

# **PRESS RELEASE**

# Piramal Pharma Solutions Expands API Capabilities at Digwal; Applies Operational Excellence Tools to Release Capacity

- Site has a capital investment program of ~\$30 million spent or committed over the last three years to expand capabilities and improve operational efficiencies
- Increased focus on services segment including development and on-patent commercial projects, while continuing to grow the generics portfolio
- Major emphasis on sustainability via improvements in solvent recovery, reduced water consumption, and process chemistry

Mumbai, India | June 14, 2022: Piramal Pharma Limited's Pharma Solutions business, a leading Contract Development and Manufacturing Organization (CDMO), today announced that the company's site in Digwal in the state of Telangana, India, has implemented various tools to unlock Active Pharmaceutical Ingredient (API) manufacturing capacity and support client needs in drug development and on-patent projects.

Since 2019, Piramal Pharma Solutions (PPS) has made or committed more than \$30 million in capital investments, both in the infrastructure and the operational culture at the Digwal site, to improve performance, gain efficiencies, and increase capacity to meet market demands. A driving force of this program is the company's emphasis on Operational Excellence (OE) as part of the global corporate culture. By applying specific OE tools such as Theory of Constraint, Value Stream Mapping, Optimization of Unit Operations, and Line Balancing, more than 20% of the site's capacity has been released to date. Additional capacity will be released in the coming months as the OE tools generate further benefits. These initiatives will further help PPS cater to the immediate requirements of global customers. Further, to reduce manual interventions, mechanization advancements are underway including investments in Powder Transfer Systems.

On the documentation side, the site is moving away from paper records to Electronic Batch Records (eBMR).

Previously, Digwal embarked on a journey to extend its offerings to include development services for late-phase clinical requirements, clients pursuing registration, and site transfers to support the commercial launch. The site enhanced its facilities, talent, and processes to support phase-appropriate customer requirements. Now, Digwal's R&D capabilities are being further strengthened, with approximately 20 new fume hoods coming online to support services projects. As a result, the site has recently partnered with clients on more than a dozen programs, including several which have been commercially launched and others that are under registration with the regulator. As part of PPS's strategy to provide simplicity and speed to customers through integrated projects which involve two or more sites, integrated project management processes and tools were developed. These initiatives have resulted in a more than 7-fold increase in order book from integrated projects for Digwal over the last three fiscal years.

As part of the company's sustainability efforts, the Digwal site is equipped with a 'Zero Liquid Discharge' facility to ensure all liquid waste gets adequately treated in-house and recycled back to utilities. The solvent recovery infrastructure has also been upgraded, resulting in increased distillation efficiency and a reduction in solvent consumption. In addition, close monitoring and improved governance have helped in reducing the overall freshwater consumption. PPS is also investigating opportunities to deploy green chemistries for some large volume products.

Based on the company's continued focus on Environmental, Health & Safety (EHS), the site was able to secure Environmental Clearance (EC) for the multi-fold expansion by the concerned authorities, covering the site for the growth envisaged in the next 7-10 years.

In addition to the increased reactor capacity, the Digwal site will benefit from infrastructure upgrades that include a renovated administration block, a new canteen facility, Quality Control lab revamp, and more. The consolidation and creation of a centralized new warehouse for the

storage of finished goods that features a warehouse management system (WMS) are currently underway.



Peter DeYoung, Chief Executive Officer, Piramal Pharma Solutions said, "We are now seeing the fruits of our labor in applying Operational Excellence practices at Digwal. Coupled with the capital investment we are making, our API capabilities at the site are moving to the next level. Digwal can now take on more complex and larger-scale projects than it could in the past. It's another example of how we continue to invest and grow to serve market demands and work

with our clients to reduce the burden of disease on patients."

The Digwal site covers more than 100 acres and employs approximately 825 FTEs. In addition to producing APIs, Digwal provides analytical services and offers anaesthetic drug product (bottling) services. The site has undergone more than twenty successful inspections by a host of regulatory agencies including FDA (US), MHRA (UK), PMDA (Japan) and ANVISA (Brazil) and has been successfully audited by numerous global customers.

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Intermediate Reaction Area, Digwal H Block



Pharma Area, Digwal H Block



Agitated Nutsche Filter Dryer (ANFD) in Pharma Area, Digwal H Block



Micronizer in Powder Processing Area, Digwal L Block

## **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 & 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 & services, and potent solid oral drug product. PPS also offers development and manufacturing services for biologics including vaccines, gene therapies, and monoclonal antibodies, made possible through Piramal Pharma Limited's investment in Yapan Bio Private Limited. Our track record as a trusted service provider with experience across varied technologies makes us a partner of choice for innovator and generic companies worldwide.

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#### **About Piramal Pharma Ltd.**

Piramal Pharma Limited (PPL) offers a portfolio of differentiated products and services through end-to-end manufacturing capabilities across 15 global facilities and a global distribution network of 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 India Consumer Healthcare business, selling over-the counter products. PPS offers end-to-end development and manufacturing solutions through a globally integrated network of facilities across the drug life cycle to innovator and generic companies. PCC's complex hospital product portfolio includes inhalation anaesthetics, intrathecal therapies for spasticity and pain management, injectable pain and anaesthetics, injectable anti-infectives, and other therapies. The Indian Consumer Healthcare business is among the leading players in India in the self-care space, with established brands in the Indian consumer healthcare market. In addition, PPL has a joint venture with Allergan, a leader in ophthalmology in the Indian formulations market. In October 2020, the company received growth equity investment from the Carlyle Group.

For more information visit: www.piramal.com | Facebook | Twitter | LinkedIn

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