



Trailblazing Cutting-edge Pharmaceutical Research



Context

Our sector is characterized by rapidly evolving trends and advancements, highlighted by the recent pandemic and the impact of climate change on health risks. We recognize the need to adapt swiftly to these changes.

For four decades, our commitment to excellence in research and development has defined us as a leading pharmaceutical manufacturer. Moving forward, we are dedicated to integrating sustainability into our R&D strategy.

India is the third-largest pharmaceutical industry globally, with a market size of around \$ 50 billion, contributing about 3.3% of the country's foreign direct investment. To capitalize on this potential, the Government of India has launched the National Policy and Scheme on Research, Development, and Innovation in the Pharma-Med Tech Sector, aiming to improve the quality, accessibility, and affordability of medicines. This initiative aligns with Granules' mission and seeks to position India as a leading hub for advanced pharmaceutical research through industry-academia partnerships.

Approach

A few months before this policy announcement, Granules established dedicated, flagship R&D centers across locations to conduct industry-leading research underlining our focus, commitment, and dedication towards continuous innovation:

- We have an integrated product development facility at Genome Valley for API and formulation R&D, with a capacity of around 170 staff, to fast-track our product development through seamless coordination and shared analytical resources

- Center of Excellence (CoE) for expanding our research endeavors on Controlled Substances APIs and KSM development at Pragathi Nagar
- Bio-Lab at Pragathi Nagar for fermentation, biotransformation, and enzyme-led projects
- R&D Center in Pune for identifying new technologies for product development and for KSM & backward integration

Apart from our in-house research centers, we have partnered with the National Institute for Pharmaceutical Education and Research to set up a Centre for Innovative and Sustainable Pharmaceutical Research. Granules prioritizes investment in R&D, enhancing our capabilities, improving portfolio quality, and increasing regulatory submissions despite recent developments.

We received – ANDA approvals and – dossiers during the year. Every one of our plants holds certifications from top drug and pharmaceutical certification authorities across the world (including HALAL).

Sustainability at the Forefront of R&D-EcoScale

Sustainability integration is critical to our R&D strategy. Our under-development greenfield facility and Granules CZRO are envisaged as supreme sustainability in high-quality research and innovation in the pharmaceutical industry.

In our R&D activities, we apply Atom Economy, Atom Efficiency, and the E-factor principles, using the Eco-Scale Concept to evaluate process efficiency. We also utilize eco-friendly enzymes and biotransformation techniques.





An E-factor score helps analyze the hydrogen, nitrogen, and carbon content of production molecules, guiding us to the most efficient processes. Molecules with low E-factor scores are rejected, regardless of financial potential, as we prioritize sustainability over cost efficiency.

Green Score in R&D Development

Implementation of Green card and Eco scale initiatives from the early stages of development.



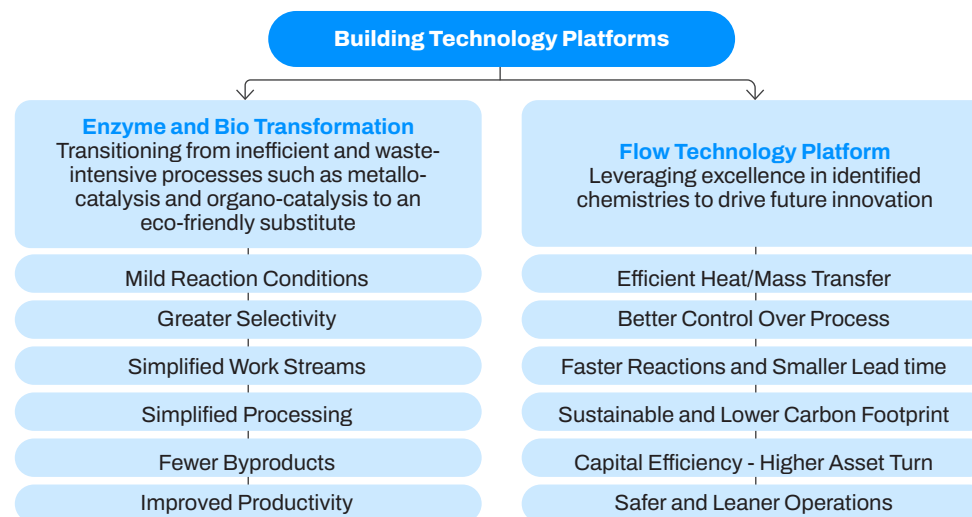
We ensure product sustainability through a strict inventory control policy. All expired products are disposed of before scaling up manufacturing, resulting in minimal losses due to effective collaboration between our R&D and production teams. Additionally, Granules India has not faced any product recalls in the past two years.

At Granules, we prioritize the safety and quality of our products throughout their lifecycle. During R&D, we conduct thorough evaluations of active pharmaceutical ingredients (APIs) and formulations through toxicological studies and dosage assessments to ensure compliance with high safety standards. In manufacturing, we implement strict quality control protocols following Good Manufacturing Practices (GMP), focusing on contamination monitoring, accurate labeling, and formulation consistency to safeguard patient health.

Our commitment to safety extends beyond production. We carefully evaluate packaging materials and methods to prevent contamination, degradation, and tampering, including child-resistant packaging and clear usage instructions. Our secure distribution practices ensure products are stored and transported under controlled conditions. We maintain ongoing pharmacovigilance to monitor safety and efficacy in the market, addressing any adverse events promptly. Our comprehensive quality systems help prevent issues, resolve customer complaints quickly, and ensure compliance with health and safety regulations, reinforcing our dedication to customer trust and satisfaction.

No incidents of non-compliance with health and safety regulations and voluntary codes were recorded during the reporting period.

Our current R&D focus is on building technology platforms that improve the efficiency of our manufacturing processes:



Collaborative Partnerships for Innovation and R&D

Granules is a founding member and anchor partner of the World Economic Forum's Centre for the Fourth Industrial Revolution (C4IR) Telangana, India's only centre focused on healthcare and life sciences. This partnership aims to leverage technology for global improvements, positioning C4IR Telangana as a catalyst for transformative change and responsible growth. Granules promotes sustainability in healthcare innovation, reducing the carbon footprint of medical procedures and pharmaceutical manufacturing while supporting climate change initiatives.

Granules prioritizes skill development and policy advocacy, particularly for women in healthcare. Empowering women through specialized training enhances their participation, promoting

gender equity. C4IR Telangana aims to equip women with skills for diverse roles, boosting their contributions to growth and innovation. Granules is committed to advancing these initiatives for societal and environmental impact.

Outlook

In the coming years, we aim to support the Government of India's vision of making India a global hub for pharmaceutical research. Our goal is to advocate for policies promoting sustainable supply chains and eco-friendly molecules. Through our green science initiatives, we seek to drive ongoing innovation and education, ultimately establishing ourselves as a leading manufacturer of clean, green pharmaceutical products in India.