

F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-VI**National Pharmaceutical Pricing Authority**

Subject: Minutes of the 64th meeting of the Multidisciplinary Committee of Experts held on 06.12.2024 at 11:30 AM.

64th meeting of the Multidisciplinary Committee of Experts was held on 06.12.2024 at 11:30 AM 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. J. J. Cherian, Scientist-E (Med), ICMR through Video Conferencing
3. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli, through Video Conferencing
4. Dr. Jai Prakash, Indian Pharmacopoeia Commission – Co-opted member
5. Prof. Y. K. Gupta, President, AIIMS, Jammu & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi – 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)

Agenda Item No. 1: 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) DPCO 2013.

1.1 The Committee noted that M/s Dr. Reddy's Laboratories Limited has requested 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) of DPCO 2013. The applicant has claimed Rs.17.90 per tablet without GST.

1.2 The Committee was apprised that Omeprazole Capsule 20mg is scheduled formulation & under explanation-1 of DPCO, 2013 the ceiling price for the Omeprazole Tablet 20mg was fixed under NLEM, 2015 and has also been refixed under NLEM, 2022. The current applicable ceiling price of Omeprazole Tablet 20mg is Rs. 4.34 per tablet (S.O. No. 1547E dated 26.03.2024).

1.3 The committee noted that the methodology approved by Authority in its 104th meeting held on 23.11.2022 and followed for pricing of conventional/novel delivery system i.e. modified release (ER/SR/XL etc.) is as below:

"Wherever, Modified Release (MR) variant is specifically mentioned in any formulation the data of only MR variants (CR, SR, XL, ER delayed release etc.) may be considered for fixation of ceiling price. However, where MR variant is not specifically mentioned, data of conventional as well as MR variants may be considered for ceiling price fixation. **Similarly, where DT/effervescent/soluble/MD, etc. is specifically mentioned in any formulation in any formulation the data of only such variants may be considered. However, in absence of any variant being specifically mentioned, the DT/effervescent/soluble/MD may be considered along with conventional form**".

Therefore, the applied formulation i.e., Omeprazole Delayed release orally disintegrating tablet is a Scheduled formulation.

1.4 The Committee also deliberated upon the technical justification provided by the applicant. It was noted that 'Delayed Release' is common to all formulation of Omeprazole tablet & capsules and are always 'Enteric coated' and it acts only in intestine. Further, the shortcomings of omeprazole with sodium bicarbonate as mentioned by the applicant were not found to be tenable.

1.5 Hence, there appears to be no incremental specified therapeutic rationale of Omeprazole Orally Disintegrating tablet over the Omeprazole Enteric Coated Tablets. Accordingly, the Committee recommended to reject the application for special/separate price for Omeprazole Delayed release orally disintegrating tablet 20 mg.

Agenda Item No. 2: Retail price fixation under Para 5 of DPCO, 2013- Each 5 ml contains: Metformin Hydrochloride IP 500 mg for M/ s Eris Therapeutics Limited (Manufacturer and Marketer) under DPCO, 2013 (File No. 4255)

2.1 The Committee noted that M/ s Eris Therapeutics Limited has applied for retail price fixation of 'Each 5 ml contains Metformin Hydrochloride IP 500 mg'. The data for the said formulation is not available in Pharmarack database. However, from web search, it is noted that the subject formulation is marketed by M/s Franco Indian Pharmaceuticals Pvt. Ltd. under the Brand name "Glyciphage" in pack of 100ml containing Metformin 500mg oral solution. However, the company has not filed any Form V for the said formulation.

2.2 The Committee deliberated up on the matter and directed that MAT & PTR details may be sought from M/s Franco Indian Pharmaceuticals Pvt. Ltd. in respect of the subject formulation and that the matter may be placed again along with the said information for further deliberation.

Agenda Item No. 3: Retail price fixation under Para 5 of DPCO, 2013 for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Micro Labs Limited (Marketer) under DPCO, 2013 (File No. 4292).

3.1 The Committee deliberated upon the matter and recommended the retail price for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Micro Labs Limited (Marketer) at Rs. 15.26 per tablet as below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg		
(a)	Derived retail price of Polmacoxib IP 2mg tablet	Mar 2024	13.56
(b)	Derived retail price of Paracetamol IP 325mg	Mar 2024	2.12
(c)	Total		15.68
(d)	Less 20% of the lower of (a) & (b) based on inference drawn from the Pronab Sen Committee Report		0.42
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		15.26
(f)	Claimed Retail price excluding GST		16.07
(g)	Recommended retail price excluding GST (Lower of claimed price & Worked Out price)		15.26

Agenda Item No. 4: Retail price fixation under Para 5 of DPCO, 2013 for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero

Labs Limited (Manufacturer) & M/s Abbott Healthcare Private Limited (Marketer) under DPC, 2013 (File No. 4299).

4.1 The Committee deliberated upon the matter and recommended the retail price for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Abbott Healthcare Private Limited (Marketer) at Rs. 15.26 per tablet as below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg		
(a)	Derived retail price of Polmacoxib IP 2mg tablet	April 2024	13.56
(b)	Derived retail price of Paracetamol IP 325mg	April 2024	2.12
(c)	Total		15.68
(d)	Less 20% of the lower of (a) & (b) based on inference drawn from the Pronab Sen Committee Report		0.42
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		15.26
(f)	Claimed Retail price excluding GST		16.52
(g)	Recommended retail price excluding GST (Lower of claimed price & Worked Out price)		15.26

Agenda Item No. 5: Retail price fixation under Para 5 of DPCO, 2013 for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Mankind Pharma Limited (Marketer) under DPCO, 2013 (File No. 4300).

5.1 The Committee deliberated upon the matter and recommended the retail price for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Mankind Pharma Limited (Marketer) at Rs. 15.26 per tablet as below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg		
(a)	Derived retail price of Polmacoxib IP 2mg tablet	April 2024	13.56
(b)	Derived retail price of Paracetamol IP 325mg	April 2024	2.12
(c)	Total		15.68
(d)	Less 20% of the lower of (a) & (b) based on inference drawn from the Pronab Sen Committee Report		0.42
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		15.26
(f)	Claimed Retail price excluding GST		19.00
(g)	Recommended retail price excluding GST (Lower of claimed price & Worked Out price)		15.26

Agenda Item No. 6: Retail price fixation under Para 5 of DPCO, 2013 for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Torrent Pharmaceuticals Limited (Marketer)

under DPCO, 2013 (File No. 4304).

6.1 The Committee deliberated upon the matter and recommended the retail price for each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg for M/s Hetero Labs Limited (Manufacturer) & M/s Torrent Pharmaceuticals Limited (Marketer) at Rs. 15.26 per tablet as below:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each uncoated tablet contains Polmacoxib 2mg + Paracetamol IP 325mg		
(a)	Derived retail price of Polmacoxib IP 2mg tablet	April 2024	13.56
(b)	Derived retail price of Paracetamol IP 325mg	April 2024	2.12
(c)	Total		15.68
(d)	Less 20% of the lower of (a) & (b) based on inference drawn from the Pronab Sen Committee Report		0.42
(e)	Worked out Retail Price (a)+(b)+(c)-(d)		15.26
(f)	Claimed Retail price excluding GST		18.00
(g)	Recommended retail price excluding GST (Lower of claimed price & Worked Out price)		15.26

Agenda Item No. 7: Retail price fixation under Para 5 of DPCO, 2013 of Each uncoated dispersible tablet Contains: Methylprednisolone IP 4 mg for M/s. J.K. Printpack (Pharma Division) (Manufacturer) & M/s Biological E. Ltd. (Marketer) (F. No. 3992)

7.1 The committee noted that M/s Biological E. Ltd. has applied for retail price fixation of each uncoated dispersible tablet Contains: Methylprednisolone IP 4 mg. SLA license submitted by the company is for 'Each uncoated dispersible tablet containing: Methylprednisolone IP 4mg', whereas DCGI permission is for 'Methylprednisolone' i.e. without mentioning the strength and dosage form.

7.2 The Committee deliberated the communication received from O/o DCGI in this regard and directed that the applicant company may be asked to submit the approval/NOC from the O/o DCGI. The current application may be returned to the applicant.

Agenda Item No. 8: Application by M/s Intas Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (ii & iii) for the formulation "Clozapine Extended Release 12.5 mg/ 25 mg/ 50 mg/ 100 mg/200 mg capsule"

8.1 The Committee recalled that the matter was earlier deliberated in 44th meeting of MDC held on 04.08.2022 and Committee was of the opinion that the different variants of a drug like extended release, modified release of a drug were in the market since a considerable period and also manufactured by a number of companies. Hence, it could not be considered as a 'New Delivery System' for qualifying for exemption under Para 32 (iii) of DPCO, 2013. Accordingly, the Committee rejected the application of M/s Intas Pharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulations "Clozapine Extended Release Capsules 12.5mg/ 25mg /50mg / 100mg / 200mg".

8.2 The applicant vide letter dated 07.10.2024, has again stated that the provisions of DPCO 2013 are not applicable to the subject formulations, since, the new drug is being produced in the country by a new process through indigenous research and development and is patented under the Indian Patent Act, 1970.

8.3 The Committee noted that applicant has submitted DCGI approval and has additionally submitted Patent certificate (Patent no. 437433) granted on 05.07.2023 along with complete specification and claims on the basis of which the patent is granted by Indian Patent Office.

8.4 The Committee also recalled its decision taken in its 61st meeting held on 14.08.2024, that w.r.t. matters related to exemption under Para 32 of DPCO 2013, an officer not below the rank of Deputy Controller of Patents & Designs from the O/o Controller General of Patents, Designs & Trade Marks (CGPDTM), DPIIT, who is well versed with the subject matter would be invited for deliberations. It was also decided that the agenda for the deliberations on the applications received under Para 32 of DPCO, 2013 may be sent in advance to O/o CGPDTM, DPIIT. The recommendations of MDC were accepted by the Authority in its 126th meeting held on 09.09.2024.

8.5 Accordingly, the agenda for the subject matter was sent to DPIIT vide letter dated 08.11.2024 to nominate an officer for participating in the MDC meeting. A copy of the same was also sent to the O/o CGPDTM. Further, reminders dated 03.12.2024 and 05.12.2024 were also sent through email. However, till date no nomination has been received from the DPIIT. Therefore, the Committee decided to defer the agenda item and requested that the matter may be pursued with DPIIT for nomination of suitable officer so that the matter can be deliberated in the next meeting.

Agenda Item No. 9 : Application from M/s Biological E Limited for exemption under Para 32 (i, ii & iii) of the DPCO, 2013 for the formulation Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX 14).

9.1 The Committee recalled its decision taken in its 61st meeting held on 14.08.2024, that w.r.t. matters related to exemption under Para 32 of DPCO 2013, an officer not below the rank of Deputy Controller of Patents & Designs from the O/o Controller General of Patents, Designs & Trade Marks (CGPDTM), DPIIT, who is well versed with the subject matter would be invited for deliberations. It was also decided that the agenda for the deliberations on the applications received under Para 32 of DPCO, 2013 may be sent in advance to O/o CGPDTM, DPIIT. The recommendations of MDC were accepted by the Authority in its 126th meeting held on 09.09.2024

9.2 Accordingly, the agenda for the subject matter was sent to DPIIT vide letter dated 03.12.2024 to nominate an officer for participating in the MDC meeting. A copy of the same was also sent to the O/o CGPDTM. Further, reminder dated 05.12.2024 was also sent through email. However, till date no nomination has been received from the DPIIT. Therefore, the Committee decided to defer the agenda item and requested that the matter may be pursued with DPIIT for nomination of suitable officer so that the matter can be deliberated in the next meeting.

Additional Agenda Item No. 1: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd

10.1 The matter was earlier deliberated in 60th, 61st, 62nd and 63rd meeting of MDC held on 26.06.2024, 14.08.2024, 25.09.2024 and 22.10.2024 respectively. In the 63rd meeting of MDC, the company demonstrated their product w.r.t. the special features claimed i.e., non-glass container with Euro head having special features like self sealability, self-collapsibility, no air vent requirement and no chances of contamination during manufacture, infusion and admixing level. After detailed deliberations, the Committee directed the company to submit an undertaking about the IP grade plastic used for the container and the reason for filling volume more than standard volume and also flow rate analysis data along with standard deviation.

10.2 The Committee noted that applicant vide email dated 22.10.2024 submitted the undertaking for plastic used in the manufacturing of bottles and validity of their state manufacturing license. Further, the applicant vide email dated 02.12.2024 has submitted the reasons for filling volume more than standard volume. The applicant was also present in the 64th meeting and clarified that they filled more volume to conduct Flow Rate Analysis, as per IP Standards which provides that 'the volume is not less than the nominal volume'.

10.3 The Committee deliberated upon the matter in detail and considering the special features of the bottles used for the subject formulation recommended the retail price at Rs. 92.82 per bottle of 500ml as per following calculations:

Details	Price (for packing with special features in 500ml pack size)
(i) Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml) – (Note 1)	9.12
(ii) Ceiling Price of Each 100ml contains: Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg OR Glucose (A) + Sodium Chloride (B) Injection 5% (A) + 0.9% (B) Pack Size – 500ml	85.52 (S.O. 4663(E) dated 25.10.2023)
Total (i+ii)	94.64
Less: 20% of Lower of (i) and (ii) based on inference drawn from the Pronab Sen Committee Report	1.82
Worked Out Price	92.82
Claimed Price	284.83
Recommended Price (Lower of worked out and claimed price)	92.82

Note 1: Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml)

Ceiling Price of Potassium Chloride injection 150mg/ml (as applicable for month ending 6 months prior date of application)= Rs. 2.40 per ML (S.O. 4663(E) dated 25.10.2023)

Subject formulation in 100ml pack contains the same quantity of API as of Scheduled formulation in 1 ml i.e. 150mg; Therefore, derived price for Potassium Chloride IP 150mg in 100ml is also Rs. 2.40.

Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml) as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1 + a \cdot \{(s - s^*)/s^*\}]$$

Where: P(s) = Price ceiling of the strength s

P^* = price ceiling for reference strength s^*
 s = strength in terms of API content
 s^* = reference strength
 a = 0.8 for tablet / capsule and 0.7 for injectables.

$$= 2.40[1+0.70\{(500-100)/100\}] = \text{Rs. } 9.12$$

Additional Agenda Item No. 2 : Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd

11.1 The matter was earlier deliberated in 60th, 61st, 62nd and 63rd meeting of MDC held on 26.06.2024, 14.08.2024, 25.09.2024 and 22.10.2024 respectively. In the 63rd meeting of MDC, the company demonstrated their product w.r.t. the special features claimed i.e non glass container with Euro head having special features like self sealability, self-collapsibility, no air vent requirement and no chances of contamination during manufacture, infusion and admixing level. After detailed deliberations, the Committee directed the company to submit an undertaking about the IP grade plastic used for the container and the reason for filling volume more than standard volume and also flow rate analysis data along with standard deviation.

11.2 The Committee noted that applicant vide email dated 22.10.2024 submitted the undertaking for plastic used in the manufacturing of bottles and validity of their state manufacturing license. Further, the applicant vide email dated 02.12.2024 has submitted the reasons for filling volume more than standard volume. The applicant was also present in the 64th meeting and clarified that they filled more volume to conduct Flow Rate Analysis, as per IP Standards which provides that 'the volume is not less than the nominal volume'.

11.3 The Committee deliberated upon the matter in detail and considering the special features of the bottles used for the subject formulation recommended the retail price at Rs. 68.30 per bottle of 500ml as per following calculations:

Details	Price (for packing with special features)
(i) Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml) (Note 1)	9.12
(ii) Retail Price of Each 100ml contains: Dextrose Monohydrate IP 5000mg OR Glucose Injection 5% Pack Size – 500ml (Note 2)	2.52
(iii) Derived Price of Each 100ml contains: Sodium Chloride IP 450mg OR Sodium Chloride Injection 0.45% Pack Size – 500ml – (Note 3)	57.16
Total (i+ii+iii)	68.80
Less: 20% of Lower of (i), (ii) and (iii) based on inference drawn from the Pronab Sen Committee Report	0.50
Worked Out Price	68.30
Claimed Price	267.00

Recommended Price (Lower of worked out and claimed price)	68.30
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Note 1: Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml)

Ceiling Price of Potassium Chloride injection 150mg/ml (as applicable for month ending 6 months prior date of application)= Rs. 2.40 per ML (S.O. 4663(E) dated 25.10.2023)

Subject formulation in 100ml pack contains the same quantity of API as of Scheduled formulation in 1 ml i.e. 150mg; Therefore, derived price for Potassium Chloride IP 150mg in 100ml is also Rs. 2.40.

Derived Price of Potassium Chloride IP 150mg in 100ml (For pack size of 500ml) as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

Where: P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectibles.

$$= 2.40[1+0.70\{(500-100)/100\}] = \text{Rs. } 9.12$$

Note-2: Retail price of Glucose 5gm as per the formula recommended in the Pronab Sen Committee Report

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

where, P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Calculated Retail price of Glucose 1gm powder as per para 5 of DPCO from Pharmatrac Data for October, 2023 = Rs. 0.60

$$\text{Derived retail price of Glucose 5000mg or 5gm} = 0.60 [1+0.8\{(5-1)/1\}] = 0.6[1+3.2] = \text{Rs. } 2.52$$

Note-3: Derived price of Sodium Chloride IP 450mg in special packaging

Ceiling Price of Sodium Chloride IP 900mg with special features 500ml pack (S.O. 4663(E) dated 25.10.2023) = Rs. 87.94

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

Where: P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectibles.

$$= 87.94[1+0.70\{(450-900)/900\}] = \text{Rs. } 57.16$$

Additional Agenda Item No. 3: Request for consideration of Price fixation for Multiple electrolytes and 5% Dextrose injection Type I USP for pack of non-glass

container in plastic bottle with Euro Head and Non-PVC bag having special feature under Para 11(3) of DPCO, 2013 as applied by M/s Otsuka Pharmaceuticals India Pvt. Ltd. (Manufacturer & Marketer)

12.1 The matter was earlier deliberated in 62nd and 63rd meeting of MDC held on 25.09.2024 and 22.10.2024 respectively. In the 63rd meeting of MDC, the company demonstrated their product w.r.t. the special features claimed i.e., non glass container with Euro head having special features like self sealability, self-collapsibility, no air vent requirement and no chances of contamination during manufacture, infusion and admixing level. After detailed deliberations, the Committee directed the company to submit an undertaking about the IP grade plastic used for the container and the reason for filling volume more than standard volume and also flow rate analysis data along with standard deviation.

12.2 The Committee noted that applicant vide email dated 22.10.2024 submitted the undertaking for plastic used in the manufacturing of bottles and validity of their state manufacturing license. Further, the applicant vide email dated 02.12.2024 has submitted the reasons for filling volume more than standard volume. The applicant was also present in the 64th meeting and clarified that they filled more volume to conduct Flow Rate Analysis, as per IP Standards which provides that 'the volume is not less than the nominal volume'.

12.3 The Committee deliberated upon the matter in detail and considering the special features of the bottles and Non-PVC bags used for the subject formulation recommended the retail price at Rs. 81.56 per bottle of 500ml and per non PVC bag of 500 ml as per following calculations:

S. No.	Particulars	Source/Method	Amount (Rs.)
	Each 100 ml contains: Sodium Chloride IP 526 mg + Sodium Gluconate USP 502 mg + Sodium Acetate Trihydrate IP 368 mg + Potassium Chloride IP 37 mg + Magnesium Chloride Hexahydrate IP 30 mg + Dextrose Monohydrate IP 5000 mg (Pack size: 500ml)		
(a)	Derived retail price of Sodium Chloride IP 526mg	Ceiling Price (S.O. No. 4663(E) dated 25.10.2023) (Note-1)	62.36
(b)	Derived retail price of Sodium Gluconate USP 502mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data (Note-2)	1.54
(c)	Derived retail price of Sodium Acetate Trihydrate IP 368mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data (Note-3)	1.19
(d)	Derived retail price of Potassium Chloride IP 37mg	Ceiling Price (S.O. No. 4663(E) dated 25.10.2023) (Note-4)	2.79

(e)	Derived retail price of Magnesium Chloride Hexahydrate IP 30mg	Ceiling Price (S.O. 4663(E) dated 25.10.2023) (Note-5)	2.71
(f)	Derived retail price of Dextrose Monohydrate IP 5000mg	Retail Price (as per the formula of Pronab Sen Committee) based on January, 2024 data (Note-6)	11.21
(g)	Less 20% of the lower of (a) to (f) based on inference drawn from the Pronab Sen Committee Report		0.24
(h)	Worked out Retail Price (sum of (a) to (f) less (g))		81.56
(i)	Claimed Retail price		379.47
(j)	Recommended retail price (Lower of worked out & claimed)		81.56

Note-1: Retail price of Sodium Chloride 526mg as per the formula recommended in the Pronab Sen Committee Report

The retail price of Sodium Chloride 526mg/100ml in 500ml Non Glass with special features has been worked out as per the formula recommended in the Pronab Sen Committee report. The calculation is as below: -

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

where, P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Ceiling price of Sodium Chloride 0.9% in 500ml Non Glass with special features is Rs. 87.94 (S.O. No. 4663(E) dated 25.10.2023)

[Sodium Chloride 0.9% in 500ml= Each 100ml contains 900mg of Sodium chloride in 500ml pack i.e. 4500mg of Sodium Chloride in 500ml]

Derived retail price of Sodium Chloride of 2630mg in 500ml pack (i.e. 526mg/100ml) as on January, 2024 after applying the formula of Pronab Sen Committee:

$$= [87.94[1+0.70\{(2630-4500)/4500\}]]$$

= Rs. 62.36 per pack of 500ml (excluding GST)

Note-2: Retail price of Sodium gluconate 502mg as per the formula recommended in the Pronab Sen Committee Report

Since no reference data is available for calculating the Retail price of Sodium gluconate 502mg, the same has been calculated by considering the powder form of Sodium pico sulphate 1000mg, based on the data available in Pharmatrac database.

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

where, P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Calculated Retail price of Sodium picosulphate 1gm or 1000mg powder as per para 5 of DPCO from Pharmatrac Data for January, 2024 = Rs. 0.75

Derived retail price of Sodium gluconate 502mg in 100ml or 2510mg for a pack of 500ml
 $= 0.75 [1+0.7\{(2510-1000)/1000\}]$

=Rs. 1.54 per pack of 500ml

Note-3: Retail price of Sodium acetate trihydrate IP 368mg as per the formula recommended in the Pronab Sen Committee Report

Since no reference data is available for calculating the Retail price of Sodium acetate trihydrate 368mg, the same has been calculated by considering the powder form of Sodium pico sulphate 1000mg, based on the data available in Pharmatrac database.

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

where, P(s) =Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Calculated Retail price of Sodium picosulphate 1gm or 1000mg powder as per para 5 of DPCO from Pharmatrac Data for January, 2024 = Rs. 0.75

Derived retail price of Sodium acetate trihydrate 368mg in 100ml or 1840mg for a pack of 500ml $= 0.75 [1+0.7\{(1840-1000)/1000\}]$

=Rs. 1.19 per pack of 500ml

Note 4: Retail price of Potassium Chloride 37mg as per the formula recommended in the Pronab Sen Committee Report

Ceiling Price of Potassium Chloride injection 150mg/ml (as applicable for month ending before 6 months of receipt of complete application) = Rs. 2.40 per ML (S.O. 4663(E) dated 25.10.2023) i.e. Price for 150mg API of potassium chloride = Rs. 2.40

Strength of Potassium chloride in the applied formulation = 37mg in 100ml or 185mg in 500ml pack size.

Derived Price of Potassium Chloride IP 185mg (For pack size of 500ml) as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

Where: P(s) =Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

$= 2.40[1+0.70\{(185-150)/150\}] = \text{Rs. } 2.79$ per pack of 500ml

Note 5: Retail price of Magnesium Chloride 30mg as per the formula recommended in the Pronab Sen Committee Report

Ceiling price of Magnesium Sulphate Injection 500mg/ml (as applicable for month ending before 6 months of receipt of complete application) = Rs. 4.87 per ML.

500mg of Magnesium sulphate contains 49.3mg of elemental magnesium (since, One gram of magnesium sulfate salt = 98.6 mg of elemental magnesium)

Strength of Magnesium chloride in applied formulation is 30mg in 100ml OR 150mg in 500ml, which is equal to 18mg of Elemental Magnesium in 500ml (since, Magnesium chloride contains 12% elemental magnesium)

Derived Price of Magnesium Chloride IP 3.6 mg in 100ml (For pack size of 500ml= 18mg) as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

Where: P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Derived Price of Magnesium Chloride IP 18 mg in 500ml = $4.87[1+0.70\{(18-49.3)/49.3\}]$
= Rs. 2.71 per Pack of 500ml

Note-6: Retail price of Glucose 5gm as per the formula recommended in the Pronab Sen Committee Report

Calculated Retail price of Glucose 1gm powder as per para 5 of DPCO from Pharmatrac Data for January, 2024 = Rs. 0.63

Derived retail price as per recommendation of Pronab Sen committee:

$$P(s) = P^*[1+a.\{(s-s^*)/s^*\}]$$

where, P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a= 0.8 for tablet / capsule and 0.7 for injectables.

Derived retail price of Glucose 5000mg or 5gm in 100ml or 25gm for a pack of 500ml = $0.63 [1+0.7\{(25-1)/1\}]$

=Rs. 11.21 per 500ml pack

The meeting ended with a vote of thanks to all.

Rashmi
17/12/2024
(Rashmi Tahiliani)
Director (Pricing)

Copy to:
All members of the Committee.

Computation of Retail Price based on Mar 2024 Data under Para 5 of DPCO, 2013

Retail price of Paracetamol IP 325 mg Tablet	Number of Companies consisting of Market Share of 1% & Above					2
	Sum of MAT value considered for price calculation (in Lakhs)					242.06
	Sum of PTR per unit considered for price calculation					3.65
	Number of Packs considered					2
	Average PTR					1.83
	Add : 16% Retailer Margin					0.29
	Retail Price (without local taxes)					2.12
% Reduction with compared to Highest Price						5.67%

Minimum Price (Rs.)			1.71
Maximum Price (Rs.)			1.94
Average of all considered (Rs.)			1.83
Retail Price (Rs.)			2.12

[illegible]

Computation of Retail Price based on Mar 2024 Data under Para 5 of DPCO, 2013

Retail price of Polmacoxib IP 2 mg Tablet		Number of Companies consisting of Market Share of 1% & Above							3
		Sum of MAT value considered for price calculation (in Lakhs)							297.27
		Sum of PTR per unit considered for price calculation							35.07
		Number of Packs considered							3
		Average PTR							11.69
		Add : 16% Retailer Margin							1.87
		Retail Price (without local taxes)							13.56
		% Reduction with compared to Highest Price							4.26%

Minimum Price (Rs.)			11.43
Maximum Price (Rs.)			12.21
Average of all considered (Rs.)			11.69
Retail Price (Rs.)			13.56

[illegible]

Computation of Retail Price based on April 2024 Data under Para 5 of DPCO, 2013

Retail price of Paracetamol IP 325 mg Tablet	Number of Companies consisting of Market Share of 1% & Above					2
	Sum of MAT value considered for price calculation (in Lakhs)					241.34
	Sum of PTR per unit considered for price calculation					3.65
	Number of Packs considered					2
	Average PTR					1.83
	Add : 16% Retailer Margin					0.29
	Retail Price (without local taxes)					2.12
% Reduction with compared to Highest Price						5.67%

Minimum Price (Rs.)			1.71
Maximum Price (Rs.)			1.94
Average of all considered (Rs.)			1.83
Retail Price (Rs.)			2.12

[illegible]

Computation of Retail Price based on April 2024 Data under Para 5 of DPCO, 2013

Retail price of Polmacoxib IP 2 mg Tablet	Number of Companies consisting of Market Share of 1% & Above					3
	Sum of MAT value considered for price calculation (in Lakhs)					352.11
	Sum of PTR per unit considered for price calculation					35.07
	Number of Packs considered					3
	Average PTR					11.69
	Add : 16% Retailer Margin					1.87
	Retail Price (without local taxes)					13.56
	% Reduction with compared to Highest Price					4.26%

Minimum Price (Rs.)			11.43
Maximum Price (Rs.)			12.21
Average of all considered (Rs.)			11.69
Retail Price (Rs.)			13.56

[illegible]

Computation of Retail Price based on January, 2024 Data under Para 5 of DPCO, 2013

Sodium pico sulphate 100GM powder	Number of Companies cosisting of Market Share of 1% & Above							0
	Sum of MAT value considered for price calculation (in Lakhs)							0.10
	Sum of PTR per unit considered for price calculation							0.65
	Number of Packs considered							1
	Average PTR							0.65
	Add : 16% Retailer Margin							0.10
	Retail Price (without local taxes)							0.75
	% Reduction with compared to Highest Price							0.00%

Minimum Price (Rs.)			0.65
Maximum Price (Rs.)			0.65
Average of all considered (Rs.)			0.65
Retail Price (Rs.)			0.75

[illegible]

Computation of Retail Price based on January, 2024 Data under Para 5 of DPCO, 2013

Computation of Retail Price based on January, 2024 Data under Para 3 of DPCO, 2013									
Glucose 75GM powder	Number of Companies cosisting of Market Share of 1% & Above								0
	Sum of MAT value considered for price calculation (in Lakhs)								255.17
	Sum of PTR per unit considered for price calculation								0.54
	Number of Packs considered								1
	Average PTR								0.54
	Add : 16% Retailer Margin								0.09
	Retail Price (without local taxes)								0.63
	% Reduction with compared to Highest Price								0.00%

Minimum Price (Rs.)		0.54
Maximum Price (Rs.)		0.54
Average of all considered (Rs.)		0.54
Retail Price (Rs.)		0.63

[illegible]