

मिसिलस.- 8(109)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(109)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 241/109/2023/F
Proceeding No: 241/109/2023/F

Minutes of the 241th(overall) and 109thmeeting of the Authority under DPCO, 2013 held on 21.02.2023 at 11:00 AM.

The 241st meeting of the Authority (overall), which is the 109th meeting under the DPCO, 2013, was held on 21 February, 2023 at 11:00 A.M. under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present.

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

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Shri R. Jegan, Jt. Director (Overcharging)
- (iv) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (v) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vi) Ms. Yuvika Panwar, Assistant Director (Overcharging /Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 108thMeeting held on 27.01.2023.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 108thMeeting held on 27.01.2023.

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 discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xxxi) (total 75 Form I applications containing retail price fixation of 75 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 74 (Seventy-four) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1:**

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i) a.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharma Laboratories Limited	27.75
4 (i) b.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	27.75
4 (i) c.	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	29.29
4 (ii) a.	Dapagliflozin, Vildagliptin (As Sustained Release)	Each film coated bilayered tablet contains:	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences	14.90

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	and Metformin Hydrochloride (as Sustained Release) Tablets	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)		Limited	
4 (ii) b.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	14.90
4 (ii) c.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s USV Pvt. Ltd.	14.90
4 (ii) d.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	14.90
4 (ii) e.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	14.90

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		(as Sustained Release)			
4 (ii) f.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Limited	14.79
4 (ii) g.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	14.79
4 (ii) h.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	14.79
4 (ii) i.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	16.44
4 (ii) j.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	16.44

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)			
4 (ii) k.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	16.44
4 (ii) l.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	16.44
4 (ii) m.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s USV Pvt. Ltd.	16.44
4 (ii) n.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	16.33

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Release)			
4 (ii) o.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	16.33
4 (ii) p.	Dapagliflozin, Vildagliptin (As Sustained Release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Limited	16.33
4 (ii) q.	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	15.65
4 (ii) r.	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	19.45
4 (iii) a.	Teneligliptin, Pioglitazone & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	16.01

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		(As Sustained Release)			
4 (iii) b.	Teneligliptin, Pioglitazone and Metformin Hydrochloride (as Sustained Release) Tablets	Each Film coated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Eris Lifesciences Limited	16.01
4 (iii) c.	Teneligliptin, Pioglitazone & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 1000mg (As Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	17.55
4 (iii) d.	Teneligliptin, Pioglitazone and Metformin Hydrochloride (as Sustained Release) Tablets	Each Film coated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Eris Lifesciences Limited	17.55
4 (iv) a.	Dapagliflozin and Teneligliptin Tablets	Each film coated table contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	14.50
4 (iv) b.	Dapagliflozin and Teneligliptin Tablets	Each film coated table contains: Dapagliflozin Propanediol Monohydrate eq. to	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	15.83

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Dapagliflozin 10mg Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg			
4 (v) a.	Bisoprolol Fumerate & Telmisartan Tablets	Each uncoated bilayered tablet contains: Bisoprolol Fumerate IP 2.5mg Telmisartan IP 40mg	1 Tablet	M/s Windlas Biotech Limited / M/s Merck Specialities Pvt Ltd.	10.92
4 (v) b.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	10.92
4 (v) c.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	10.92
4 (v) d.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	10.92
4 (v) e.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	10.92
4 (v) f.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris lifesciences Limited	10.92
4 (v) g.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	10.92
4 (v) h.	Bisoprolol Fumerate & Telmisartan Tablets	Each uncoated bilayered tablet contains: Bisoprolol Fumerate IP 5mg Telmisartan IP 40mg	1 Tablet	M/s Windlas Biotech Limited / M/s Merck Specialities Pvt Ltd.	12.52
4 (v) i.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	12.52
4 (v) j.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Glenmark Pharmaceuticals Ltd.	12.52

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (v) k.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt.Ltd. / M/s Alkem Laboratories Ltd.	12.52
4 (v) l.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	12.52
4 (v) m.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris lifesciences Limited	12.52
4 (v) n.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Limited	12.52
4 (v) o.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	12.52
4 (v) p.	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	10.92
4 (vii) a.	Indacaterol and Budesonide Inhalation	Each actuation delivers: Indacaterol Maleate eq. to Indacaterol 75mcg Budesonide IP 200mcg	Per MDI	M/s Zydus Healthcare Limited	35.22
4 (vii) b.	Indacaterol and Budesonide Powder for Inhalation	Each capsule delivers: Indacaterol Maleate eq. to Indacaterol 75mcg Budesonide IP 200mcg	Per DPI	M/s Zydus Healthcare Limited	36.22
4 (vii) c.	Indacaterol and Budesonide Powder for Inhalation	Each capsule delivers: Indacaterol Maleate eq. to Indacaterol 150mcg Budesonide IP 400mcg	Per DPI	M/s Zydus Healthcare Limited	60.71
4 (viii) a.	Atorvastatin and Clopidogrel Tablets	Each uncoated bilayered tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40 mg Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceuticals Industries Ltd.	27.60
4 (viii) b.	Atorvastatin and Clopidogrel Tablets	Each uncoated bilayered tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Sun Pharma Laboratories Limited	27.60

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		mg Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg			
4 (viii) c.	Atorvastatin and Clopidogrel Tablets	Each uncoated bilayered tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40 mg Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd.	27.60
4 (ix)	Bilastine and Montelukast Ondispersible Tablets	Each uncoated Orodispersible tablet contains: Montelukast Sodium IP Eq. to Montelukast 4mg Bilastine 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	14.38
4 (x)	Ibuprofen Injection	Each ml contains: Ibuprofen IP 100mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	Deferred (Note 1)
4 (xi) a.	Lobeglitazone Sulphate and Metformin Hydrochloride Extended-Release Tablets	Each uncoated bilayer tablet contains: Lobeglitazone Sulphate 0.5mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Glenmark Pharmaceuticals Limited	9.90
4 (xi) b.	Lobeglitazone Sulphate and Metformin Hydrochloride Extended Release Tablets	Each uncoated bilayer tablet contains: Lobeglitazone Sulphate 0.5mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Glenmark Pharmaceuticals Limited	11.44
4 (xii)	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine maleate, Ammonium Chloride, Sodium Citrate & Menthol Suspension	Each 5ml (teaspoonful) contains: Paracetamol IP 250mg Phenylephrine Hydrochloride IP 5mg Chlorpheniramine maleate IP 2mg Ammonium Chloride IP 120mg Sodium Citrate IP 60mg Menthol IP 1mg	1 ml	M/s Windlas Biotech Limited / M/s Torrent Pharmaceuticals Limited	0.89
4 (xiii)	Amoxicillin and Potassium Clavulanate Tablets IP	Each film coated tablet contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 875mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Alps Communications Pvt. Ltd. / M/s Aristo Laboratories Pvt. Ltd.	34.68

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xiv)	Amoxicillin and Potassium Clavulanate Oral suspension	Each 5ml reconstituted suspension contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 400mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 57mg	1 ml	M/s Alps Communications Pvt. Ltd. / M/s Aristo Laboratories Pvt. Ltd.	3.97
4 (xv)	Cefixime and Ofloxacin Tablets	Each film coated tablet contains: Cefixime eq. to Cefixime Anhydrous IP 200mg Ofloxacin IP 200mg	1 Tablet	M/s Alps Communications Pvt. Ltd. / M/s Aristo Laboratories Pvt. Ltd.	12.74
4 (xvi)	Bilastine and Montelukast Oral Suspension	Each 5ml suspension contains: Bilastine 10mg Montelukast Sodium IP eq. to Monelukast 4mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited	1.71
4 (xvii)	Bilastine and Montelukast Oral Suspension	Each 5ml suspension contains: Bilastine 10mg Montelukast Sodium IP eq. to Monelukast 4mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Paraceuticals Limited	1.71
4 (xviii)	Amoxicillin & Potassium Clavulanate Oral Suspension IP 457mg	Each 5ml of reconstituted suspension contains: Amoxicillin trihydrate USP eq. to Amoxicillin 400mg Potassium Clavulanate Diluted eq. to Clavulanic Acid 57mg	1 ml	M/s Medicef Pharma / M/s Troikaa Pharmaceuticals Ltd.	3.9
4 (xix)	Dextromethorphan hydrobromide, Chlorpheniramine Meleate & Phenylephrine Hydrochloride Surup	Each 5ml contains: Dextromethorphan Hydrobromide IP 5mg Chlorpheniramine Meleate IP 1mg Phenylephrine Hydrochloride IP 2.5mg	1 ml	M/s Pure and Cure Healthcare Pct. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.86
4 (xx)	Dextromethorphan hydrobromide, Chlorpheniramine Meleate & Phenylephrine Hydrochloride Surup	Each 5ml contains: Dextromethorphan Hydrobromide IP 15mg Chlorpheniramine Meleate IP 2mg Phenylephrine Hydrochloride IP 5mg	1 ml	M/s Pure and Cure Healthcare Pct. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.87
4 (xxi)	Aceclofenac, Paracetamol & Serratiopeptidase Tablets	Each Film Coated Tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Serratiopeptidase IP 15mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	7.78
4 (xxii)	Desvenlafaxine Extended release and Clonazepam Tablets	Each uncoated bilayered tablet contains: Desvenlafaxine	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd.	13.24

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Succinate USP eq. to Desvenlafaxine 50mg (As Extended release form) Clonazepam IP 0.25mg			
4 (xxiii)	Trastuzumab 150mg	Combipack of Each pack contains: Vial-1 Lyophilized Powder for concentrate for solution for Intravenous Infusion, Multi use vial Composition: Trastuzumab (r-DNA Origin) IH (Active ingredient) 150mg, α,α -Trehalose Dihydrate USP (as Lyoprotectant) 136.2mg L-Histidine Hydrochloride Monohydrate EP (as buffering agent) 3.36mg L-Histidine USP (as buffering agent) 2.16mg Polysorbate 20 IP (as surfactant) 0.6mg Vial -2 Bacteriostatic Water for Injection 10 ml Single use vial Composition: Benzyl Alcohol IP 1.1% V/V Water for Injection	1 ml	M/s Hetero Biopharma Ltd. / M/s Hetero Healthcare Ltd.	15522.3 2
4 (xxiv)	Aceclofenac, Paracetamol and Serratiopeptidase tablets	Each Film Coated Tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Serratiopeptidase IP 15mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s Zydus Healthcare Limited	7.78
4 (xxv)	Trypsin-Chymotrypsin, Paracetamol & Aceclofenac Tablets	Each Film coated tablet contains: 50000 Armour Units of Enzymatic Activity (Supplied by a Purified Concentrate which has specific Trypsin & Chymotrypsin Activity in a Ratio of Approximately Six One)(As enteric coated granules) Paracetamol IP 325 Aceclofenac IP 100mg	1 Tablet	M/s Biogenetic Drugs Pvt. Ltd. / M/s Lupin Limited	9.84
4 (xxvi)	Cilnidipine, Telmisartan & Chlorthalidone	Each film coated tablet contains: Cilnidipine IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Aristo	13.72

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Telmisartan IP 40mg Chlorthalidone IP 12.50mg		Pharmaceuticals Pvt. Ltd.	
4 (xxvii)	Paclitaxel (protein bound particles) for Injectable Suspension (Lyophilized)	Each Vial contains: Paclitaxel IP 100mg Human Albumin IP approximately 900mg (After reconstitution)	1 vial	M/s Samarth Life Sciences Pvt. Ltd.	5866.76
4 (xxviii)	Ferrous Fumarate, Folic Acid and Cyanocobalamin Syrup	Each 5ml contains: Ferrous Fumarate IP 100mg eq. to Elemental Iron 32.8mg Folic Acid IP 0.5mg Cyanocobalamin (Vitamin B12) IP 5mcg	1 ml	M/s Zydus Healthcare Limited	0.55
4 (xxix)	Amoxicillin and Potassium Clavulanate Tablets IP	Each film coated tablet contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 250mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Alps Communications Pvt. Ltd. / M/s Aristo Laboratories Pvt. Ltd.	16.15 (Note 2)
4 (xxx)	Amoxicillin, Dicloxacillin & Lactic Acid Bacillus Capsule	Each hard gelatin capsule contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg Dicloxacillin Sodium IP eq. to Dicloxacillin 250mg Lactic Acid Bacillus 2.5 billion Spores	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Private Limited	8.77
4 (xxxi)	Multivitamin Tablets with Mineral and Trace Element	Each sugar coated tablet contains: Vitamin A (As Acetate) IP 10000 IU. Cholecalciferol IP 1000 IU (In Stabilized form...) Thiamine Mononitrate IP 10mg Riboflavin IP 10mg Pyridoxine Hydrochloride IP 3mg Cyanocobalamin IP 15mcg Nicotinamide IP 100mg Calcium Pantothenate IP 16.30mg Ascorbic Acid IP 150mg α Tocopheryl Acetate IP 25mg Biotin USP 0.25mg Tribasic Calcium Phosphate IP 129mg Light Magnesium Oxide	Tablets	M/s Aristo Pharmaceuticals Pvt. Ltd.	1.88 (Note 3)

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		IP 60mg Dried Ferrous Sulphate IP 32.04mg Manganese Sulfate Monohydrate BP 2.03mg Total Phosphorus in the preparation 25.80mg Copper Sulfate Pentahydrate BP 3.39mg Zinc Sulphate IP 2.20mg Sodium Molybdate Dihydrate BP 0.25mg Sodium Borate BP 0.88mg			

Note 1: The Authority noted the representation filed by M/s Cipla Limited on 07.02.2023 and directed that the matter may be placed before next MDC for examination of the representation of the applicant.

Note 2: The Authority was apprised that the draft worksheet recommending the retail price of Rs. 17.17 per tablet excluding GST was uploaded on NPPA's website on 17.01.2023. However, M/s FDC Limited vide email dated 17.01.2023 represented that pack size of their item is taken as 6 tablets instead of 10 and also submitted Form V to support their claim. Further, Clarification for one more line item was sought from M/s Pharmatrac regarding the pack size. Based on these clarifications/representations, the revised retail price works out to Rs. 16.15.

Note 3: M/s Aristo Pharmaceuticals Pvt. Ltd. vide letter dated 06.01.2023 filed a representation regarding the line item considered for the retail price fixation. The Authority was apprised that the contention of the applicant in the representation is not tenable and no change in worksheet is required.

4.2 During discussion on the agenda item on retail price fixation of new drugs, Shri Venkatesh, the Authority Member made an observation on the methodology adopted by MDC to reduce 20% of one of the component having lower price while recommending retail prices of the formulations. Pricing division explained to the Authority members that this formula follows from the relevant recommendation of the Pronab Sen Committee and is in practice for long. While agreeing to the continuation of the practice, the Authority members agreed that MDC while working out the retail price in such cases may suitably make references in such cases.

5. Agenda item no. 5 – Retail price fixation in view of Review application of M/s Abbott Healthcare Pvt. Ltd. against NPPA's notification S.O. No. 3400(E) dated 19.08.2021 in respect of "Nervup Forte Plus- Alpha Lipoic Acid USP 100mg + Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3mg + Methylcobalamin 1500mcg + Folic Acid IP 1.5mg Tablet"

5.1 The Authority was apprised about the review order dated 21.10.2022 issued by Department of Pharmaceuticals relating to Nervup Forte Plus- Alpha Lipoic Acid USP

100mg + Vitamin D3 IP 1000 IU + Pyridoxine Hydrochloride IP 3mg + Methylcobalamin 1500mcg + Folic Acid IP 1.5mg. In the review order, DOP has remanded the review application dated 17.09.2021 back to NPPA to reconsider the same strictly as per the provisions of DPCO 2013. The Authority noted that the retail price has been recalculated based on data received from M/s Pharmatrac at Rs.12.23 per tablet (excluding GST). The draft worksheet was uploaded on NPPA's website on 16.01.2023 and no further representations have been received on the same. Accordingly, the Authority after deliberations approved the retail price of Rs. 12.23 per tablet (excluding GST).

6. Agenda item no. 6 – Status of implementation of Review cases

Noted

7. Agenda item no. 7 –Minutes of 48th meeting of Multidisciplinary Committee of Experts held on 20.01.2023.

Noted

8. Agenda item no. 8 - Fixation of Ceiling Price for Hormone Releasing Intrauterine Devices (IUDs) and IUDs containing Copper under Revised Schedule I (NLEM 2022).

8.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for Hormone Releasing IUD and IUD containing Copper was uploaded on the NPPA website on 12.01.2023.

8.2 The Authority was apprised that one representation was received against the draft working sheet on 13.01.2023. The Authority deliberated upon the agenda including the representation and approved the ceiling prices as appearing in column (7) of the below table.

Table 2: Ceiling Prices of Hormone Releasing IUD and IUD containing Copper

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./Unit)	S.O & date		
1	2	3	4	5	6	7	8
1	18.2.2.1	Hormone Releasing IUD	Contains 52 mg of Levonorgestrel	4295.01	S.O. 1499(E) dated 30.03.2022	3456.44	1 Hormone Releasing IUD
2	18.2.2.2	IUD containing Copper	As licensed	319.22	S.O. 1499(E) dated 30.03.2022	250.62	1 IUD

9. Agenda item no. 9 - Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022).

9.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of the Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for formulations are uploaded on the NPPA website 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. The details of draft working sheets uploaded are given in **Table 3**.

Table 3: Status of Draft Working Sheets Uploaded on NPPA's Website

S.No	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	Approved in earlier meetings	No. of formulations proposed for approval
1.	25.11.2022	09.12.2022	121	119	-
2.	01.12.2022	15.12.2022	43	40	-
3.	02.12.2022	16.12.2022	51	50	-
4.	05.12.2022	19.12.2022	15	15	-
5.	13.12.2022	27.12.2022	69	68	-
6.	20.12.2022	03.01.2023	30	30	-
7.	23.12.2022	06.01.2023	35	34	-
8.	06.01.2023	20.01.2023	45	42	2
9.	28.01.2023	10.02.2023	45	-	45
10	02.02.2023	16.02.2023	55	-	37
11.	Separate Ceiling Prices for formulations with special features			2	
Total			509	400	84

9.2 NPPA has received total 920 representations till 17.02.2023 and companies have submitted copy of invoice showing the revised PTR and snapshots of sample pack showing revised MRP. The representations broadly covered the following:

(a) Related to data in worksheets:

- i. Price to Retailer considered as per July, 2022 Pharmatrac database is not reflecting the WPI increase availed by the companies in April, 2022
- ii. Incorrect pack sizes
- iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

These claims have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS as per provisions of DPCO, 2013.

(b) Related to methodology:

- i. Representations received on methodology are same as already deliberated in 105th meeting of Authority held on 15.12.2022.

9.3 Authority noted that there was price revision in 38 formulations as compared to the ceiling prices reflected in the draft uploaded working sheets. The Authority deliberated and approved the ceiling prices of 79 formulations as appearing in column (7) of the Table 4.

Table 4: Ceiling Prices of 79 formulations

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	5.1.10	Sodium Valproate	Tablet 200mg	3.44	SO1499 dated 30.3.2022	3.20	1 Tablet
2	5.1.10	Sodium Valproate	Modified Release - Tablet 500mg	10.82	SO1499 dated 30.3.2022	8.28	1 Tablet
3	5.1.10	Sodium Valproate	Tablet 500mg	7.71	SO1499 dated 30.3.2022	7.24	1 Tablet
4	22.2.2	Nifedipine	Tablet 10mg	1.37	SO1499 dated 30.3.2022	1.37	1 Tablet
5	10.4.4	Noradrenaline	Injection 2mg/mL	28.61	SO1499 dated 30.3.2022	17.99	1 ML
6	1.1.1	Halothane	Liquid for inhalation	6.50	SO1499 dated 30.3.2022	5.44	1 ML
7	7.3.2	Cyclosporine	Capsule 50 mg	58.45	SO1499 dated 30.3.2022	49.15	1 Capsule
8	7.3.2	Cyclosporine	Capsule 100mg	113.81	SO1499 dated 30.3.2022	91.96	1 Capsule
9	3.1	Adrenaline	Injection 1mg/mL	17.38	SO1499 dated 30.3.2022	10.91	1 ML
10	1.3.4	Morphine	Injection 10mg/mL	26.37	SO1499 dated 30.3.2022	17.48	1 ML
11	1.3.4	Morphine	Injection 15mg/mL	32.91	SO1499 dated 30.3.2022	13.32 (Note 2)	1 ML
12	7.4.5	Filgrastim	Injection 300mcg	1523.73	SO1499 dated 30.3.2022	1034.51	1 Vial
13	1.3.3	Midazolam	Injection 1mg/mL	6.56	SO1499 dated 30.3.2022	5.28	1 ML
14	1.3.3	Midazolam	Injection 5mg/mL	16.12	SO1499 dated 30.3.2022	9.70	1 ML
15	8.1.1	Erythropoietin	Injection 2000IU/mL	684.16	SO1499 dated 30.3.2022	490.14 (Note 1)	1 ML
16	8.1.1	Erythropoietin	Injection 10000 IU/mL	2888.54	SO1499 dated 30.3.2022	1756.13 (Note 1)	1 ML
17	15.1	Furosemide	Injection 10mg/mL	2.76	SO1499 dated 30.3.2022	2.67	1 ML
18	7.1.3	Actinomycin D	Powder for Injection 0.5mg	352.13	SO1499 dated 30.3.2022	295.22	1 Vial
19	7.1.9	Calcium folinate	Tablet 15mg	45.29	SO1499 dated 30.3.2022	42.40	1 Tablet

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
20	18.3.2.1	Glucose	Injection 25%	0.19	SO1499 dated 30.3.2022	0.18	1 ML
21	8.1.7	Iron sucrose	Injection 20mg/mL	59.68	SO1499 dated 30.3.2022	51.2	1 ML
22	23.1.2	Fluphenazine	Injection 25mg/mL	55.55	SO1499 dated 30.3.2022	49.29	1 ML
23	21.6.2	Hydroxypropyl methyl cellulose	Injection 2%	41.64	SO1499 dated 30.3.2022	26.05	1 ML
24	20.1	Alprostadil	Injection 0.5mg/mL	6288.11	SO1499 dated 30.3.2022	5446.23	1 ML
25	7.1.13	Cisplatin	Injection 1mg/mL	7.65	SO1499 dated 30.3.2022	6.32	1 ML
26	21.2.1	Prednisolone	Drops 1%	5.58	SO1499 dated 30.3.2022	5.14	1 ML
27	12.2.4	Meglumine diatrizoate	Injection 60 %w/v	9.17	SO1499 dated 30.3.2022	8.45	1 ML
28	12.2.4	Meglumine diatrizoate	Injection 76 %w/v	10.60	SO1499 dated 30.3.2022	9.10	1 ML
29	26.7	Thiamine	Injection 100 mg/mL	27.54	SO1499 dated 30.3.2022	20.15	1 ML
30	7.1.11	Carboplatin	Injection 10mg/mL	59.08	SO1499 dated 30.3.2022	52.68	1 ML
31	6.2.2.8	Gentamicin	Injection 10mg/mL	3.53	SO1499 dated 30.3.2022	2.15 (Note 3)	1 ML
32	5.1.6	Magnesium sulphate	Injection 500mg/mL	5.31	SO1499 dated 30.3.2022	4.34	1 ML
33	5.3.2	Trihexyphenidyl	Tablet 2mg	1.35	SO1499 dated 30.3.2022	1.22	1 Tablet
34	21.5.1	Atropine	Drops 1%	3.81	SO1499 dated 30.3.2022	3.51	1 ML
35	21.5.1	Atropine	Ointment 1%	4.20	SO1499 dated 30.3.2022	4.20	1 GM
36	1.3.1	Atropine	Injection 0.6mg/mL	4.65	SO1499 dated 30.3.2022	4.08	1 ML
37	1.2.2	Lignocaine	Topical forms 2-5 %	1.20	SO1499 dated 30.3.2022	1.01	1 GM/ML
38	1.2.2	Lignocaine	Injection 2%	1.10	SO1499 dated 30.3.2022	0.93	1 ML
39	14.1.5	Povidone iodine	Solution 5%	0.43	SO1499 dated 30.3.2022	0.39	1 ML
40	14.1.5	Povidone iodine	Solution 7.5%	0.85	SO1499 dated 30.3.2022	0.73	1 ML
41	14.1.5	Povidone iodine	Solution 10%	1.03	SO1499 dated 30.3.2022	0.86	1 ML
42	5.1.10	Sodium Valproate	Modified Release - Tablet 300mg	6.99	SO1499 dated 30.3.2022	5.44	1 Tablet

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
43	5.1.10	Sodium Valproate	Injection 100mg/mL	6.40	SO1499 dated 30.3.2022	6.02	1 ML
44	7.4.10	Metoclopramide	Injection 5mg/mL (Less than 10ML Pack)	2.59	SO1499 dated 30.3.2022	2.38	1 ML
45	11.3.1	Betamethasone valerate	Cream 0.05%	0.64	SO1499 dated 30.3.2022	0.60	1 GM
46	11.3.1	Betamethasone valerate	Cream 0.1%	0.93	SO1499 dated 30.3.2022	0.93 (Note 3)	1 GM
47	8.2.4	Protamine Sulphate	Injection 10mg/mL	10.27	SO1499 dated 30.3.2022	8.72	1 ML
48	11.2.2	Fusidic acid	Cream 2 %	10.14	SO1499 dated 30.3.2022	8.77	1 GM
49	1.1.6	Propofol	Injection 10mg/mL	8.02	SO1499 dated 30.3.2022	5.80	1 ML
50	21.4.3	Pilocarpine	Drops 2 %	11.22	SO1499 dated 30.3.2022	9.66	1 ML
51	22.1.1	Dinoprostone	Gel 0.5mg	90.01	SO1499 dated 30.3.2022	75.56	1 GM
52	24.1.7	Tiotropium	Inhalation (MDI) 9 mcg/dose	2.67	SO1499 dated 30.3.2022	2.48	1 MD
53	24.1.7	Tiotropium	Inhalation(DPI) 18mcg/dose	10.31	SO1499 dated 30.3.2022	9.55	1 DP
54	21.1.2	Ciprofloxacin	Ointment 0.3%	1.26	SO1499 dated 30.3.2022	1.15 (Note 3)	1 GM
55	11.4.1	Benzoyl peroxide	Gel 2.5%	4.16	SO1499 dated 30.3.2022	3.23	1 GM
56	11.4.1	Benzoyl peroxide	Gel 5%	Not fixed	Not fixed	7.11	1 GM
57	17.5.2	Ispaghula	Granules/Husk/Powder	0.85	SO1499 dated 30.3.2022	0.84	1 GM
58	18.3.1.3	Insulin Intermediate Acting (NPH)	Injection 40IU/mL	16.71	SO1499 dated 30.3.2022	15.15	1 ML
59	25.1.4	Potassium chloride	Injection 150mg/mL	2.69	SO1499 dated 30.3.2022	2.14	1 ML
60	6.4.15	Rifampicin	Oral liquid 100mg/5mL (p)	0.43	SO1499 dated 30.3.2022	0.42 (Note 3)	1 ML
61	19.4.1	Rabies vaccine	As licensed	379.43	SO1499 dated 30.3.2022	337.75	1 Vial
62	11.4.4	Salicylic acid	Ointment 6%	1.99	SO1499 dated 30.3.2022	1.80	1 GM
63	21.1.1	Acyclovir	Ointment 3%	11.56	SO1499 dated 30.3.2022	10.41	1 GM

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
64	8.2.3	Phytomenadione (VitaminK1)	Injection 10mg/mL	53.17	S01499 dated 30.3.2022	47.35	1 ML
65	18.4.2	Human chorionic gonadotropin	Injection 5000 IU	463.41	S01499 dated 30.3.2022	372.32	1 Vial
66	18.6.2	Levothyroxine	Tablet 12.5mcg	1.5	S01499 dated 30.3.2022	1.32 (Note 2)	1 Tablet
67	18.6.2	Levothyroxine	Tablet 100mcg	1.33	S01499 dated 30.3.2022	1.18 (Note 2)	1 Tablet
68	18.6.2	Levothyroxine	Tablet 125mcg	1.71	S01499 dated 30.3.2022	1.51 (Note 2)	1 Tablet
69	6.1.2.2	Diethylcarbamazine(DEC)	Tablet 50mg	0.62	S01499 dated 30.3.2022	0.5 (Note 2)	1 Tablet
70	10.1.3	Isosorbidedinitrate	Tablet 10mg	0.81	S01499 dated 30.3.2022	0.72 (Note 2)	1 Tablet
71	5.3.1	Levodopa (A) +Carbidopa(B)	Modified Release-Tablet 100 mg (A) + 25 mg (B)	3.7	S01499 dated 30.3.2022	2.49 (Note 2)	1 Tablet
72	6.4.14	Pyrazinamide	Tablet 1500mg	11.6	S01499 dated 30.3.2022	10.53 (Note 2)	1 Tablet
73	5.1.8	Phenobarbitone	Oral liquid 20mg/5mL (p)	0.49	S01499 dated 30.3.2022	0.44 (Note 2)	1 ML
74	3.4	Hydrocortisone	Tablet 10mg	6.54	S01499 dated 30.3.2022	5.98 (Note 2)	1 Tablet

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
75	18.1.3	Hydrocortisone	Tablet 20mg	New	New	13.28 (Note 2)	1 Tablet
76	1.4.3	Neostigmine	Tablet 15mg	5.18	S01499 dated 30.3.2022	4.09 (Note 2)	1 Tablet
77	6.1.2.2	Diethylcarbamazine(DEC)	Oral liquid 120mg/5mL(p)	0.54	S01499 dated 30.3.2022	0.43 (Note 2)	1 ML
78	3.4	Hydrocortisone	Powderforlnjection 200mg	66.61	S01499 dated 30.3.2022	58.51 (Note 2)	1 Vial
79	3.4	Hydrocortisone	Tablet 5mg	3.37	S01499 dated 30.3.2022	2.78 (Note 2)	1 Tablet

Note 1- Authority was apprised that the prices of formulations mentioned at S.No. 15 and 16 were fixed on per pack basis under NLEM 2015. However, under the present NLEM 2022, the ceiling prices are proposed on per ml basis.

Note 2 - The Authority noted that prices of formulations at Sr. No. 11 and 66 to 79 shall be fixed under Para 6 (1) of DPCO 2013.

Note 3- The Authority noted that prices of formulations at Sr. No. 31,46,54 and 60 shall be fixed under Para 6 (2) of DPCO 2013.

9.4. With respect to the formulation as mentioned in the Table 5 below, the Authority, after deliberations, deferred the fixation of ceiling prices for the reasons stated in the notes given below the **Table 5**.

Table 5


S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	7.1.31	Oxaliplatin	Injection 5 mg/mL in 20mL vial	4962.1	S01499 dated 30.3.2022	Deferred (Note1)	per Vial

S.No	Section	Formulation s	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs./Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
2	6.2.2.8	Gentamicin	Injection 40 mg/mL (upto 2ml)	9.35	SO1499 dated 30.3.2022	Deferred (Note 2)	1 ML
3	6.2.2.8	Gentamicin	Injection 40 mg/mL (3ml-10ml)	19.95	SO1499 dated 30.3.2022	Deferred (Note 2)	1 ML
4	6.2.2.8	Gentamicin	Injection 40 mg/mL (11ml-20ml)	30.24	SO1499 dated 30.3.2022	Deferred (Note 2)	1 ML
5	6.2.2.8	Gentamicin	Injection 40 mg/mL (more than 20ml)	33.1	SO1499 dated 30.3.2022	Deferred (Note 2)	1 ML

Note 1- After deliberations Authority directed to recheck the ceiling price of formulations Oxaliplatin Injection 5 mg/mL in 20mL vial i.e. S. No.1 . Hence, the same is deferred.

Note 2 - With respect to the formulations mentioned at S. No. 2 to 5 of table 5 i.e. Gentamycin Injection the Authority was apprised that the prices of formulations were fixed on per pack basis under NLEM 2015. However, under the present NLEM 2022, the ceiling prices are proposed on per ml basis. However, in these cases, the Authority observed that the working sheets were uploaded on per pack basis for different ranges of pack sizes. However, considering the fact that the formulations are available in different pack sizes, the ceiling prices are proposed on per ml basis for different ranges of pack sizes. The Authority deliberated on the matter and directed that Draft worksheets for these formulations mentioned at S.No. 2 to 5 of table 5 i.e. Gentamicin Injection may be uploaded again for 10 working days. Accordingly, the proposed ceiling prices of these items were deferred by the Authority.

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


 (Dr. Vinod Kotwal)
 Member Secretary