F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-VI

National Pharmaceutical Pricing Authority

Subject: Minutes of the 71st meeting of the Multidisciplinary Committee of Experts held on 16.09.2025 at 2:00 PM.

71st meeting of the Multidisciplinary Committee of Experts was held on 16.09.2025 at 2:00 PM under the convenorship of Shri Sanjay Kumar, Advisor (Cost). The following members attended the meeting:

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO
2. Dr. Rakesh Kr. Singh, Professor & Dean, NIPER Raebareli, through Video Conferencing
3. Dr. J. J. Cherian, Scientist-E (Med), ICMR, through Video Conferencing
4. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – Co-opted member
5. Dr. Sanjay Mendiratta, Principal Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member

The following officers of NPPA attended and presented the cases before the Committee:

1. Ms. Rashmi Tahiliani, Director (Pricing)
2. Shri Mahaveer Saini, Deputy Director (Pricing)
3. Ms. Yuvika Panwar, Assistant Director (Pricing)
4. Shri Bhiva Ram Yadav, Assistant Director (Pricing & Overcharging)
5. Shri Mayur Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Retail price fixation of Povidone Iodine IP 10.0% w/v (available iodine 1.0% w/v) + Ethanol IP 30% v/v for M/s G.S. Pharmbutor Pvt Ltd. (Manufacturer) & M/s Win-Medicare Pvt Ltd. (Marketer) (File No. 4813)

1. The committee deliberated on the application of the company and recommended the retail price for Povidone Iodine IP 10.0% w/v (available iodine 1.0% w/v) + Ethanol IP 30% v/v as below:

S. No.	Particulars	Source/ Method	Amount (Rs.)
(a)	Povidone Iodine IP 10.0% w/v	Ceiling Price as applicable six months prior to month in which application is received i.e. December 2024 [SO. 1547(E) dated 26.3.2024]	0.96/ml
(b)	Ethanol IP 30% v/v	**Note 1**	0.23/ml
(c)	Total		1.19/ml
(d)	Less 20% of the lower of (a) and (b)		0.05/ml
(e)	Worked out Retail Price (c)-(d)		1.14/ml
(f)	Claimed Retail price		1.25/ml
(g)	**Recommended retail price per tablet (lower of worked out (e) and claimed price (f))**		1.14/ml

Note 1: Derived Retail Price of Ethanol IP 30% v/v

The Committee noted that the ceiling price of Ethyl Alcohol (Denatured) 70% has already been notified @ Rs. 0.53 per ml (Excluding GST) vide S.O. 1548(E) dated 26.03.2024. The Committee observed that to prepare a lower concentration, a measured volume of the stronger solution is mixed with the required amount of water to achieve the desired final concentration. As such, the Derived Retail Price of Ethanol IP 30% v/v has been worked out as under:

Derived Retail Price of Ethanol IP 30% v/v = 0.53 X 30%/70% = 0.23/ml

Agenda Item No. 2: Application or approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for Dual Port Bottles of Large Volume Parenteral by M/s Life Infusion Pharmaceuticals Pvt. Ltd

1. The Committee noted that M/s Life Infusion Pharmaceuticals Pvt. Ltd applied for separate ceiling prices under Para 11(3) of the DPCO, 2013 on 29.07.2025 for IV fluids in non-glass with special features i.e., dual port automatically sealable plastic collapsible bottles through ISBM technology, self sealable and having no chances of contamination and for the following formulations:

Sr. No.	Name of Product	Pack Size
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml
2.	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	500ml
3.	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml
9.	Compound Sodium Lactate Injection	500ml
10.	Compound Sodium Lactate Injection	1000ml
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml
13.	Ciprofloxacin Injection IP (0.2% w/v)	100ml

2. The Committee deliberated upon the application of the company and directed that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the committee in next meeting to present their case and demonstrate the product for special features claimed in the application.

Agenda Item No. 3: Application or approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head / PP Bottles with special features by M/s IV Tech Healthcare

1. The Committee noted that M/s IV Tech Healthcare applied on 18.07.2025 for separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that their IV fluids packaged in Twin port Euro Head / PP bottles, which incorporate special features enhancing their utility and performance for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification	Claimed MRP ex. GST
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	1486(E) dt. 27.03.25	25.00
2.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70
3.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	1485(E) dt. 27.03.25	101.68
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22
9.	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09
10.	Compound Sodium Lactate Injection	1000ml	1474(E) dt. 27.03.25	116.20
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	1486(E) dt. 27.03.25	41.00
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	1486(E) dt. 27.03.25	24.00

2. The Committee noted that the matter was deliberated in 70th meeting held on 05.08.2025, wherein the Committee directed the applicant to appear in the next meeting to present their case and demonstrate their product. Accordingly, the applicant company appeared before the committee and demonstrated its products.

3. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The committee noted that the product bears the features of self-sealability, self-collapsibility and has a twin port Euro head to prevent the contamination. Accordingly, the Committee recommended the separate ceiling price for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification	Separate Ceiling price ex. GST
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	1486(E) dt. 27.03.25	0.25/ml
2.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70/pack
3.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77/pack
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01/pack
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	1485(E) dt. 27.03.25	101.68/pack
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79/pack
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47/Pack
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22/Pack
9.	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09/Pack
10.	Compound Sodium Lactate Injection	1000ml	1474(E) dt. 27.03.25	116.20/Pack
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	1486(E) dt. 27.03.25	0.41/ml
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	1486(E) dt. 27.03.25	0.24/ml

Agenda Item No. 4: Application for approval of company for scheduled drugs under special features (Euro Head) by M/s Safal Lifescience Private Limited (Manufacturer) and M/s One Drip Healthcare Private Limited (Marketer).

1. The Committee noted that M/s Safal Lifescience Private Limited (Manufacturer) and M/s One Drip Healthcare Private Limited (Marketer) applied on 17.06.2025 (complete application on 20.08.2025) for separate ceiling prices under Para 11(3) of the DPCO, for their IV fluids packaged in LDPE Bottle

with EURO Head having special features i.e., Self collapsibility, self seal-ability, secure closure, sterility, clear labeling and material selection etc. for the following formulations:

Sr. No.	Name of Product	Pack Size	Brand Name
1.	Dextrose Injection IP 5% w/v – 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
2.	Sodium Chloride Injection IP 0.9% w/v – 100ml LDPE Bottle with EURO Head	100ml	DRIPEURO
3.	Sodium Chloride Injection IP 0.9% w/v – 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
4.	Dextrose 5% w/v + Sodium Chloride 0.9% w/v Injection IP – 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
5.	Compound Sodium Lactate Injection IP – 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO

2. The Committee deliberated upon the application and directed that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the committee in the next meeting to present their case and demonstrate the product for special features as claimed in the application.

Agenda Item No. 5: Application for exemption of patented non-scheduled formulation Nafithromycin Tablets under Para 32(i) of DPCO, 2013 by M/s Wockhardt Limited

1. The Committee noted that M/s Wockhardt Limited submitted an application on 14.07.2025 seeking exemption for the non-scheduled formulation Nafithromycin Tablets under Para 32(i) of the DPCO, 2013. The company had submitted the permission of the formulation granted by the Central Drugs Standard Control Organization (CDSCO) and the Patent Certificate (Patent No. 415319, granted on 23.12.2022) under the Patent Act, 1970

2. The Committee further observed that Nafithromycin is a non-scheduled formulation. During its deliberations, the Committee noted that Patent No. 415319, granted on 23.12.2022 is registered in the name of Wockhardt Limited for an invention titled "Pharmaceutical compositions". However, the drug approval from CDSCO (Approval No. IND/MA/24/00001 dated 01.01.2025) pertains specifically to "Nafithromycin Tablets – Immediate release film-coated tablets – each film-coated tablet containing Nafithromycin 400 mg."

3. It was also noted that neither the patent certificate nor the claims filed with the Patent Office explicitly mention the name 'Nafithromycin'. Accordingly, NPPA vide letter dated 7.08.2025 sought the complete set of claims as submitted to the Patent office by the company. In response the company along with other documents furnished Summary of inventions & claims and the scientific publication from a peer reviewed journal "Chromatographia (2019) 82:1059-1068", as published in Springer Nature 2019.

4.The Committee directed that inputs be obtained from CDSCO and the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) to verify whether the formulation approved by CDSCO corresponds to the one for which the patent was granted. The committee further directed that the application along with the necessary clarifications may be placed before the Committee for further consideration.

Agenda Item No. 6: Application for exemption of 'New Drug'- Povidone Iodine Throat Spray 0.45 % w/v under Paragraph 32(iii) of the Drugs (Prices Control) Order 2013.

1. The Committee noted that M/s G.S. Pharmbutor Private Limited on 30.04.2025 submitted the application for exemption of Povidone Iodine Throat Spray 0.45% w/v under Para 32(iii) of the DPCO, 2013. The matter was placed in the 70th meeting of the Multidisciplinary Committee (MDC) held on 05.08.2025. During the meeting, the Committee reviewed the company's application and decided that the applicant should be invited to attend the next meeting to present their case and demonstrate the product.

2. Accordingly, the applicant company gave a presentation before the Committee. The applicant informed that the new drug product combining Povidone-Iodine and ethanol has been developed through indigenous R&D, featuring a novel drug delivery system that allows precise application deep into the throat for targeted anti-infective action and improved patient compliance. This specialized formulation and its packaging have undergone extensive quality and performance testing—including pH, viscosity, spreadability, content uniformity, spray pattern, droplet size, and plume geometry—to ensure effective delivery and prolonged adherence to throat tissues. These features distinguish it from conventional products like mouthwashes and gargles.

3. It was also noted that while the applicant markets other Povidone Iodine-based products in gargle form, the current formulation is claimed to be different by the applicant on the basis of novel dosage delivery system. Applicant has also informed that they have applied for the patent of the subject formulation on 03.03.2023 and the application is currently under examination.

4. The Committee deliberated upon the matter and directed the applicant to provide evidence in support of its claim that povidone iodine throat spray (0.45%) is superior than existing gargles and also to furnish the Clinical Trial Protocol, CMC (Chemistry, Manufacturing & Control) Data, and other relevant data records demonstrating better efficacy that have been submitted to CDSCO for clinical trial.

Agenda Item No. 7: Application by M/s. Biodeal Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulation "Midazolam nasal spray 1.25 mg".

1. The Committee noted that the application submitted by M/s Biodeal Pharmaceuticals Limited seeking exemption from the provisions of the DPCO, 2013 under Para 32(iii) for their product *Midazolam Nasal* Spray 1.25% w/v had been earlier deliberated during the 68th and 69th MDC meetings held on 03.06.2025 and 03.07.2025 respectively.

2. During the 69th meeting, the Committee directed the applicant to submit supporting documents to substantiate their claim regarding the novel drug delivery system developed through indigenous R&D. In response, the company submitted, on 22.07.2025, the minutes of the SEC (Neurology & Psychiatry) meeting held on 18.04.2024. The company highlighted that while tablet and parenteral forms of Midazolam were previously approved, the intranasal route had not been approved by CDSCO until the permission granted to them, thereby establishing the novelty of their drug delivery system.

3. Inputs were sought from the Office of CDSCO vide letter dated 28.07.2025. In response, the O/o CDSCO, through communication dated 01.08.2025, that *"M/s Biodeal Pharmaceuticals Limited was granted New Drug permission by the Central Drugs Standard Control Organization (CDSCO) for aforesaid formulation on 05-May-2025 and earlier Midazolam Nasal spray 1.25% w/v was not approved by this office".*

4. The Committee in its 70th meeting held on 05.08.2025 deliberated on the same and directed to seek further clarification from the CDSCO and also directed that the applicant may be asked to appear before the Committee in the next meeting along with relevant product development documentation with respect to their claim under Para 32(iii).

5. During the meeting, the applicant made a presentation explaining therein the details of the indigenous development of the nasal spray formulation and its novel delivery mechanism. Also, the Committee deliberated upon the additional inputs provided by the O/o DCGI, vide letter dated 11.09.2025, reiterating therein that *"M/s Biodeal Pharmaceuticals Limited was granted New Drug Permission for the drug product - Midazolam Nasal Spray 1.25% w/v strength only, on 05.05.2025 and no other strength of Midazolam Nasal Spray has been approved by this office till date".*

6. The Committee noted that Midazolam Nasal Spray has been included in the National List of Essential Medicines (NLEM), 2022. As per NLEM 2022 report, one of the criteria for inclusion of a medicine in the NLEM was *'The medicine should be approved/ licensed in India.'*. Also, NPPA has already notified ceiling price of the applied formulation based on the market data wherein 3 companies were appearing manufacturing/marketing the applied formulation.

7. In view of the above, the Committee recommended that views/inputs may be obtained from the Standing National Committee on Medicines (SNCM) and CDSCO regarding the approval and inclusion of Midazolam Nasal Spray in NLEM 2022. The matter may again be placed before the Committee with inputs from SNCM and CDSCO.

Agenda Item No. 8: Application for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head with packaging in non-glass with special feature by M/s Klokter Life Sciences Pvt. Ltd. (manufacturer) and Zee Laboratories Limited (marketer)

1. The Committee noted that M/s Klokter Life Sciences Pvt. Ltd. (manufacturer) and Zee Laboratories Limited (marketer) applied on 09.09.2025 for separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that their IV fluids packaged in Euro Head bottles, bear special features viz. (i) self-collapsibility and self-sealability, (ii) not having air-vent, (iii) having no chance of contamination during manufacture / infusion / admixing level for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification
1.	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25
2.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25

Sr. No.	Name of Product	Pack Size	Notification
3.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25
4.	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25

2. The Committee deliberated upon the application of the company and directed that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the committee in next meeting to present their case and demonstrate the product for separate features as claimed in the application.

Agenda Item No. 9: Application for separate ceiling price for IV fluids in special features under the provisions of Para 11 of the DPCO, 2013 by M/s Virchow Biotech Private Limited packed in LVP bags

1. The Committee noted that M/s Virchow Biotech Private Limited applied on 10.09.2025 for separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that their IV fluids packaged in two port **LVP bags,** which incorporate special features viz. (i) self-collapsibility and self-sealability, (ii) not having air-vent, (iii) having no chance of spillage or leakage during the procedure for the following formulations:

Sr. No.	Name of Product	Pack Size	Notification	Claimed MRP ex. GST
1	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79
2	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	250ml	1485(E) dt. 27.03.25	63.18
3	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47
4	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22
5	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70
6	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77
7	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09
8	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01
9	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	250ml	Not fixed for special packaging	34.00
10	Dextrose Injection IP 10% w/v: Each 100ml contains Dextrose Anhydrous IP 10gm	500ml	Not fixed for special packaging	42.00

Sr. No.	Name of Product	Pack Size	Notification	Claimed MRP ex. GST
11	Dextrose Injection IP 10% w/v: Each 100ml contains Dextrose Anhydrous IP 10gm	1000ml	Not fixed for special packaging	39.00
12	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	250ml	Not fixed for special packaging	34.00

2. The Committee deliberated upon the application of the company and directed that the authorized person of the company who is well-versed with the documents and claims submitted may be asked to appear before the committee in next meeting to present their case and demonstrate the product for special features as claimed in the application.

The meeting ended with a vote of thanks to all.

RASHMI TAHILIANI
Digitally signed by RASHMI TAHILIANI
Date: 2025.09.26 16:12:57 +05'30'

(Rashmi Tahiliani)
Director (Pricing)

Copy to:
All members of the Committee.