(Published in Part II, Section 3, Sub Section (ii) of the Gazette of India Extraordinary)

Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
(National Pharmaceuticals Pricing Authority)

New Delhi, the 15th September, 2023

ORDER

S.O. 4077(E) – Whereas, **(i) Piperacillin 2gm + Tazobactum 250mg and (ii) Piperacillin 4gm + Tazobactum 500 mg** are scheduled formulation under Schedule-I of DPCO 2013 and its ceiling price is fixed.

And whereas, **M/s Gufic Biosciences Limited** have applied for separate ceiling price of **(i) Tazofic Injection 2.25 gm containing Piperacillin 2gm + Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm + Tazobactum 500 mg** having special features of dual chamber bags stating that it is designed to allow the separation of different solutions that require admixing just before administration helping to reduce the administration time, assurance of right dosages, avoidance of hospital contamination, provides high stability & convenience etc.

And whereas, the Multidisciplinary Committee of Experts in its 45th meeting & 52nd meeting dated 13.09.2022 &11.07.2023 respectively observed that **(i) Tazofic Injection 2.25 gm containing Piperacillin 2gm + Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm + Tazobactum 500 mg** are scheduled formulation. The Committee further observed that packages in **(i) Tazofic Injection 2.25 gm containing Piperacillin 2gm + Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm + Tazobactum 500 mg** of M/s Gufic Biosciences Limited have special feature of dual chamber bag helping in reduction of administration time, reconstitution of the drug with distilled water in accurate dose with reduction in the possibility of contamination.

And whereas, the Multidisciplinary Committee of Experts recommended that an increase of 15% over and above the ceiling price of **Tazofic Injection 2.25 gm and Tazofic Injection 4.5 gm** be allowed to M/s Gufic Biosciences Limitedfor the formulation**(i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactum 500 mg**on account of special packaging in dual chamber bag.

And whereas, NPPA in its 116thAuthority meeting dated 06.09.2023 decided to accept the recommendation of the Multidisciplinary Committee of Experts.

Therefore, in exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 5249(E) dated 11th November, 2022 issued by the Government of India in the Ministry of Chemicals and Fertilizers in so far as it relates to **(i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactum 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactum 500 mg** having special feature of dual chamber bag helping in reduction of administration time, reconstitution of the drug with distilled water in accurate dose with reduction in the possibility of contamination., manufactured by the manufacturers specified in Table 'B', the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table 'A' herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and

unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table 'A'

Sl. No.	Name of the Scheduled Formulation	Dosage form and Strength	Unit	Ceiling Price excluding GST (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Piperacillin (A) + Tazobactam (B)	Powder for Injection 2 g (A) + 250 mg(B)	Per Dual chamber bag	220.26
2	Piperacillin (A) + Tazobactam (B)	Powder for Injection 4 g (A) + 500 mg(B)	Per Dual chamber bag	459.28

Table 'B'

Sl. No.	Name of Manufacturer
(1)	(2)
1	M/s Gufic Biosciences Limited

Note:

(a) The ceiling price specified in column (5) of Table A is only applicable to the manufacturer mentioned in Table B. The manufacturer specified in Table B, selling the branded or generic or both the versions of scheduled formulations with dosage form and strength specified in column (2) and (3) of Table A respectively, at a price higher than the ceiling price (plus Goods and Services Tax as applicable) so fixed and notified by the Government, shall revise their prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus local taxes as applicable, if any.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(c) The manufacturer shall issue a price list in Form-V in compliance from date of this notification as per paragraph 24 of the DPCO, 2013.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) Any other manufacturer claiming separate ceiling price having special feature of dual chamber bag helping in reduction of administration time, reconstitution of the drug with distilled water in accurate dose with reduction in the possibility of contamination. shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.

(g) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above Table A, launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(h) The manufacturer(s) of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of the production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(i) The manufacturer(s) not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Price Control) Order, 2013 read with Essential Commodities Act, 1955.

(j) Consequent to the issue of ceiling prices of such formulations for specified in column (2) of the above Table A in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/248/116/2023/F F. No. 8(116)/2023/D.P./NPPA-Div.II

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