Rules 2019, etc.

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 Sixty-Five (65) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (lxv) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of Sixty-Five (65) 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

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4 (i)	Acebrophylline and N-Acetylcysteine Tablets	Each film coated tablet contains: Acebrophylline 100 mg N-Acetylcysteine Ph. Eur. 600 mg	Tablet	M/s Win Medicare Pvt. Ltd./ M/s Modi-Mundipharma Pvt. Ltd.	14.31
2	4 (ii)	Acyclovir Sustained-Release Tablets	Each uncoated sustained-release tablet contains: Acyclovir IP 1200mg	Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Mankind Pharma Ltd.	56.21
3	4 (iii)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40 mg Ezetimibe IP 10 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharma Laboratories Limited	34.65
4	4 (iv)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40 mg Ezetimibe IP 10 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharmaceutical Industries Limited	34.65
5	4 (v)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20 mg Ezetimibe IP 10 mg	Tablet	M/s Sun Pharma Laboratories Limited/ M/s Sun Pharmaceutical Industries Limited	27.38
6	4 (vi)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20 mg Ezetimibe IP 10 mg	Tablet	M/s Sun Pharma Laboratories Limited	27.38

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
7	4 (vii)	Dispersible Amoxycillin & Potassium Clavulanate Tablets BP	Each uncoated dispersible tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 400 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57 mg	Tablet	M/s Malik Lifesciences Pvt. Ltd./ M/s Micro Labs Ltd.	24.66
8	4 (viii)	Bisoprolol Fumarate and Amlodipine tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Amlodipine besylate IP eq. to Amlodipine 5 mg	Tablet	M/s Dr. Miltons Laboratories Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	8.40
9	4 (ix)	Bisoprolol Fumarate and Amlodipine tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Amlodipine besylate IP eq. to Amlodipine 5 mg	Tablet	M/s Dr. Miltons Laboratories Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	6.32
10	4 (x)	Cefuroxime Axetil and Potassium clavulanate Tablets	Each film coated tablet contains: Cefuroxime Axetil IP eq. to Cefuroxime 500 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	Tablet	M/s Alps communication Pvt. Ltd./ M/s Aristo Laboratories Pvt. Ltd.	58.08
11	4 (xi)	Cefuroxime Axetil & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefuroxime Axetil IP eq. to Cefuroxime 500mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	Tablet	M/s Innova Captab Limited /M/s Dr. Reddy's Laboratories Limited	58.08
12	4 (xii)	Vitamin D3 Oral Drops	Each ml contains: Cholecalciferol (Vitamin D3) IP 800 IU	Per ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Alkem Laboratories Ltd.	5.75
13	4 (xiii)	Cholecalciferol (Vitamin D3) oral solution	Each 5 ml contains: Cholecalciferol IP (in nano droplet form) 60000IU	Per ml	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Laboratories Pvt. Ltd.	18.93

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
14	4 (xiv)	Cholecalciferol (Vitamin D3) oral solution	Each 5 ml contains: Cholecalciferol IP 60000IU	Per ml	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Macleods Pharmaceuticals Ltd.	20.23
15	4 (xv)	Cilnidipine & Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Cilnidipine 10mg Metoprolol Succinate USP 23.75mg eq. to Metoprolol Tartrate 25mg (in extended-release form)	Tablet	M/s Ravenbhel Biotech / M/s Mankind Pharma Ltd.	9.91
16	4 (xvi)	Cilnidipine & Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Cilnidipine 10mg Metoprolol Succinate USP 47.5mg eq. to Metoprolol Tartrate 50mg (in extended release form)	Tablet	M/s Ravenbhel Biotech/ M/s Mankind Pharma Ltd.	11.02
17	4 (xvii)	Dextromethorphan Hydrobromide, Bilastine & Phenylephrine Hydrochloride Syrup	Each 5ml contains: Dextromethorphan Hydrobromide IP 10mg Bilastine IP 3.3mg Phenylephrine Hydrochloride IP 5mg	Per ml	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Akumentis Healthcare Ltd.	1.17
18	4 (xviii)	Diclofenac Injection IP	Each ml contains: Diclofenac sodium IP 75 mg	Per ml	M/s Nitin Lifesciences Ltd / M/s Aristo Laboratories Pvt. Ltd.	31.38
19	4 (xix)	Esomeprazole and Domperidone Sustained Release capsules	Each hard gelatin capsule contains: Esomeprazole Magnesium IP eq. to Esomeprazole 40 mg (as enteric coated pellets) Domperidone Maleate IP eq. to Domperidone 30 mg (sustained release)	Capsule	M/s Windlas Biotech Ltd./ M/s Intas Pharmaceuticals Ltd.	12.39

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
20	4 (xx)	Esomeprazole & Domperidone Capsules	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40 mg (as enteric coated pellets) Domperidone IP 30 mg (as sustained release pellets)	Capsule	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	12.50
21	4 (xxi)	Etamsylate & Tranexamic Acid Tablets	Each film coated tablet contains: Etamsylate BP 250 mg Tranexamic Acid IP 250 mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	19.59
22	4 (xxii)	Glimepiride IP, Voglibose IP, Metformin Hydrochloride (SR) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 0.5 mg, Voglibose IP 0.2 mg, Metformin Hydrochloride IP (as sustained release form) 500 mg	Tablet	M/s Windlas Biotech Limited/ M/s Intas Pharmaceuticals Ltd.	9.12
23	4 (xxiii)	Gliclazide MR & Metformin Hydrochloride ER tablets	Each uncoated bilayered tablet contains: Metformin Hydrochloride (in extended release form) IP 500 mg Gliclazide (in modified release form) IP 30 mg	Tablet	M/s Unison Pharmaceuticals Pvt. Ltd	7.46
24	4 (xxiv)	Gliclazide MR & Metformin Hydrochloride ER tablets	Each uncoated bilayered tablet contains: Metformin Hydrochloride (in extended release form) IP 500 mg Gliclazide (in modified release form) IP 60 mg	Tablet	M/s Unison Pharmaceuticals Pvt. Ltd	9.74

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
25	4 (xxv)	Glimepiride, Voglibose IP, Metformin Hydrochloride IP (as sustained release form) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 0.5mg Voglibose IP 0.2mg Metformin Hydrochloride IP 500mg (as sustained release form)	Tablet	M/s Windlas Biotech Ltd./ M/s Lupin Limited	9.12
26	4 (xxvi)	Glimepiride, Voglibose and Metformin Hydrochloride (ER) tablets	Each uncoated bi-layered tablet contains: Glimepiride IP 1mg, Voglibose IP 0.2mg and Metformin Hydrochloride IP 500mg (Extended-Release form)	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.62
27	4 (xxvii)	Glimepiride, Voglibose and Metformin Hydrochloride (ER) tablets	Each uncoated bi-layered tablets contains: Glimepiride IP 2 mg, Voglibose IP 0.2mg and Metformin Hydrochloride IP 500mg (Extended-Release form)	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	14.79
28	4 (xxviii)	Itraconazole Capsules BP	Each hard gelatin capsule contains: Itraconazole BP 50 mg	Capsule	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Biological E. Limited	11.51

72

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
29	4 (xxix)	Multivitamin & Multimineral Drops	Each ml contains : Cholecalciferol (as Stabilized) IP 200 IU Pyridoxine HCl IP 0.5mg Niacinamide IP 5mg Cyanocobalamin IP 1mcg Sodium Selenite Pentahydrate BP eq. to elemental Selenium 10 mcg Zinc Sulphate Monohydrate IP eq. to elemental Zinc 2 mg Manganese sulphate Monohydrate BP eq. to elemental Manganese 3 mcg Sodium molybdate dihydrate BP eq. to elemental Molybdenum 1 mcg L-Lysine Hydrochloride IP 30 mg Potassium Iodide IP eq. to elemental Iodine 20 mcg Biotin IP 5 mcg Chromium Picolinate IP eq. to elemental Chromium 1 mcg Myo-Inositol IP 10 mg Beta Carotene Dispersion 2.5% 18 mg	Per ml	M/s Ordain Health Care Global Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	3.10
30	4 (xxx)	Pantoprazole & Cinitapride SR capsules	Each hard gelatin capsule contains: Pantoprazole Sodium IP eq. to Pantoprazole 40 mg (as enteric coated tablet) Cinitapride Hydrogen tartrate eq. to Cinitapride (as Sustained release tablet) 3 mg	Capsules	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Dr Reddy's Laboratories Ltd.	24.82
31	4 (xxxi)	Paracetamol & Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 250 mg Mefenamic Acid IP 100 mg	Per ml	M/s Tirupati Medicare Ltd./ M/s Dr Reddy's Laboratories Limited	0.92

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
32	4 (xxxii)	Paracetamol and Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 125 mg Mefenamic Acid IP 50 mg	Per ml	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.73
33	4 (xxxiii)	Paracetamol IP & Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 125 mg Mefenamic Acid IP 50 mg	Per ml	M/s Tirupati Medicare Limited / M/s Dr Reddy's Laboratories Limited	0.73
34	4 (xxxiv)	Riboflavin, Folic Acid Niacinamide & Lactic Acid Bacillus Spores Tablets	Each uncoated tablet contains: Riboflavin IP 10mg Folic Acid IP 1.5mg Niacinamide IP 100mg Lactic Acid Bacillus Spores 60 million	Tablet	M/s Marine Medicare Pvt. Ltd. / M/s Nicholas Healthcare Limited	4.25
35	4 (xxxv)	Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate Oral Suspension	Each 5 ml contains: Sodium Alginate IP 250 mg Sodium Bicarbonate IP 133.5 mg Calcium Carbonate IP 80 mg	Per ml	M/s Windlas Biotech Ltd./ M/s Biological E. Ltd.	0.83
36	4 (xxxvi)	Tacrolimus Ointment	Composition: Tacrolimus I.P. eq. to Anhydrous Tacrolimus 0.1%w/w	Per gm	M/s Rivpra Formulation Pvt. Ltd./ M/s RPG Life Sciences Ltd.	35.64
37	4 (xxxvii)	Telmisartan & Chlorthalidone Tablets	Each uncoated tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.59
38	4 (xxxviii)	Telmisartan & Cilnidipine Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.11
39	4 (xxxix)	Telmisartan & Cilnidipine Tablets	Each film coated bilayered tablet contains: Telmisartan IP 80 mg Cilnidipine IP 10 mg	Tablet	M/s Macleods Pharmaceuticals Ltd.	16.10

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
40	4 (xl)	Telmisartan & Indapamide tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Indapamide IP 1.5mg (as sustained release)	Tablet	M/s Windlas Biotech Ltd. / M/s Eris Lifesciences Limited	13.25
41	4 (xli)	Telmisartan, Cilnidipine and Chlorthalidone tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 12.50 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	15.15
42	4 (xlii)	Telmisartan, Amlodipine and Hydrochlorothiazide Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Hydrochlorothiazide IP 12.5 mg	Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.00
43	4 (xliii)	Tranexamic Acid and Mefenamic Acid tablets	Each film coated tablet contains: Tranexamic Acid IP 500 mg Mefenamic Acid IP 250 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Pharmed Limited	31.50
44	4 (xliv)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (extended release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 1 mg, Metformin Hydrochloride (extended release) IP 500 mg	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	12.42
45	4 (xlv)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (extended release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 2 mg, Metformin Hydrochloride IP 500 mg (extended release)	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	12.42

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
46	4 (xlvi)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (extended release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 1 mg, Metformin Hydrochloride (extended release) IP 500 mg	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	12.42
47	4 (xlvii)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (extended release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 2 mg, Metformin Hydrochloride (extended release) IP 500 mg	Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	12.42
48	4 (xlviii)	Sitagliptin, Dapagliflozin and Metformin Hydrochloride (extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 100mg Dapagliflozin propanediol USP eq. to Dapagliflozin 10mg Metformin hydrochloride IP (as extended release form) 1000mg	Tablet	M/s Mascot Health Series Pvt. Ltd/ M/s FDC limited	18.21
49	4 (xlix)	Sitagliptin, Dapagliflozin and Metformin Hydrochloride (extended release) Tablets	Each film coated bilayered tablet contains: Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 100mg Dapagliflozin propanediol USP eq. to dapagliflozin 10mg Metformin hydrochloride IP (as extended release form) 500mg	Tablet	M/s Mascot Health Series Pvt. Ltd/ M/s FDC Limited	17.26

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
50	4 (I)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (sustained release) Tablets	Each film coated bilayered tablet contains: Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin hydrochloride IP (as sustained release form) 500mg	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Cadila Pharmaceuticals Ltd.	14.15
51	4 (li)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (sustained release) Tablets	Each film coated bilayered tablet contains: Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin hydrochloride IP (as sustained release form) 1000mg	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Cadila Pharmaceuticals Ltd.	15.43
52	4 (lii)	Sitagliptin & Metformin Hydrochloride tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Metformin Hydrochloride IP 500 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Blue Cross Laboratories Pvt. Ltd.	9.00
53	4 (liii)	Sitagliptin & Metformin Hydrochloride tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Metformin Hydrochloride IP 1000 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Blue Cross Laboratories Pvt. Ltd.	9.87
54	4 (liv)	Vildagliptin (SR) & Metformin Hydrochloride (SR) tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100 mg (as sustained release form) Metformin Hydrochloride IP 500 mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ / M/s Primus Remedies Pvt. Ltd.	10.24

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			(as sustained release form)			
55	4 (lv)	Vildagliptin (SR) & Metformin Hydrochloride (SR) tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100 mg (as sustained release form) Metformin Hydrochloride IP 1000 mg (as sustained release form)	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	11.55
56	4 (lvi)	Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated bilayered tablet contains: Linagliptin 5 mg Metformin hydrochloride IP (as extended release form) 500 mg	Tablet	M/s Mascot Health series Pvt. Ltd. / M/s Eris Lifesciences Limited	10.68
57	4 (lvii)	Ceftazidime and Avibactam Powder for concentrate Solution for Infusion	Each vial contains: Sterile Ceftazidime Pentahydrate IP eq. to Anhydrous Ceftazidime 2 gm Sterile Avibactam sodium eq. to Avibactam 0.5 gm	Per vial	M/s GMH Organics / M/s Aurobindo Pharma Limited	1422.21
58	4 (lviii)	Ceftriaxone, Disodium Edetate and Sulbactam Powder for Solution for Infusion	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sulbactam Sodium IP eq. to Sulbactam 500mg Disodium Edetate IP 37mg	Per vial	M/s Alkem Health Science (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	515.57
59	4 (lix)	Ceftriaxone, Disodium Edetate and Sulbactam Powder for Solution for Infusion	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 2000mg Sulbactam Sodium IP eq. to Sulbactam 1000mg Disodium Edetate IP 74mg	Per vial	M/s Alkem Health Science (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	1036.60
60	4 (lx)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg	Tablet	M/s Cipla Ltd.	8.50

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Metformin Hydrochloride IP 500 mg			
61	4 (lxi)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	Tablet	M/s Cipla Ltd.	12.00
62	4 (lxii)	Ferrous Bis-glycinate, Folic Acid, Zinc Bis-glycinate & Vitamin B12 (Cyanocobalamin) Tablets	Each film coated tablet contains: Ferrous Bis-glycinate eq. to Elemental Iron 60mg Zinc Bis-glycinate eq. to Elemental Zinc 15mg Folic Acid IP 1mg Vitamin B12 IP 15mcg (Cyanocobalamin)	Tablet	M/s Windlas Biotech Limited / M/s Biological E. Limited	8.17 (Note 1)
63	4 (lxiii)	Iron tonic with Vitamin B12 and Folic Acid	Each 5ml contains: Ferric Ammonium Citrate IP 80mg Folic Acid IP 0.166mg Vitamin B12 IP 1mcg	Per ml	M/s Aagya Biotech Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Ltd.	0.45
64	4 (lxiv)	Atorvastatin and Ezetimibe tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 80 mg, Ezetimibe IP 10mg	Tablet	M/s Windlas Biotech Ltd. / M/s Intas pharmaceuticals Ltd.	50.00
65	4 (lxv)	Famotidine, Calcium Carbonate & Magnesium Hydroxide Chewable Tablets	Each chewable tablet contains: Famotidine IP 10mg Calcium Carbonate IP 800mg Magnesium Hydroxide IP 165mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Akumentis Healthcare Ltd.	5.30

Note 1: The Authority noted that M/s Biological E. Ltd represented against the draft working sheet vide email dated 16.11.2024 stating that applied formulation is Ferrous Bis-Glycinate eq to Elemental Iron 60mg + Zinc Bis-Glycinate eq. to Elemental Zinc 15 mg + Folic acid IP 1 mg +Vitamin B12 IP 15mcg whereas in the draft working sheet formulation considered contains Vitamin B12 as 5 mcg. In this regard, it was noted that as per confirmation of data received from M/s Pharmarack including the pack shot, the content of Vitamin B12 in the formulation considered in draft worksheet is 15 mcg and also pack shot of the same has been provided. The heading of the draft worksheet also mentions 15 mcg; however, it was inadvertently mentioned as 5 mcg in pack description though SKU

considered in draft worksheet is for the same formulation for which the company has filed Form I application. Accordingly, the Authority approved the price as uploaded at Rs.8.17 per tablet.

5. Agenda item no. 5: Status of implementation of Review cases

5.1 Noted.

6. Agenda item no. 6: Minutes of 62nd and 63rd meeting of Multidisciplinary Committee of Experts held on 25.09. 2024 and 22.10.2024 respectively.

6.1 Noted

7. Agenda item no. 7: Fixation of ceiling price under NLEM, 2022

7.1 The Authority noted that ceiling price of 742 formulations have been fixed under NLEM 2022 based on the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) that was deliberated in the 104th, 111th and 112th meeting of the Authority held on 23.11.2022, 29.03.2023 and 01.05.2023 respectively. Further, the Authority also recalled the decision taken in 120th meeting held on 24.01.2024 wherein it was decided to use October 2023 database and the data for the month of October, 2023 for fixation of the ceiling prices of remaining formulations under NLEM, 2022 under para 9 (7) of DPCO, 2013.

7.2 The Authority noted that based on approved methodology, ceiling prices for ten formulations were uploaded on NPPA website on 19.09.2024 and for another five formulations on 07.10.2024 for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals based on database of October 2023 & month of October 2023. Further, the effect of WPI for 2024 i.e. (+) 0.00551% (effective from 01.04.2024) has also been given in the draft uploaded worksheet.

7.3 The Authority was informed that in respect of two formulations i.e., Anti-D immunoglobulin 300mcg and 150mcg uploaded on 19.09.2024, Delhi High Court has passed order dated 19.11.2024 in the W.P.(C) 9304/2022 filed by M/s Bharat Serums and Vaccines Limited. Since the same is under examination, the ceiling prices of these are not placed for the approval of the Authority in this meeting.

7.4 In respect of other formulations, it was noted that representations received for correction in PTR have been carried out based on verification done with Form-II/Form-V filed by the companies till 15.05.2023 as per provisions of DPCO, 2013.

7.5 In addition, following representations were also received from the companies:

- (i) Inclusion of certain SKUs as the same are available in the market though not captured in the Pharmarack database and hence, non-application of para 6 of DPCO, 2013;
- (ii) exclusion of SKUs as the same are not available in the market and IQIVIA database though captured in the Pharmarack database; and

- (iii) corrigendum of ceiling price notified vide SO No. 4663 (E) dated 25.10.2023 may be treated as refixation of ceiling price under NLEM 2022 and hence no refixation is required under para 18 (1) of DPCO, 2013.

The Authority considered these representations based on the various provisions of DPCO,2013 and did not accept the contentions made therein.

7.6 Accordingly, the Authority deliberated upon matter in detail and approved the ceiling prices of thirteen scheduled formulations as mentioned in **Table 2** below-

Table 2: Revised Ceiling prices of 13 Formulations under NLEM,2022

S. No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price (In Rs.)	Ceiling Prices under NLEM, 2022 (In Rs.)	Unit
1.	19	Anti-rabies immunoglobulin	As Licensed 150 IU	3454.06	3107.59	1 ML
2.	19	Anti-rabies immunoglobulin	As Licensed 300 IU	121.77	109.56	1 ML
3.	19	Measles vaccine	As licensed	63.47	50.20	Each Vial of 0.5ml
4.	19	Anti-tetanus immunoglobulin	As Licensed (250 IU)	1383.57	1244.79	1 Vial
5.	19	Anti-tetanus immunoglobulin	As Licensed (500IU)	Not fixed	1875.75	1 Vial
6.	19	Anti-tetanus immunoglobulin	As Licensed (1000IU)	Not fixed	2684.19	1 Vial
7.	19	BCG vaccine	As licensed	11.12	8.01	Each dose (0.10 ML)
8.	19	Measles Rubella vaccine	As licensed	110.07	71.19	Each Vial of 0.5ml
9.	6.5.1 & 6.9.2.1	Amphotericin B Liposomal	Injection 50mg/ vial	9295.41	6648.23	1 Vial
10.	6.5.1 & 6.9.2.1	Amphotericin B Lipid	Injection 50mg/ vial	3990.62	1887.75	1 Vial
11.	25.2.1	Water for injection	Injection	2.89	2.42	Each Pack (10 ml)
12.	24.1.2	Budesonide (A) + Formoterol (B)	Inhalation 400mcg (A) + 6mcg (B)	3.80	3.37	Per Metered dose

S. No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price (In Rs.)	Ceiling Prices under NLEM, 2022 (In Rs.)	Unit
13.	24.1.2	Budesonide (A) + Formoterol (B)	Inhalation 200mcg (A) + 6mcg (B)	3.33	2.96	Per Metered dose

8. Agenda item no. 8: Revision of ceiling prices based on Review Orders.

8.1 The Authority noted the following review orders issued by Department of Pharmaceuticals (DoP):

Table 3: Review Orders of DoP

S. No	Date & No. of Review Order	Formulation and Notification
1.	Order no. 31015/45/2023- Pricing dated 04.10.2024	'Thiamine Injection 100mg/ml of M/s Ordain Health Care Global Pvt Ltd against NPPA notification S.O No. 879(E) dated 24.02.2023
2.	Order no. 31015/38/2023- Pricing dated 04.10.2024	'Clarithromycin Oral Suspension 125mg/5ml' of M/s Cipla Limited against NPPA notification S.O No. 194(E) dated 11.01.2023
3.	Order no. 31015/46/2023- Pricing dated 04.10.2024	'Lignocaine 2% Injection' of M/s Neon Laboratories Limited against NPPA notification S.O No. 879(E) dated 24.02.2023
4.	Order no. 31015/86/2023- Pricing dated 04.10.2024	The following formulations of M/s Abbott Healthcare Private Limited: (i) Clarithromycin 250mg Tab. (ii) Atorvastatin 10mg Tab.
5.	Order no. 31015/68/2023- Pricing dated 04.10.2024	'Ascorbic Acid 500mg Tablet' of M/s Koye Pharmaceuticals Private Limited against NPPA notification S.O No. 1577(E) dated 31.03.2023
6.	Order no. 31015/15/2023- Pricing dated 27.05.2024	Atorvastatin 10mg Tablet of M/s Cipla Limited against NPPA notification S.O No. 5938(E) dated 19.12.2022 and 89 (E) dated 06.01.2023

8.2 The Authority noted that based on the review orders as mentioned in **Table 3** above; draft calculation sheets with revised ceiling prices were uploaded on NPPA website for comments. It was noted that no representations were received except for formulation mentioned at S. No. 3 i.e., Lignocaine 2% Injection

8.3 The Authority noted that based on the review application filed by M/s Neon Laboratories Limited in r/o Lignocaine 2% Injection, DoP referred back the case to NPPA

for recalculation of ceiling price for the subject formulation and other impacted formulation. Accordingly, revised calculation sheet for 'Lignocaine 2% Injection' and the impacted formulation i.e., 'Lignocaine topical forms 2-5%' were uploaded on website. It was noted that revised ceiling price for the impacted formulation i.e. 'Lignocaine topical forms 2-5%' was calculated at Rs.1.08 Per gm or per ml.

8.4 M/s Neon Laboratories Limited represented requesting for fixation of separate ceiling price for 'Lignocaine topical Forms 2 - 5% **per ml**' and 'Lignocaine Topical Forms 2- 5%' **per gram**. Authority noted that draft worksheet of the subject formulation was initially uploaded and notified under NLEM 2022 with unit mentioned as per GM/ML by considering all the dosage forms topically including gels, jellies, ointment and solution. However, the company neither made any representation on the uploaded worksheet nor raised this issue in its review application. Further, the same methodology was followed while fixing the ceiling price of the under NLEM 2015 also. Hence, the contention of the company was not considered.

8.5 The Authority deliberated upon the matter in detail and approved the ceiling prices as mentioned in Column 5 of **Table 4** based on the review orders as per the revised draft working sheet uploaded on NPPA website. It was further noted that these prices have been calculated after giving effect of WPI increase of 12.1218% w.e.f. 1.04.2023 and WPI increase of (+)0.00551% w.e.f. 01.04.2024.

Table 4: Revision in Ceiling Prices based on Review Orders

S. No.	Formulation	Dosage form(s) and strength(s)	Current Ceiling Price (in Rs.)	Revised Ceiling Price (in Rs.) [based on Review orders]	Unit
1	2	3	4	5	6
1.	Thiamine	Injection 100mg/ml	22.59	26.70	Per ml
2.	Clarithromycin	Oral liquid 125mg/ 5ml	4.61	4.65	Per ml
3.	Lignocaine	2% injection	1.04	1.14	Per ml
4.	Lignocaine	Topical forms 2-5%	1.13	1.08	per GM/ML
5.	Clarithromycin	Tablet 250 mg	23.89	24.06	Per tablet
6.	Ascorbic acid	Tablet 500 mg	1.48	1.54	Per tablet
7.	Atorvastatin	Tablet 10 mg	4.94	4.97	Per tablet

9. **Agenda item no. 9: Application filed by M/s Cipla Limited vide their letter dated 15.02.2024 for grant of separate price/special price for 'Ciphaler inhaler device' under the provision of Para 11(3) of DPCO, 2013.**

ME

9.1 The Authority noted that M/s Cipla Limited vide letter dated 15.02.2024 applied for separate price/special price under the provision of Para 11(3) of DPCO, 2013 for 'Ciphaler inhaler device'.

9.2 It was noted that M/s Cipla Limited had earlier also applied for grant of separate/special price for the same device. The matter was deliberated in the 92nd Authority meeting held on 08.09.2021 wherein the Authority rejected the application of M/s Cipla Ltd. based on the recommendation of 35th MDC held on 18.08.2021 as the claim of the company regarding the efficacy of the product was not validated and the report submitted by the company was not based on its own product.

9.3 The Authority noted that now M/s Cipla Limited vide letter dated 15.02.2024 has again submitted the application seeking separate/ special price for 'Ciphaler inhaler device'. It was also noted that the matter has been deliberated in 59th and 60th meeting of MDC held on 08.05.2024 and 26.06.2024. As per the directions of MDC clarification was sought from O/o DCGI regarding licensing requirement of this drug-device combination. The reply from O/o DCGI is awaited. Meanwhile, the application has been withdrawn by M/s Cipla Ltd though its email dated 26.09.2024. The matter was deliberated in the 63rd MDC held on 24.10.2024 and based on the request of the company, MDC has recommended to treat the matter/ application as closed.

9.4 The Authority deliberated upon the matter and decided to treat the matter as closed based on the request of the company and recommendation of the MDC.

10. Agenda item no. 10 Application for grant of separate price/special price for 'Synchrobreathe Inhaler device' under the provision of Para 11(3) of DPCO, 2013 by M/s.Cipla Ltd.

10.1 The Authority noted that M/s Cipla Limited has applied for a separate ceiling price for the 'Synchrobreathe Inhaler device' under the provisions of Paragraph 11(3) of the DPCO 2013 in relation to following scheduled formulations: **(i) Budesonide 100mcg-200 MDI, (ii) Budesonide 200mcg-200 MDI, and (iii) Formoterol 6mcg + Budesonide 100mcg-120 MDI** vide letter dated 09.09.2024.

10.2 The Authority recalled the decision taken in the 71st Authority meeting held on 09.12.2019 wherein a separate price under Para 11(3) for 'Synchrobreathe inhaler' for the formulations **"Formoterol 6mcg + Budesonide 200mcg 120MDI" and "Formoterol 6mcg + Budesonide 400mcg 120MDI** was fixed at Rs. 67.20 for M/s Cipla Ltd. The price was considered @ 20% of the average of then prevailing ceiling price of these two formulations. It was also noted that the same separate price was extended to 'Synchrobreathe Inhaler Device' for **Tiotropium 9 mcg/ dose** in 80th Authority meeting held on 26.10.2020. Further, Authority in its 84th meeting held on 10.03.2021 allowed the

company to avail WPI on the price of 'Synchrobreathe inhaler device' for the above formulations w.e.f. 01.4.2021.

10.3 The Authority noted that the applicant has now requested a separate price for the same device i.e., the 'Synchrobreathe inhaler device' for three other formulations as mentioned in point 10.1 above. It was noted that the matter was placed in 62nd meeting of the MDC held on 25.09.2024 wherein the Committee noted that the company has provided a study report and published journal literature in support of the price. Accordingly, the Committee recommended that in line with previous practice of granting 20% additional price in case of innovation being supported by published literature, separate price may be granted for "Synchrobreathe inhaler" @ 20% of the prevailing ceiling price of (i) Budesonide 100mcg-200 MDI, (ii) Budesonide 200mcg-200 MDI, and (iii) Formoterol 6mcg + Budesonide 100mcg-120 MDI.

10.4 The Authority deliberated on the recommendation of the Committee and accepted its recommendations for fixation of separate price for "Synchrobreathe inhaler" @ 20% of the prevailing ceiling price of (i) Budesonide 100mcg-200 MDI, (ii) Budesonide 200mcg-200 MDI, and (iii) Formoterol 6mcg + Budesonide 100mcg-120 MDI. Accordingly, the Authority approved the price as below under Para 11(3) for "Synchrobreathe inhaler" for the three formulations:

Table 5: Separate Ceiling Price for Scheduled formulations in Synchrobreathe Inhaler Device

S. No	Formulation	Unit	Separate Ceiling Price of Synchrobreathe Inhaler in respect of formulations in column (2) (in Rs.)
(1)	(2)	(3)	(4)
1	Synchrobreathe Inhaler for Budesonide Inhalation (MDI) 100 mcg/dose for 200 doses in one inhaler	1 inhaler	56.40
2	Synchrobreathe Inhaler for Budesonide Inhalation (MDI) 200 mcg/dose for 200 doses in one inhaler	1 inhaler	41.20
3	Synchrobreathe Inhaler for Budesonide 100mcg + Formoterol 6mcg for 120 doses in one inhaler	1 inhaler	50.88

10.5 The Authority also approved the annual revision based on change in WPI for the "Synchrobreathe inhaler" in line with approval granted earlier.

11. Agenda item no. 11 Application by M/s Pulse Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulation "Paracetamol Oral solution (taste masked) 125mg/5ml and 250mg/5ml produced utilizing indigenously developed innovative LYOMATRIX Technology offering Novel Drug Delivery System".

11.1 The Authority noted that M/s Pulse Pharmaceuticals Private Limited has submitted application for exemption under Paragraph 32 (iii) for their formulation, "Paracetamol Oral Solution (taste masked) 125mg/5ml and 250mg/5ml," claiming that the formulation has been developed utilizing the indigenously developed LYOMATRIX Technology involving a Novel Drug Delivery System.

11.2 The Authority noted that the applicant has claimed various benefits like unmet medical need, the innovative LYOMATRIX technology, faster absorption indicated by bioequivalence studies, clinical trial demonstrating quicker temperature reduction, and higher acceptability compared to existing products in terms of taste, smell, and mouthfeel. It was also noted that the applicant claimed high efficacy, reduced dosage frequency for pharmacoeconomic advantages.

11.3 It was noted that the matter was deliberated in 62nd meeting of the MDC held on 25.09.2024 and 63rd meeting held on 22.10.2024. The applicant made a presentation in 63rd meeting of MDC. The committee observed that there is no significant difference in the formulation as manufactured by M/s Pulse Pharmaceuticals Private Limited and the conventional paracetamol oral liquid with respect to faster absorption as mentioned by the company and delivery system as developed by the company does not fall under the definition of 'New Drug Delivery System' as solutions are covered under oral liquid dosage forms which are already in existence. Accordingly, the Committee recommended that the application does not qualify for exemption from price control under the provisions of Para 32(iii).

11.4 The Authority further noted that applicant vide email dated 05.11.2024 has requested to present their case again before MDC supplemented with the additional data.

11.5 The Authority deliberated on the matter and the request made by the applicant subsequent to the recommendation of MDC and directed that the applicant may be given one more opportunity to represent their case before the Committee.

12. Agenda item no. 12 Application for extension of Ceiling price of IV fluids (Double Port) under (JEDUX DOUBLE PORT WITH EURO HEAD, JPORT PLUS) with packaging in non-glass with special feature filed by M/s Jedux Parenteral Private Limited.

12.1 The Authority noted that M/s Jedux Parenteral Private Limited vide letter dated 27.08.2024 has applied for extension of separate ceiling price of IV fluids (Double Port) under (JEDUX DOUBLE PORT WITH EURO HEAD, JPORT PLUS) with packaging in non-glass with special feature for the sixteen (16) formulations as mentioned in the Table below:

Table 6: Formulations applied by M/S Jedux Parenteral Pvt. Ltd.

S. No.	Name of Product	Composition Each 100ml	Pack Size
1.	Dextrose Injection IP 5% w/v	Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	500ml & 1000ml
2.	Dextrose Injection IP 10% w/v	Dextrose Anhydrous IP 10gm, Water for injections IP q.s.	500ml & 1000ml
3.	Sodium Chloride 0.9% & Dextrose Injection 5% w/v	Sodium Chloride IP 0.9gm, Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	500ml & 1000ml
4.	Sodium Chloride Injection IP 0.9% w/v	Sodium Chloride IP 0.9gm, Water for injections IP q.s.	100ml, 500ml & 1000ml
5.	Ringer Lactate Solution for Injection IP	Sodium Chloride IP 0.6gm, Potassium Chloride IP 0.04gm, Calcium Chloride IP 0.027gm, Sodium Lactate USP 0.32gm. Water for injection IP q.s.	500ml & 1000ml
6.	Mannitol Injection IP 20% w/v	Mannitol IP 20gm, Water for injections IP q.s.	100ml
7.	Ciprofloxacin Injection IP	Sodium Chloride IP 0.9gm, Ciprofloxacin Lactate eq. to Ciprofloxacin 0.2gm, Water for injections IP q.s.	100ml
8.	Metronidazole Injection IP	Metronidazole IP 0.5gm, Sodium Chloride IP 0.8gm, Water for injections IP q.s.	100ml
9.	Dextrose Injection IP 25% w/v	Dextrose Anhydrous IP 25gm, Water for injections IP q.s.	100ml & 500ml

12.2 The Authority noted that the matter was deliberated in the 62nd meeting held on 25.09.2024 and 63rd meeting held on 22.10.2024. The applicant company demonstrated their product in 63rd MDC meeting. Committee noted that that the applicant company requested to withdraw its application in respect of Dextrose Injection IP 10% w/v in 500 ml and 1000 ml pack and accepted the same. The Committee noted the special features of the products demonstrated by the applicant and the data submitted by the applicant and recommended to extend separate ceiling prices for M/s Jedux Parenteral Private Limited for fourteen (14) formulations.

12.3 The Authority deliberated upon the recommendation of the Committee and approved the extension of separate ceiling prices for M/s Jedux Parenteral Private Limited for the below mentioned formulations:

Table 7: Ceiling Prices extended to M/S Jedux Parenteral Pvt. Ltd. for packaging in non-glass with special feature

S. No.	Name of Product	Composition Each 100ml	Pack Size	Applicable Ceiling Price / Unit	S.O. No. & Date
1.	Dextrose Injection IP 5% w/v	Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	500ml	82.27 per pack	1552(E) dt. 26.03.2024
2.	Dextrose Injection IP 5% w/v	Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	1000ml	95.11 per pack	1552(E) dt. 26.03.2024
3.	Sodium Chloride 0.9% & Dextrose Injection 5% w/v	Sodium Chloride IP 0.9gm, Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	500ml	85.52 per pack	1552(E) dt. 26.03.2024
4.	Sodium Chloride 0.9% & Dextrose Injection 5% w/v	Sodium Chloride IP 0.9gm, Dextrose Anhydrous IP 5gm, Water for injections IP q.s.	1000ml	99.94 per pack	1552(E) dt. 26.03.2024
5.	Sodium Chloride Injection IP 0.9% w/v	Sodium Chloride IP 0.9gm, Water for injections IP q.s.	100ml	42.06 per pack	1552(E) dt. 26.03.2024
6.	Sodium Chloride Injection IP 0.9% w/v	Sodium Chloride IP 0.9gm, Water for injections IP q.s.	500ml	87.94 per pack	1552(E) dt. 26.03.2024
7.	Sodium Chloride Injection IP 0.9% w/v	Sodium Chloride IP 0.9gm, Water for injections IP q.s.	1000ml	98.51 per pack	1552(E) dt. 26.03.2024
8.	Ringer Lactate Solution for Injection IP	Sodium Chloride IP 0.6gm, Potassium Chloride IP 0.04gm, Calcium Chloride IP 0.027gm, Sodium Lactate USP 0.32gm. Water for injection IP q.s.	500ml	64.96 per pack	1553(E) dt. 26.03.2024
9.	Ringer Lactate Solution for Injection IP	Sodium Chloride IP 0.6gm, Potassium Chloride IP 0.04gm, Calcium Chloride IP 0.027gm, Sodium Lactate USP 0.32gm. Water for injection IP q.s.	1000ml	114.21 per pack	1553(E) dt. 26.03.2024
10.	Mannitol Injection IP 20% w/v	Mannitol IP 20gm, Water for injections IP q.s.	100ml	0.40 per ML	1556(E) dt. 26.03.2024

Handwritten signature/initials

S. No.	Name of Product	Composition Each 100ml	Pack Size	Applicable Ceiling Price / Unit	S.O. No. & Date
11.	Ciprofloxacin Injection IP	Sodium Chloride IP 0.9gm, Ciprofloxacin Lactate eq. to Ciprofloxacin 0.2gm, Water for injections IP q.s.	100ml	0.23 per ML	2286(E) dt. 14.06.2024
12.	Metronidazole Injection IP	Metronidazole IP 0.5gm, Sodium Chloride IP 0.8gm, Water for injections IP q.s.	100ml	0.25 per ML	1555(E) dt. 26.03.2024
13.	Dextrose Injection IP 25% w/v	Dextrose Anhydrous IP 25gm, Water for injections IP q.s.	100ml	0.24 per ML	1557(E) dt. 26.03.2024
14.	Dextrose Injection IP 25% w/v	Dextrose Anhydrous IP 25gm, Water for injections IP q.s.	500ml	0.24 per ML	2289(E) dt. 14.06.2024

13. Agenda item no. 13 Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

13.1 Record Note of Discussion

14. Agenda item no. 14 Form-IV intimation received from M/s Serum Institute of India Pvt Ltd in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection 0.5ml and (ii) Tetanus Toxoid Injection 5 ml of M/s Serum Institute of India Pvt Ltd

14.1 The Authority noted that directions under Para 3 of DPCO, 2013 were issued to M/s Serum Institute of India Pvt. Ltd. from time to time for continued production/sale in respect of two scheduled formulations (i) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack manufactured by M/s Serum Institute of India Pvt. Ltd. The period of continuation of production/sale was extended up to 31.12.2024 in the 119th Authority meeting held on 15.12.2023.

14.2 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3. of DPCO, 2013 to direct M/s Serum Institute of India Pvt. Ltd to continue the production and sales of two scheduled formulations (1) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack up to 31.12.2025.

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

वि. कोटवाल
18/12/2024
(Dr. Vinod Kotwal)
Member Secretary