PRESS RELEASE

Piramal Pharma Solutions Achieves Regulatory Compliance for Nitrosamine Impurities

- *Piramal Pharma Solutions implemented a robust action plan to address evolving regulatory requirements pertaining to nitrosamine impurities.*
- *Through comprehensive risk assessments, confirmatory testing, and control strategies, the Company is ensuring the safety and compliance of its drug substances and drug products.*
- *By investing in site improvements and capability enhancements, the Company will continue to meet international regulatory guidelines for nitrosamines.*

Mumbai, India | November 26, 2025: Piramal Pharma Solutions, a leading global Contract Development and Manufacturing Organization (CDMO) and part of Piramal Pharma Ltd. (NSE: PPLPHARMA | BSE: 543635), today announced the successful completion of its journey to compliance with global requirements for nitrosamine impurities in pharmaceuticals.

Nitrosamines are unintended carcinogenic byproducts that can be found in certain medications. International guidelines on nitrosamine drug substance-related impurities (NDSRIs) have evolved significantly over the last few years, requiring pharmaceutical companies to adapt their operations to maintain compliance. In response, Piramal Pharma Solutions has implemented a robust, multi-step action plan to ensure regulatory alignment with the latest NDSRI guidelines, and more importantly, patient safety.

The first step of this proactive approach involved the development of a cross-functional core team comprised of subject matter experts from Regulatory Affairs, Central Quality, R&D, and Manufacturing. These experts offered specialized insights from their unique perspective, interpreted regulatory guidance as it was published, and ensured every operation across our organization remains compliant with international NDSRI guidelines.

This team played a pivotal role in the publication and continual update of the Position Paper, a centralized guidance document aligned with the latest regulatory expectations. By clearly defining roles and responsibilities, the Position Paper enabled site teams to adapt to the challenges and changes associated with the new requirements.

A critical component of the Company's journey to nitrosamine compliance was prioritizing risk assessments for all relevant drug substances and drug products to analyze their level of safety and regulatory impact. All identified products received confirmatory testing, with control strategies and administrative controls implemented as needed. Currently, all existing Piramal Pharma Limited commercial products comply with global regulatory requirements. Some customer products are still pending approval, and new batches will only be executed following regulatory alignment.

The action plan also involved the development of in-house testing capabilities at key facilities, alongside the qualification of external laboratories to support additional testing needs. This included investments into new state-of-the-art equipment and capabilities at the Ahmedabad and Digwal pharmaceutical development sites to expedite testing and compliance processes and mitigate potential drug shortage issues. These enhancements also address industry-wide challenges posed by impurity standards and synthesis difficulties, enabling Piramal to synthesize and qualify impurities in-house, minimize impurity formation, and conduct additional screening studies to confirm product safety.

"At Piramal Pharma Solutions, patient well-being is our top priority. We are proud to have achieved regulatory compliance for nitrosamine impurities, which reflects our unwavering commitment to patient safety and operational excellence, while also solidifying our position as a trusted partner in the industry," said **Rashida Najmi, Chief Quality Officer, Piramal Pharma Limited**. "With our proactive approach and enhanced capabilities, we are well-equipped to adapt to evolving global NDSRI standards, ensuring the highest safety and quality standards for our products."

As international guidelines surrounding nitrosamines evolve, Piramal Pharma Solutions remains committed to patient safety, regulatory compliance, and operational excellence. The Company will continue to support partners as they navigate the complex landscape of nitrosamine control, prioritizing transparent communication and continuous improvement to maintain the highest standards of pharmaceutical quality and patient safety.

About Piramal Pharma Solutions

Piramal Pharma Solutions (PPS) is a Contract Development and Manufacturing Organization (CDMO) offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our customers through a globally integrated network of facilities in North America, Europe, and Asia. This enables us to offer a comprehensive range of services including drug discovery solutions, process and pharmaceutical development services, clinical trial supplies, commercial supply of APIs, and finished dosage forms. We also offer specialized services such as the development and manufacture of highly potent APIs, antibody-drug conjugations, sterile fill/finish, peptide products and services, and potent solid oral drug products. PPS also offers development and manufacturing services for biologics including vaccines and gene therapies, made possible through Piramal Pharma Limited's associate company, Yapan Bio Private Limited.

For more information visit: Piramal Pharma Solutions | LinkedIn| Facebook | X

About Piramal Pharma Limited

Piramal Pharma Limited (PPL, NSE: PPLPHARMA I BSE: 543635), offers a portfolio of differentiated products and services through its 17* global development and manufacturing facilities and a global distribution network in over 100 countries. PPL includes Piramal Pharma Solutions (PPS), an integrated contract development and manufacturing organization; Piramal Critical Care (PCC), a complex hospital generics business; and the Piramal Consumer Healthcare business, selling over-the-counter consumer and wellness products. In addition, one of PPL's associate companies, Abbvie Therapeutics India Private Limited, a joint venture between Abbvie and PPL, has emerged as one of the market leaders in the ophthalmology therapy area in the Indian pharma market. Further, PPL has a strategic minority investment in Yapan Bio Private Limited, that operates in the biologics / bio-therapeutics and vaccine segments.

For more information, visit: Piramal Pharma | LinkedIn

* Includes one facility via PPL's minority investment in Yapan Bio.

For Investor Queries:
Gagan Borana
Investor Relations & Enterprise Risk Management
gagan.borana@piramal.com

For Media Queries:
Madiha Vahid
Lead – Branding & Communications
madiha.vahid@piramal.com