

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

New Delhi, the 1st July, 2021

ORDER

S. O. 2653(E):- Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 32 of the said order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas an application received from M/s Torrent Pharmaceutical Limited, for exemption from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative) which was duly approved by the Office of Central Drugs Standard Control Organisation (India) as 'new drug' under the Drugs and Cosmetics Act, 1940 and Rules thereunder. Further, the Patent Office, Government of India has granted Patent to M/s Torrent Pharmaceutical Limited for an invention entitled 'Pharmaceutical invention of Tapentadol' for the term of 20 years from 19th July 2012 in accordance with the provisions of the Patents Act, 1970 (Patent No. 355890 and Date of Grant: 15.01.2021).

4. And whereas the NPPA at its 89th meeting dated 28.06.2021 noted that M/s Torrent Pharmaceutical Limited meets the requirement of Para 32(i) of DPCO 2013 and decided that exemption may be granted to M/s Torrent Pharmaceutical Limited under Para 32(i) of DPCO, 2013 for their formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative).

5. Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, M/s Torrent Pharmaceuticals Limited is exempted from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative) for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. Further, the period of five years is co-terminus with the duration of Indian Patent.

6. M/s Torrent Pharmaceutical Ltd shall inform NPPA, the date of commercial marketing of the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative) in the country and the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above said formulation by issuing a price list in Form V under DPCO, 2013.

7. M/s Torrent Pharmaceutical Ltd shall also seek retail price approval for the formulation "Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative), if applicable, three month before the expiry of the exemption granted under Para 32(i) of DPCO 2013

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