

Doctor's Analytical Laboratories Pvt Ltd.,
B-49 , C/O Shruti Flexipack, 1st Floor, MIDC Road
TTC Industrial Area, Off Thane-Belapur Road Airoli,
Navi Mumbai, Maharashtra, 400708 India

Dear Mr. Ashay S. Mehta, Director:

Attached to this email is a copy of the establishment inspection report (EIR) for the inspection completed at your establishment located at B - 49 Ttc Industrial Area, 1st Floor; M I D C Road, Navi Mumbai, Maharashtra conducted on 06/29/2022 by or on behalf of the U.S. Food and Drug Administration (FDA). The Agency concluded that the inspection is "closed" under 21 C.F.R.20.64(d)(3), and therefore is releasing a copy of the EIR to you.

The copy provided to you is the narrative portion of the report. It may contain redactions in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. You may request additional information under FOIA. For more information on how to make a FOIA request [click here](#)

The attached EIR is password protected to secure your firm's proprietary information and/or trade secrets. The password needed to open and/or print the document will be forwarded to you in a separate e-mail. You may need to check your Spam folder if you do not see the password in your e-mail inbox. If you did not receive the password in a separate e-mail, please contact the POC below.

If there are any questions about the released information, feel free to contact Paul Mouris at 9146822826 ext. 13 or Paul.Mouris@FDA.HHS.GOV.



**U.S. FOOD & DRUG
ADMINISTRATION**

Doctors Analytical Laboratories Pvt Ltd.pdf
210K

Establishment Inspection Report
Doctors' Analytical Laboratories Pvt Ltd
Navi Mumbai, Maharashtra, 400708 India

FEI: **3009890383**
EI Start: 6/27/2022
EI End: 6/29/2022

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SUMMARY

A preapproval inspection of this contract testing laboratory was conducted as per FACTS ID # 11985695 and eNSpect Op. ID # 147402, in accordance with Compliance Policy Guidance Manual (CPGM) 7346.832 - *Pre-Approval & Post Approval Inspections* and CPGM 7356.002- *Drug Manufacturing Inspections*. This PAI-only inspection assignment called for review of this firm as a contract testing Laboratory for testing of Platinum Content in Saproterin Dihydrochloride Active Pharmaceutical Ingredient (API) by ICP-MS for ANDA# 216650 (Saproterin Dihydrochloride Powder, 100mg/ Packet and 500mg/Packet). The sponsor of this ANDA is Teva Pharmaceutical. Systems covered during the inspection (as they relate to the PAI product) included: Quality, Materials, Equipment/ Facilities, and Laboratory.

The previous inspection was PAI only of Doctors' Analytical Laboratories was conducted from 10/30/2017 to 11/02/2017. A four-item Form FDA 483 was issued on 11/02/2017 and the final classification of the inspection was VAI. The current inspection was conducted between 06/27/2022 and 06/29/2022. No Form FDA 483 was issued, and inspection was classified as NAI.

There is no manufacturing of drug products; however, the firm does test commercial products intended for the US market.

No samples were collected during the inspection. No refusals were encountered.