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PTI | March 19, 2019 13:10 IST

TCG Lifesciences receives USFDA nod for Hyderabad plant
Kolkata, Mar 19 (PTI) TCG Lifesciences, a part of the The Chatterjee Group (TCG) which controls Haldia Petrochemicals Limited in West Bengal, has received the US FDA approval for its chemical development and manufacturing facility in Hyderabad.

TCG Lifesciences, Clinivent Research, a 100 per cent subsidiary of The Chatterjee Group, has passed successfully the pre-approval inspection of the manufacturing plant, a company statement said on Tuesday, adding that the site was found to be compliant with the principles and guidelines of Good Manufacturing Practices (GMP).

MD of TCG Lifesciences said "this marks another step



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Chatterjee Group receives USFDA approval for its Hyderabad based plant

DECCAN CHRONICLE Published: Mar 19, 2019, 11:12 am IST Updated: Mar 19, 2019, 11:12 am IST

The plant is equipped with multiple reactors totaling of a huge scale of production capacity.



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TCG Lifesciences' Hyd plant gets nod

USFDA gives approval to the chemical development facility

Y V PHANI RAJ
HYDERABAD

TCG Lifesciences, part of New York-based The Chatterjee Group, promoted by Dr Purnendu Chatterjee, has received the US Food and Drug Administration approval for its chemical development and manufacturing facility in Hyderabad. Supported by over 800 qualified scientists of TCG Lifesciences, Clinivent Research, the 100 percent subsidiary of the company, has passed a pre-approval inspection as a manufacturing plant, by the USFDA. The inspection confirmed the site to be compliant with the principles and guidelines of Good Manufacturing Practices (GMP).

The chemical development and manufacturing facility is located at Anantaram in Hyderabad and manufactures advanced intermediates and Regulatory Starting Materials (RSMs) and custom manufacturing of new chemical entities (NCEs). The plant is equipped with multiple reactors totaling of a huge scale of production capacity. Swapan Bhattacharya, managing director, TCG Lifesciences says, "This marks another important step for the TCG group in providing the US customers with innovative, high quality and intensive small molecule cGMP drug development synthesis services, covering IND enabling studies, clinical trials, and commercial production. At



REGULATED MARKETS: The approval will help in foraying into high growth generic bulk drugs and intermediates.

Getting USFDA approval within two years of its inception proves the commitment of the team

—SUBHO ROY, VP, TCG LIFESCIENCES

the same time, it marks our entry into the high growth generic APIs and intermediates domain for regulated markets. The key differentiators for TCGs are our ability to handle very complex synthesis challenges, deliver comprehensive CMC packages and implement high end analytical and regulatory quality systems."

A company spokesperson said, "The plant was built on

eight acres in 2017. The facility will focus on wider therapeutic categories through its range of bulk drugs and intermediates, except highly potent/toxic compounds. We will primarily look at export markets such as Europe, US and rest of the world. And the facility will be utilised for making new chemical entities, generic intermediates and bulk drugs besides new technology development."

"The pre-approval inspection was triggered by a DMF filing by one of our clients and subsequent ANDA filing" said Subho Roy, VP, TCG Lifesciences. "Getting USFDA approval within two years of its inception proves the commitment of the Clinivent team and the ability to meet the highest quality standards in the manufacturing of critical products," he added.



TCG Lifesciences gets FDA nod for Hyd plant

The chemical development, manufacturing facility is located at Anantaram

HANS BUSINESS


Hyderabad: TCG Lifesciences, part of New York-based The Chatterjee Group, promoted by Dr Purnendu Chatterjee, has on Monday announced that it has received the USFDA approval for its chemical development and manufacturing facility in Hyderabad.

The chemical development and manufacturing facility is located at Anantaram in Hyderabad and boasts of manufacturing advanced intermediates and Regulatory Starting Materials (RSMs) and custom manufacturing of New Chemical Entities (NCEs). The plant is equipped with multiple reactors totaling of a huge scale of production capacity.

Swapan Bhattacharya, Managing Director, TCG Lifesciences, says, "This marks another im-

portant step for the TCG group in providing the US customers with innovative, high quality and integrated small molecule cGMP drug development synthesis services, covering IND enabling studies, clinical trials, and commercial production. At the same time, it marks our entry into the high growth generic APIs and intermediates domain for regulated markets. The key differentiators for TCGs are our ability to handle every complex synthesis challenges, deliver comprehensive CMC packages and implement high end analytical and regulatory quality systems."

"The pre-approval inspection was triggered by a DMF filing by one of our clients and subsequent ANDA filing" mentioned Subho Roy, Vice President, TCG Lifesciences.

THE HANS INDIA Tue, 19 March 2019 

Hans India



టీసీజీ లైఫ్ సైన్సెస్ యూనిట్ కు యూఎస్ఎఫ్డీ అనుమతి


హైదరాబాద్, మార్చి 19: టీసీజీ లైఫ్ సైన్సెస్ హైదరాబాద్ ప్రొఫెషనల్ క్వాలిటీ సిస్టమ్స్ (ఎస్ఎఫ్డీ) అనుమతి పొందింది. యుఎస్ఎఫ్డీ అనుమతి పొందింది. టీసీజీ లైఫ్ సైన్సెస్ ఫలస్టర్ గ్రూప్ భాగం. హైదరాబాద్ కు సమీపంలో ఆంధ్ర

టీసీజీ లైఫ్ సైన్సెస్ కు యూఎస్ ఎఫ్ డీ అనుమతి హైదరాబాద్ బిజినెస్ బ్యూరో: కెమికల్, డ్రగ్ మ్యానుఫాక్చరీంగ్ కంపెనీ టీసీజీ లైఫ్ సైన్సెస్ కు చెందిన హైదరాబాద్ ప్రొఫెషనల్ క్వాలిటీ సిస్టమ్స్ (ఎస్ఎఫ్డీ) అనుమతి లభించింది. ఆనంతారంలో ఏడున్నర ఎకరాల్లో ఉన్న ఈ ఫ్యాక్ట్లో ఆధ్వర్యం వహిస్తున్న టీసీజీ లైఫ్ సైన్సెస్ యొక్క రెగ్యులేటరీ స్టాఫ్ మెటీరియల్స్ (ఆర్ఎస్ఎం), కస్టమ్ మాన్యుఫాక్చరీంగ్ ఆఫ్ న్యూ కెమికల్స్ ఎంటిటీస్ (ఎన్సీఈ) లను అభివృద్ధి చేస్తుంది టీసీజీ లైఫ్ సైన్సెస్ ఎండ్ స్వస్థ్ ఫలస్టర్ గ్రూప్ ఒక ప్రకటనలో తెలిపారు. క్షిణివెంట్ రీసెర్చ్ ప్రై.లి. వంద శాతం ఆనుబంధ కంపెనీ ఈ టీసీజీ లైఫ్ సైన్సెస్.

సాక్షి Tue, 19 March 2019 <https://epaper.sakshi.com>

Sakshi

టీసీజీ లైఫ్ సైన్సెస్: టీసీజీ లైఫ్ సైన్సెస్ కు చెందిన హైదరాబాద్ లోని రసాయన అభివృద్ధి తయారీ యూనిట్ కు యూఎస్ఎఫ్డీ అనుమతి లభించింది. టీసీజీ లైఫ్ సైన్సెస్ న్యూయార్క్ కు చెందిన ఫలస్టర్ గ్రూప్ భాగం.

ఆంధ్రజ్యోతి Tue, 19 March 2019 

Andhra Jyothi

టీసీజీ లైఫ్ సైన్సెస్ కు యూఎస్ఎఫ్డీ అనుమతి హైదరాబాద్ : న్యూయార్క్ ప్రధాన కార్యాలయం వసతున్న టీసీజీ లైఫ్ సైన్సెస్ ది చలన్ గ్రూపుకు చెందిన కంపెనీ. దీని ప్రయోగశాలలో డ్రగ్ ఫరండు చలన్ ఒక ప్రకటనలో హైదరాబాద్ లోని తమ రసాయన తయారీ కంపెనీ అమెరికా ఔషధ నియంత్రణ సంస్థ నుండి అనుమతి లభించినట్లు తెలిపారు. హైదరాబాద్ కు సమీపంలో ఉన్న ఆనంతారంలో తమ రసాయన తయారీ ఫ్యాక్ట్ ఉంది తెలిపారు. తమ ఫ్యాక్ట్ కు యూఎస్ఎఫ్డీ అనుమతి సందర్భంగా గ్రేడ్ లైఫ్ సైన్సెస్ ప్రకారం నిబంధనలకు లొబ్ద నాణ్యతల ఎలాంటి రాజీ లకుండా ఉత్పత్తులు తయారు చేస్తున్నట్లు తెలిపారు టీసీజీ లైఫ్ సైన్సెస్ ఎండ్ స్వస్థ్ ఫలస్టర్ ఒక ప్రకటనలో తెలిపారు.

ఆంధ్రప్రభ Tue, 19 March 2019 <https://epaper.prabhanews.com/c/> 

Andhra Prabha

వెలుగు Tue, 19 March 2019 <https://epaper.v6velugu.com/c/37739148>

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