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Biodeal Pharma receives New Drug Permission from CDSCO for indigenously developed Midazolam Nasal Spray

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Marks R&D milestone with India's first approved Midazolam Nasal Spray



Biodeal Pharmaceuticals Limited, a Contract Development and Manufacturing Organisation (CDMO), has announced a significant regulatory milestone for its indigenously developed Midazolam Nasal Spray 1.25% w/v, which has received New Drug Permission from India's Central Drugs Standard Control Organisation (CDSCO). This is the first approval of this product and strength in India.

Further recognising its innovation, the National Pharmaceutical Pricing Authority’s (NPPA) Multidisciplinary Committee of Experts has recommended a five-year exemption under Para 32(iii) of the Drug Price Control Order (DPCO), 2013, recognising the product as a genuinely new, indigenously developed drug delivery system rather than a reformulation of an existing medicine.

Midazolam is an established medicine used in the rapid management of emergency situations, primarily acute seizures. Traditionally administered through injection, its nasal delivery offers a new well established delivery system innovated in US, through the nasal route, particularly in emergency and out-of-hospital settings where intravenous access may not be readily available.

The product has been developed primarily at Biodeal’s Department of Scientific and Industrial Research (DSIR)-accredited R&D facility. The development involved formulation science, device engineering, dosing precision and manufacturing expertise, reflecting the company's growing focus on differentiated pharmaceutical products and specialised drug delivery.