November 2, 2026

NPPA

Midazolam nasal spray exempted from price control for 5 years

NPPA order S.O. 6000(E) of November 2, 2026 exempts Biodeal Pharmaceuticals' Midazolam Nasal Spray 1.25 mg from the DPCO, 2013 for five years from May 5, 2025.

THE NATIONAL Pharmaceutical Pricing Authority (NPPA), under the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers, issued Order S.O. 6000(E) dated November 2, 2026, published the same day in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 5768. It uses the power in paragraph 32 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), delegated to NPPA by S.O. 1394(E) of May 30, 2013 under sections 3 and 5 of the Essential Commodities Act, 1955.

KEY FACTS

AUTHORITY

NPPA

PUBLISHED

November 2, 2026

ISSUED BY

National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers

DOCUMENT

Order S.O. 6000(E), under paragraph 32 of the Drugs (Prices Control) Order, 2013



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M/s. Biodeal Pharmaceuticals Limited applied for exemption under paragraph 32(iii) for "Midazolam Nasal Spray 1.25 mg", which the Central Drugs Standard Control Organization (CDSCO) approved as a new drug under the Drugs and Cosmetics Act, 1940 and its rules. At its 153rd meeting, held on October 29, 2026, NPPA considered the recommendations of the Multidisciplinary Committee (MDC) and approved the exemption.

The order exempts the company from the provisions of the DPCO, 2013 for this formulation for five years with effect from May 5, 2025, the date CDSCO granted marketing approval. The company must tell NPPA the Price to Retailer (PTR) and Maximum Retail Price (MRP) it fixes, by issuing a price list in Form V. Three months before the exemption ends, it must follow the ceiling price or seek retail price approval for the formulation, as applicable.

The order does not state the PTR or MRP, the date by which the Form V price list is due, or why the formulation qualifies under paragraph 32(iii). It covers only this formulation of this company. It is signed by Bhiva Ram Yadav, Assistant Director, under PN/285/153/2026/F/F. No. 8(153)/2026/D.P./NPPA-Div.-II.

Issued by	National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers
Document	Order S.O. 6000(E), under paragraph 32 of the Drugs (Prices Control) Order, 2013
Dated	November 2, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 5768, November 2, 2026
Applies to	M/s. Biodeal Pharmaceuticals Limited, for "Midazolam Nasal Spray 1.25 mg"
Exemption	From the provisions of the DPCO, 2013, under paragraph 32(iii)

Period	Five years with effect from May 5, 2025, the date of CDSCO's marketing approval
Decided at	NPPA's 153rd meeting, October 29, 2026, on the Multidisciplinary Committee's recommendations
Price list	PTR and MRP to NPPA in Form V
Before the exemption ends	Follow the ceiling price or seek retail price approval, as applicable, three months before expiry
Signed by	Bhiva Ram Yadav, Assistant Director

The order (PDF, 619 KB)

Source: Gazette of India, CG-DL-E-03112026-277621.

Checked against the official copy on November 7, 2026.

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