MANUFACTURING

# Reddy's gets EIR but inspection is still open

Dr Reddy's has received an establishment inspection report (EIR) from the US Food and Drug Administration (FDA) for its Indian finished-dose formulations manufacturing facility in Duvvada, Vishakhapatnam, following an audit in March. However, the agency has not closed the inspection, the firm has revealed in a filing to the Bombay Stock Exchange (BSE).

"In the cover letter to the EIR," Reddy's stated, "the FDA has explained that the inspection has not closed, and the site's status remains unchanged." The agency released the EIR "in order to be transparent about its regulatory process", the Indian firm observed. "We are planning to request a re-inspection in 2018 after further discussion on scheduling with the FDA," Reddy's noted.

In March, the FDA issued Reddy's oncology formulations plant with a 'Form 483' containing 13 observations following a re-inspection of the site (**Generics *bulletin***, 17 March 2017, page 3). At the time, the company said it was addressing the problems highlighted by the US agency, but disclosed no further details.

The Duvvada facility was one of three Indian sites – along with active pharmaceutical ingredient (API) plants in Miryalaguda and Srikakulam – cited by the FDA warning letter issued in late 2015 (**Generics *bulletin***, 20 November 2015, page 3). The Duvvada deficiencies noted by the US regulator included failing to investigate properly injectable batch failures, failing to follow written procedures for avoiding microbiological contamination, and failing to establish adequate production and process controls.

Reddy's was also hit with another setback earlier this year when German regulators identified six "major observations" of current good manufacturing practice (cGMP) deficiencies at the Duvvada site following an audit (**Generics *bulletin***, 15 September 2017, page 3). The firm noted however that the Bavarian regulatory authority, the *Regierung von Oberbayern*, had identified "no critical observations", and moreover underlined that products manufactured at the facility were not currently exported to the European Union (EU).

At the time, Reddy's responded that it would be submitting a corrective and preventive action plan (CAPA) to the inspection authorities, which had "cautioned that the facility will receive EU-GMP certification up to November 2018 only when the regulator approves the CAPA". The firm added that the regulator was due to review the Duvvada site again by this date.

BUSINESS STRATEGY

# Idifarma offers small high-potency batches

Spanish niche contract development and manufacturing organisation (CDMO) Idifarma is targeting clients seeking small batches of highly-potent compounds, following the installation of new equipment at its facility in Pamplona, Spain.

A Bosch capsule-filling machine, capable of producing 3,000 to 42,000 hard capsules per hour, that the firm installed earlier this year is now fully operational, adding to the firm's small-scale clinical and commercial capabilities (**Generics *bulletin***, 7 July 2017, page 4).

Business development director Manuel Leal told **Generics *bulletin*** that the company – which was founded in 2001, and currently employs around 120 people – developed oral-solid, liquid and injectable formulations for clients, with a particular focus on high-potency drugs in product categories including oncology, hormones, central nervous system and controlled substances, especially those that require a high degree of packaging customisation.

## In-house oral solid capacity

Idifarma could supply contract-manufacturing services for Oral-solid batches up to 60kg-70kg, Sánchez said, adding that the company could make coated and uncoated immediate- and modified-release tablets, as well as capsules. For other dosage forms, the company transfers technology to trusted third-party producers.

"We generate intellectual property for our clients as we develop processes," Leal explained. While around two-thirds of the firm's business was currently in traditional and niche generics, he revealed, Idifarma was also working on hybrid candidates and patent-circumvention opportunities that clients had identified as having commercial potential.

Around 45% of the €6.7 million (US$7.9 million) turnover that the Spanish CDMO is forecasting for 2017 – up from €5.3 million last year – is set to come from its domestic market, with up to another quarter from clients in Germany. Leal stressed that Idifarma's relatively small size enabled it to be flexible and independent, as well as to offer personal service.

Last year's investment from raw materials supplier Suanfarma – which took an undisclosed stake in Idifarma (**Generics *bulletin***, 23 September 2016, page 2) – had not only offered synergies in helping clients with active pharmaceutical ingredient (API) sourcing, Leal explained. It had also broadened the Spanish CDMO's presence beyond Europe, into the Americas, Asia, the middle East and North Africa.

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