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Neuland Laboratories Unveils Dedicated Process Engineering Lab

Strengthens Quality by Design (QbD) Approach to Drug Substance Manufacturing

Hyderabad, India, July 20, 2017 – Neuland Laboratories Limited(NLL) (NSE: NEULANDLAB; BSE-Scrip Code:524558), a pharmaceutical manufacturer providing active pharmaceutical ingredients (APIs), complex intermediates and custom manufacturing solutions services to customers located in about 80 countries has brought online a fully operational dedicated Process Engineering Lab at its R&D Center. The new lab includes state-of-the-art instrumentation, systems and innovative devices to support operations and safety studies using a QbD approach.

"Our new Process Engineering Lab integrates the key attributes of QbD process understanding, process control, and continuous improvement with advanced equipment, Design of Experiments Software, and Design Space methodology, to optimize process design, operations, and productivity," says Saharsh Davuluri, Joint Managing Director at Neuland.

Neuland's new Process Engineering Lab includes a stirred, controlled HEL reaction calorimeter that measures the rate of heat release during reactions. Automated parallel HEL reactors enable a chemist to perform multiple experiments at temperatures ranging from -60 to 225°C. The lab's new Thermal Screening Unit (TSU) indicates the thermal stability of chemicals and safe processing temperatures. Ideal for risk analysis, the TSU uses only 0.5-5 g of sample.

"This important addition to our capabilities will better enable Neuland to develop cost-effective procedures and quality products, meet regulatory requirements, improve scale-up efficiency, and accelerate time to market," says Dr. Ravi Ponnaiah, President – Science & Technology.

A QbD approach includes three fundamental elements: 1) a clear understanding of the target product profile; 2) determination of critical quality attributes (CQAs) and 3) ensuring that processes and products remain within defined range limits.

Continual risk assessment of all aspects of a process, from the quality of the raw materials to the process parameters and their potential effects on CQAs enables continuous improvement of processes and products. A QbD program relies on applying this information to develop a design space and a process control strategy, continually monitoring the process to assess its capabilities, introducing changes to improve product quality, cost, and process efficiency.

About Neuland Laboratories Limited

Neuland Laboratories Limited, established in 1984, is headquartered in Hyderabad, India, with offices in the U.S. and Japan. Neuland produces quality APIs for customers across 80+ countries in more than 10 diverse therapeutic segments. Along with generic drug products, Neuland offers contract and custom manufacturing services for APIs and advanced intermediates. The company has a stellar track record of successful regulatory inspections from the U.S. Food and Drug Administration (FDA, inspected 12 times), PMDA-Japan, EDQM, EMA, KFDA, TGA, ANVISA Brazil and AFSSAPS (France), ISO9001, ISO14001, OHSAS18001 and ISO 27001. Current regulatory filings exceed 650 with 51 USDMFs, 19 CEPs and 5 JDMFs. Neuland has more than 523,000 L of reactor volume.

For more information, visit www.NeulandLabs.com.

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