Axxelent
Pharma Science Private Limited

Date:31.07.2024

Axxelent Receives its first US FDA Establishment Inspection Report (EIR)

Axxelent Pharma Science Private Limited ("Axxelent") is pleased to announce receipt of first EIR from US FDA for its oral solid dosage facility situated in Sri City SEZ, AP. US FDA inspected the facility from 17th -21st June 2024.

Commenting on the outcome of the inspection, Jitesh Devendra, Co-Founder and Chairman, said "We are very glad about the outcome of our first US FDA inspection for our oral solid dosage facility. We expect further inspections for our other dosage forms in the coming 12 months from US FDA as well as other Regulatory agencies. Our next step is to trigger our sterile facility with the qualification expected to complete by Q3 FY25. We have a pipeline of around 45 projects in various phases across multiple geographies and dosage forms"

About Axxelent

Axxelent Pharma Science Private Limited ("Axxelent") headquartered in Chennai is a speciality Pharma company offering various development and manufacturing capabilities in immediate and modified release oral dosage forms, oral liquids, semi-solids, injectables and ophthalmic.

Axxelent B2B business model is focused on CDMO, Partnership and Licensing for Regulated Markets like US, Canada, Europe, UK and Australia.

Axxelent Sri City manufacturing facility comprises of two manufacturing blocks.

Block 1 – Non-Sterile Facility with Oral Solid, Oral liquids and Semi-solids dosage forms
Block 2 - Sterile Facility for injectables and ophthalmic is currently under qualification.

Axxelent R&D is based out of IITM Research Park, Chennai. Axxelent R&D is recognised under DSIR and EoU certified.

For more information, please contact Mr. Devesh Jain at devesh@axxelent.com.

Axxelent Pharma Science Private Limited
'Axxelent House' No.3, Jagadeeswaran Street
T Nagar, Chennai - 600017. Tamil Nadu, India.
Tel: +91 44 61727900 / 901 / 902
info@axxelent.com www.axxelent.com
CIN No. U24110TN2019PTC131943