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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 79th meeting of the Multidisciplinary Committee of Experts held on 27.07.2026 at 02:00 PM.

79th meeting of the Multidisciplinary Committee of Experts was held on 27.07.2026 at 02:00 PM under the convenorship of Shri Rajiv Wadhawan, Advisor (Cost). The following members attended the meeting:

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO, through Video Conferencing
2. Dr. Rakesh Kr. Singh, Professor & Dean, NIPER Raebareli, through Video Conferencing
3. Dr. Balu V Gopal, Scientist C, HTAIn, D/o Health Research
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. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission – Co-opted member

The following officers of NPPA attended and presented the cases before the Committee:
1. Ms. Priyanka Sachdeva, Joint Director (Pricing)
2. Shri Bhiva Ram Yadav, Assistant Director (Pricing)
3. Shri Mayur Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Retail price fixation of 'Each Film Coated Tablet contains: Lamivudine IP 300 mg + Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25 mg + Dolutegravir Sodium IP eq. to Dolutegravir 50 mg' for M/s Emcure Pharmaceuticals Ltd. (Manufacturer & Marketer) (F.No.5228).

1. After detailed deliberations, the Committee worked out and recommended the price of the FDC as below:

Calculation of Retail Price of 'Each Film Coated Tablet contains: Lamivudine IP 300 mg + Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25 mg + Dolutegravir Sodium IP eq. to Dolutegravir 50 mg'			
S.N.	**Particulars**	**Source / Method**	**₹**
1	Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg Tablet	Ceiling price as on 6 months prior to application date i.e. November 2025 [SO 1489(E) dated 27.03.2025]	116.99
2	**Less:** Ceiling price of Tenofovir Disoproxil Fumarate 300mg tablet		(46.64)
3	**Add:** Ceiling price of Tenofovir Alafenamide Fumarate (TAF) 25 mg tablet		49.72
4	Worked out Price of applied FDC per tablet		120.07
5	**Recommended Price of applied FDC per tablet**		**120.07**

Agenda Item No. 2: Application for extension of ceiling price of IV fluids with special features - under para 11(3) of DPCO, 2013 by M/s Silica Healthcare Pvt. Ltd. (Manufacturer & Marketer)

1. The Committee noted that M/s Silica Healthcare Pvt. Ltd. applied for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 vide email dated 24.04.2026 for their IV fluids packaged in Euro Head/ Euro Head Dual Port bottles, which incorporate special features viz. (i) self-collapsibility and self-sealability, (ii) Can be administered without use of Air Vent, (iii) having no chance of contamination during manufacture / infusion / admixing level, for the following formulations:

No.	Product Name	Concentration / Volume	Packaging Type
1	Compound Sodium Lactate Injection IP	500 ml	Euro Head Dual Port
2	Compound Sodium Lactate Injection IP	500 ml	Euro Head
3	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head Dual Port
4	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head
5	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head Dual Port
6	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head
7	Mannitol Injection IP	20% w/v (100 ml)	Euro Head Dual Port
8	Mannitol Injection IP	20% w/v (100 ml)	Euro Head
9	Mannitol Injection IP	20% w/v (300 ml)	Euro Head

2. The Committee noted that the matter was deliberated in 77th MDC meeting held on 15.05.2026, wherein the Committee 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. Accordingly, the matter was deliberated in 78th meeting held on 24.06.2026 wherein the representative of company demonstrated their products. In the said meeting, 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 and during the demonstration of the products, the Committee observed that certain clarifications regarding the flow rate of the products are required. Therefore, after deliberations, the Committee directed that the authorized person of the company who is well versed with the subject to appear in the next meeting of Committee for detailed demonstration.

3. Accordingly, the applicant company representative appeared before the Committee in 79th MDC meeting held on 27.07.2026 and demonstrated its products. 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 Euro Head/ Euro Head Dual Port to prevent the contamination.

4. The Committee noted that the ceiling price for Mannitol Injection 20% has been notified on per ML basis and a separate ceiling price for said formulation in special feature has been notified on per ml basis for the pack size of 100ml & 350ml. However, the company has applied for separate ceiling price for 300ml pack for Mannitol Injection 20% in addition to 100ml pack. Accordingly, the Committee recommended the separate ceiling price for the following formulations:

No.	Product Name	Concentration / Volume	Packaging Type	Ceiling Price (in ₹)	Notification details
1	Compound Sodium Lactate Injection IP	500 ml	Euro Head Dual Port	66.52 / each pack	1584(E) dated 25.03.2026
2	Compound Sodium Lactate Injection IP	500 ml	Euro Head		

3	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head Dual Port	0.25 per ml	1586(E) dated 25.03.2026
4	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head		
5	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head Dual Port	0.23 per ml	
6	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head		
7	Mannitol Injection IP	20% w/v (100 ml)	Euro Head Dual Port	0.41 per ml	
8	Mannitol Injection IP	20% w/v (100 ml)	Euro Head		
9	Mannitol Injection IP	20% w/v (300 ml)	Euro Head	0.41 per ml	

Agenda Item No. 3: Application for extension of ceiling price of IV fluids with packaging in non-glass with special features - under para 11(3) of DPCO, 2013 by M/s Indbest Healthcare Pvt. Ltd. (Manufacturer & Marketer)

1. The Committee noted that M/s Indbest Healthcare Pvt. Ltd. applied for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 vide email dated 09.06.2026 for their IV fluids packaged in ISBM technology PP Bottles with dual port, which incorporate special features viz. (i) Self-collapsibility & cap self-seal ability (ii) can be administered without use of air vent (iii) Having no chance of contamination during manufacture/ infusion /admixing level; for the following formulations:

No.	Product Name	Concentration / Volume	Packaging Type
1	Sodium Chloride Injection IP 0.9% w/v	100 ml	PP bottles- Dual Port cap
2	Sodium Chloride Injection IP 0.9% w/v	250 ml	PP bottles- Dual Port cap
3	Sodium Chloride Injection IP 0.9% w/v	500 ml	PP bottles- Dual Port cap

2. The Committee noted that the matter was deliberated in 78th meeting held on 24.06.2026, wherein the Committee 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. 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 dual port to prevent the contamination. Accordingly, the Committee recommended the separate ceiling price for the following formulations:

S. No.	Name of the Formulation	Pack size	Ceiling Price (in ₹)	Notification details
1	Sodium Chloride Injection IP 0.9% w/v	100 ml	43.07 / each pack	1583(E) dated 25.03.2026
2	Sodium Chloride Injection IP 0.9% w/v	250 ml	63.59 / each pack	
3	Sodium Chloride Injection IP 0.9% w/v	500 ml	90.05 / each pack	

Agenda Item No. 4: Review application of M/s Vantive Healthcare Private Limited under Para 31 of DPCO, 2013 against NPPA's notification S.O. No. 5018(E) dated 04.11.2025 for the formulation "Peritoneal Dialysis Solution".

1. The Committee noted that the ceiling price for Peritoneal Dialysis Solution was notified vide S.O. 5018(E) dated 04.11.2025. It further noted that, pursuant to the review application filed by M/s Vantive Healthcare Private Limited regarding the inclusion of its Icodextrin-based product, Extraneal, the Department of Pharmaceuticals had referred the matter back to NPPA for re-examination of whether a common or separate ceiling price should be fixed as per the extant provisions of DPCO, 2013. The Committee noted that the matter was deliberated in 78th meeting held on 24.06.2026, the Committee deliberated upon the matter and directed that the authorized person of the company who is well-versed with the documents and claims submitted may be given an opportunity to appear before the committee in next meeting to present their case. Accordingly, the applicant company appeared before the Committee and made a presentation.

2. The Committee noted the submissions of M/s Vantive Healthcare Private Limited that Extraneal (Icodextrin 7.5%) is a clinically distinct, innovative, starch-derived glucose polymer based peritoneal dialysis solution designed for long dwell exchanges, with significant differences in composition, therapeutic profile, patient population, and clinical outcomes compared to conventional glucose-based PD solutions. The company submitted that Extraneal is the only Icodextrin-based PD solution marketed in India, is imported, and that application of the notified ceiling price would render its supply financially unviable and Extraneal icodextrin should be treated separately for ceiling price fixation, supported by scientific evidence, clinical data, and global pricing comparisons.

3. The Committee sought clarification from the applicant company regarding the claimed economic benefits arising from the use of Icodextrin, particularly with respect to any studies demonstrating cost savings attributable to extended peritoneal dialysis dwell time, reduction in healthcare resource utilization, or improvement in treatment outcomes. The Committee also enquired whether any Health Technology Assessment (HTA), pharmacoeconomic evaluation, or cost-effectiveness analysis had been undertaken to substantiate the company's claim. In response, the company informed the Committee that, while certain international studies and published literature are available, no India-specific Health Technology Assessment or comprehensive pharmacoeconomic study demonstrating the overall cost-effectiveness of Icodextrin in the Indian healthcare setting had been conducted. The Committee observed that the material placed on record is not sufficient to conclusively establish the clinical and economic advantages claimed by the company. Accordingly, the Committee decided to defer consideration of the request and directed the company to submit substantive evidence, including a comprehensive Health Technology Assessment/pharmacoeconomic evaluation, demonstrating the overall cost-benefit and cost-effectiveness of Icodextrin-based peritoneal dialysis in comparison with conventional glucose-based peritoneal dialysis solutions, for further examination by the Committee.

Agenda Item No. 5: 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 recalled its earlier recommendation in 75th meeting held on 11.02.2026 to grant exemption under Para 32(iii) of DPCO, 2013 to M/s G.S. Pharmbutor Private Limited for Povidone Iodine Throat Spray 0.45% w/v, noting that it is a CDSCO-approved new drug involving novel delivery system developed in a lab approved by DSIR for indigenous research

and development. It further noted that the Authority in 144th Authority meeting held on 24.03.2026 had deferred the matter for further examination. After detailed deliberations, the Committee in 78th meeting held on 24.06.2026 observed that exemption under Para 32(iii) requires clear evidence of both a new drug involving a new delivery system and indigenous research and development. While the company had submitted CDSCO approval for new drug involving a new delivery system, demonstrated the product, and furnished DSIR laboratory approval, the Committee directed the company to provide specific documentary evidence establishing that **the product was developed through indigenous research and development (emphasis supplied)**. Accordingly, the company vide email dated 10.07.2026 furnished its response regarding evidence of indigenous research and development and appeared before the Committee.

2. The Committee noted that, in response to NPPA's letter dated 09.07.2026 seeking evidence of indigenous research and development, the company submitted a comprehensive set of documents on 10.07.2026 to substantiate its claim. The submissions included DSIR recognition, details of its in-house R&D infrastructure and equipment, records of DSIR filings demonstrating the product's development over time, extensive formulation, analytical, packaging, process validation and stability development documents, CDSCO new drug approval supported by Phase III clinical trial data, and details of the R&D team involved.

3. The Committee observed that these documents establish that the product was conceived, developed, validated, and brought to market through the company's indigenous research and development efforts carried out at DSIR-recognized R&D facility. The Committee deliberated upon the matter in detail and reiterated its earlier recommendation to grant exemption under Para 32(iii) of DPCO, 2013 to M/s G.S. Pharmbutor Private Limited for “Povidone Iodine Throat Spray 0.45% w/v” for a period of five years from the date of its market approval in India.

The meeting ended with a vote of thanks to all.

PRIYANKA SACHDEVA
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(Priyanka Sachdeva)
Joint Director (Pricing)

Copy to:
All members of the Committee.