

मिसिलस.- 8(135)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(135)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 267/135/2025/F

Proceeding No: 267/135/2025/F

Minutes of the 267th (overall) and 135th meeting of the Authority under DPCO, 2013 held on 30.07.2025 at 03.30 p.m.

The 267th meeting of the Authority (overall), which is the 135th meeting under the DPCO, 2013 was held on 30th July, 2025 at 03.30 p.m. under the Chairmanship of Shri P. Krishnamurthi, 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

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)

1. Agenda item no. 1 - Confirmation of Minutes of the 134th Meeting held on 26.06.2025.

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 134th Meeting held on 26.06.2025.

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

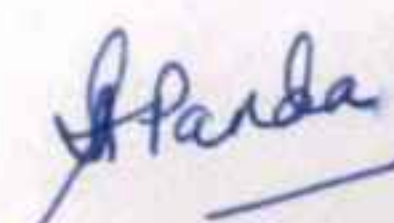
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4.1 The Authority deliberated on 38 (Thirty-eight) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (37) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 37 (Thirty-seven) 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

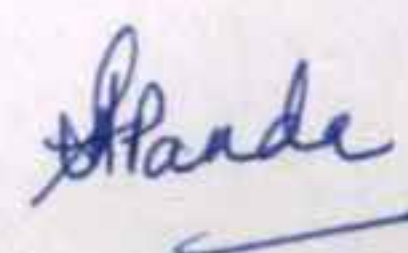
Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1	Aceclofenac, Paracetamol & Trypsin Chymotrypsin Tablets	Each enteric coated tablet contains: Proteolytic enzymes Trypsin & Chymotrypsin in the ratio of Approximately 6:1 and provides enzymatic activity Eq. to 1,50,000 Armour units Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Dr. Reddy's Laboratories Ltd.	13.00
2	Aceclofenac, Paracetamol & Trypsin Chymotrypsin Tablets	Each enteric coated tablet contains: Proteolytic enzymes Trypsin & Chymotrypsin in the ratio of Approximately 6:1 and provides enzymatic activity Eq. to 1,50,000 Armour units Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Cadila Pharmaceuticals Ltd.	15.01
3	Amoxycillin & Potassium Clavulanate Oral suspension	Each 5 ml of reconstituted suspension contains: Amoxycillin Trihydrate IP equivalent to Amoxycillin 600 mg Potassium Clavulanate Diluted IP equivalent to Clavulanic Acid 42.9 mg	1 ml	M/s Copmed Pharmaceuticals Pvt. Ltd./ M/s Zydus Healthcare Ltd.	3.32
4	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)
5	Atorvastatin & Clopidogrel Tablets	Each uncoated bilayered tablet contains: Atorvastatin Calcium IP Equivalent to Atorvastatin 40 mg Clopidogrel Bisulphate IP	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	25.61

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		equivalent to Clopidogrel 75 mg			
6	Atorvastatin & Ezetimibe Tablets	Each Film Coated Tablet Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 10 mg Ezetimibe IP 10 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	19.86
7	Atorvastatin & Ezetimibe Tablets	Each Film Coated Tablet Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 20 mg Ezetimibe IP 10 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	30.10
8	Atorvastatin & Ezetimibe Tablets	Each Film Coated Tablet Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 40 mg Ezetimibe IP 10 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	30.47
9	Atorvastatin Calcium and Clopidogrel Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP equivalent to Atorvastatin 10mg (As pellets) Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd./ M/s Alkem Laboratories Ltd.	15.94
10	Atorvastatin, Clopidogrel and Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP Eqv. to Atorvastatin 10 mg (As Pellets) Clopidogrel Bisulphate IP Eqv. to Clopidogrel 75 mg (As Pellets) Aspirin IP 75 mg (As enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd./ M/s Aristo Laboratories Pvt. Ltd.	5.88
11	Atorvastatin, Clopidogrel and Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP Eqv. to Atorvastatin 20 mg (As Pellets) Clopidogrel Bisulphate IP Eqv. to Clopidogrel 75 mg (As Pellets) Aspirin IP 75 mg (As enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd./ M/s Aristo Laboratories Pvt. Ltd.	8.33
12	Bilastine & Montelukast Tablet	Each film coated bilayered tablet contains: Bilastine IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals	22.78



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Montelukast Sodium IP eq. to Montelukast 10 mg		Ltd./ M/s Lupin Ltd.	
13	Bisoprolol Fumarate & Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Amlodipine Besylate IP equivalent to Amlodipine 5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s Cadila Pharmaceuticals Ltd.	6.70
14	Cefixime Oral Suspension (Combipack)	One Combipack contains: Part (A) Each 5ml of reconstituted suspension contains: Cefixime IP equivalent to Cefixime Anhydrous 200 mg Part (B) Each ampoule contains Sterile Water for Injection IP 25ml	1 ml	M/s Alps Communication Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	3.72
15	Cefixime, Dicloxacillin (CR) and Lactic Acid Bacillus Tablets	Each film coated tablet contains: Cefixime IP as Trihydrate Eq. to Anhydrous Cefixime 200mg Dicloxacillin Sodium IP Eq. to Dicloxacillin 500 mg (Controlled release) Lactic Acid Bacillus 2.5 Billion Spores (Appropriate Overages of Lactic Acid Bacillus Spores Added)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.	15.25
16	Cholecalciferol Oral Drops	Each ml contains: Cholecalciferol (Vitamin D3) IP 800 IU (as Stabilized)	1 ml	M/s Ravenbhel Biotech/ M/s Zydus Healthcare Ltd.	6.11
17	Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 20 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Lupin Ltd.	14.51
18	Diclofenac Sodium, Paracetamol & Chlorzoxazone Tablets	Each uncoated tablet contains: Diclofenac Sodium IP 50 mg Paracetamol IP 325 mg Chlorzoxazone USP 250 mg	1 Tablet	M/s Innova Captab Ltd./ M/s Dr. Reddys Laboratories Ltd.	6.03
19	Escitalopram Oxalate & Clonazepam Tablets	Each Film Coated Tablet Contains: Escitalopram Oxalate IP eq.to Escitalopram	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Abbott Healthcare Pvt. Ltd.	8.38

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		5 mg Clonazepam IP 0.25 mg			
20	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablets	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (I) Overseas / M/s Troikaa Pharmaceuticals Ltd.	5.15
21	Empagliflozin, Linagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Linagliptin 5 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Corona Remedies Pvt. Ltd.	33.13
22	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s USV Ltd.	27.50
23	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Ltd.	16.50
24	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Aristo Pharmaceuticals Pvt. Ltd.	17.42



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
25	Empagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Aristo Pharmaceuticals Pvt. Ltd.	14.74
26	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Eris Lifesciences Ltd.	18.70
27	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 Medley Pharmaceuticals Ltd.	13.40
28	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Medley Pharmaceuticals Ltd.	14.30
29	Sitagliptin + Pioglitazone + 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	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Workcell Solutions Pvt. Ltd.	14.11
30	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP 64.25 mg equivalent to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Tristar Formulations Pvt. Ltd./ M/s Franco Indian Pharmaceuticals Pvt. Ltd.	11.16
31	Sitagliptin, Glimepiride	Each film coated bilayered tablet contains:	1 Tablet	M/s Tristar Formulations Pvt.	12.59

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	& Metformin Hydrochloride Tablets	Sitagliptin Phosphate Monohydrate IP 64.25 mg equivalent to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 1000 mg		Ltd/ M/s Franco Indian Pharmaceuticals Pvt. Ltd.	
32	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Primus Remedies Pvt. Ltd.	12.19
33	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Aristo Pharmaceuticals Pvt. Ltd.	11.52
34	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Primus Remedies Pvt. Ltd.	13.87
35	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Aristo Pharmaceuticals Pvt. Ltd.	14.69
36	Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate Suspension	Each 5 ml contains: Paracetamol IP 250 mg Phenylephrine Hydrochloride IP 5 mg Chlorpheniramine Maleate IP 2 mg	1 ml	M/s Res- Sancta Limited / M/s Biological E. Limited	0.71
37	Paracetamol, Phenylephrine HCl, Chlorpheniramine	Each 5ml (teaspoonful) contains: Paracetamol IP 250 mg Phenylephrine Hydrochloride	1 ml	M/s Windlas Biotech Limited / M/s Biological E. Limited	0.41



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	mine Maleate, Ammonium Chloride, Sodium Citrate & Menthol Suspension	IP 5 mg Chlorpheniramine Maleate IP 2 mg Ammonium Chloride IP 120 mg Sodium Citrate IP 60 mg Menthol IP 1 mg			
38	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75 mg	1ml	M/s Nitin Lifesciences Ltd. /M/s. Mankind Prime Labs Pvt. Ltd.	31.77

Note 1: The Authority directed to re-examine the data for retail price fixation.

5. Agenda item no. 5: Minutes of 69th meeting of Multidisciplinary Committee of Experts held on 03.07.2025.

5.1 Noted.

6. Agenda item no. 6: Application for grant of separate price/special price for Omeprazole Delayed release orally disintegrating tablet 20 mg "OMEZ ODT" under the provision of Para 11 (3).

6.1 The Authority noted that M/s Dr. Reddy's Laboratories Limited vide emails dated 06.11.2024 and 25.11.2024 had requested for grant of separate price/special price of Rs. 17.90 per tablet for Omeprazole Delayed release orally disintegrating tablet 20 mg "OMEZ ODT" under the provision of Para 11 (3) of DPCO 2013.

6.2 The Authority noted that the matter was deliberated by the Committee in its 64th, 65th, 66th and 69th meeting held 6.12.2024, 23.01.2025, 3.03.2025 and 3.07.2025 respectively.

6.3 The Authority noted that the Committee in its 69th meeting held on 03.07.2025 while deliberating upon the representation of the company, re-examined the applicability of Para 11(3) and noted that it is applicable in case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I. Since, the dosage form of the applied formulation is tablet and the strength is same as mentioned in the Schedule-I, the current application does not fall in the purview of Para 11(3). Hence, the Committee recommended to reject the application.

6.4 The Authority deliberated upon the matter in detail and accepted the recommendation of the MDC.

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7. Agenda item no. 7: Application to fix a separate Ceiling Price under Paragraph 11(3) of DPCO-2013, of a Scheduled formulation of Amoxicillin 200 mg + Clavulanic acid 28.5 mg Suspension in a Dual Chamber Pack with Novel Technology, being introduced in India for the first time, -Seeking additional Price for Dual Chamber Pack over and above Existing Ceiling Price.

7.1 The Authority noted that M/s Sun Pharmaceutical Industries Limited applied for a separate ceiling price for scheduled formulation 'Amoxicillin 200 mg + Clavulanic acid 28.5 mg Suspension in a Dual Chamber Pack with Novel Technology' under para 11(3) of DPCO, 2013. The company claimed the salient features like invention in packing, Dose Accuracy and avoids contamination.

7.2 The Authority recalled that matter was examined in 56th, 57th and 59th meeting of MDC held on 15.12.2023, 27.02.2024 and 8.5.2024 respectively, wherein the MDC recommended to reject the application. The Authority accepted the recommendation of the Committee in its 124th meeting held on 7.06.2024.

7.3 Authority noted that DoP vide its letter dated 2.12.2024 forwarded the representation dated 20.11.2024 of the company to NPPA and requested NPPA to examine the matter and place it before MDC for reconsideration.

7.4 Accordingly, the matter was deliberated in the 65th meeting of MDC held on 23.1.2025, 66th meeting of the MDC held on 03.03.2025 and 69th meeting of the MDC held on 03.07.2025, wherein the Committee examined the additional submissions and presentation made by the applicant. The Committee also deliberated upon the applicability of Para 11 (3).

7.5 The Committee noted that Para 11(3) is applicable in case of injections, inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I. Since, the dosage form of the applied formulation is oral suspension and the strength is same as mentioned in the Schedule-I, the current application does not fall in the purview of Para 11(3). Hence, the Committee recommended to reject the application.

7.6 The Authority deliberated upon the matter in detail and accepted the recommendation of the MDC.

8 Agenda item no. 8: Fixation of ceiling prices of 6 scheduled formulations under Revised Schedule-I (NLEM, 2022)

8.1 The Authority noted that the ceiling price of 764 formulations have been fixed under NLEM 2022 based on the approved methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022).

8.2 The Authority noted that draft working sheets for ceiling prices of 6 formulations, based on data and database of October, 2023 were uploaded on NPPA website on 14.07.2025 for 10 working days. Further, the effect of change in WPI for 2024 @ (+)

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0.00551% (effective from 01.04.2024) and WPI for 2025 @ (+) 1.74028% (effective from 01.04.2025) have also been duly considered in the draft worksheets.

8.3 It was noted that representation has been received in respect of two formulations:

- (i) Paracetamol Injection 150mg/ml (pack size: 5ML): The Authority observed that the price was proposed based on the data of M/s Neon Laboratories Limited only. However, the company represented stating that the product with pack of 5ml as considered for calculation was never manufactured or marketed by it. The same has been verified from the Pharmarack also. Accordingly, the Authority decided to defer the ceiling price fixation since no other data is available for ceiling price fixation.
- (ii) DPT Vaccine: The Authority noted that the draft working sheet was initially uploaded on NPPA website on 03.03.2023. Representation received on the said draft worksheet was examined in consultation with CDSCO and MoHFW. Accordingly, revised draft worksheet was uploaded on 14.07.2025. Representation filed by M/s Zydus Lifesciences Limited on the revised draft worksheet uploaded on 14.07.2025 was examined and not found tenable. However, based on the replies of the companies, the Authority noted that DPT vaccine is mainly supplied under Universal Immunization Programme. Therefore, Authority directed defer the matter for further examination.

8.4 Accordingly, the Authority approved the ceiling price of following four scheduled formulations:

Table 2: Revised Ceiling prices of 4 formulations under NLEM, 2022

S. No.	Medicines	Dosage form(s) and strength(s)	Prevailing Ceiling Price (in Rs.)	Ceiling Price under NLEM, 2022 (in Rs.)	Unit
1	Ipratropium	Respirator solution for use in nebulizer 250mcg/mL	3.20	2.96	Per ml
2	Sodium nitroprusside	Injection 10mg/mL	32.71	28.99	Per ml
3	Povidone iodine	Ointment 10%	6.59	6.26	Per gm
4	Diltiazem	Modified Release Capsule 180mg	Not Fixed	26.72	Per Capsule

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


(Sai Ahladi Pandi)
 Member Secretary