

FDA Inspections



Introduction:

- * The Food and Drug Administration (FDA) conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations, such as the Food, Drug, and Cosmetic Act. This typically involves an investigator visiting a firm's location.
- * After an inspection, FDA determines if the areas evaluated are in compliance with applicable laws and regulations. FDA discloses a segment of inspection information to help improve the public's understanding of how the FDA works to protect the public health.
- * The FDA takes its responsibility seriously to ensure the medical products we use are safe and meet rigorous standards for quality, safety and effectiveness. The agency uses risk-based approaches to identify foreign and domestic facilities for inspection.
- * During an FDA inspection, investigators visit regulated facilities to assess compliance with applicable regulations and guidelines. If the investigators identify any violations or non-compliance issues, they may issue a written citation which outlines the observations made during the inspection.
- * The citation typically includes specific details about the observed violations, such as deviations from good manufacturing practices (GMPs) or failure to meet product labeling requirements.
- * The purpose of posting a citation is to formally notify the regulated entity about the violations identified during the inspection. The citation serves as an official record of the inspection findings and provides the regulated entity with an opportunity to respond and take corrective actions to address the identified issues.



www.linkedin.com/in/raviteja-padala/



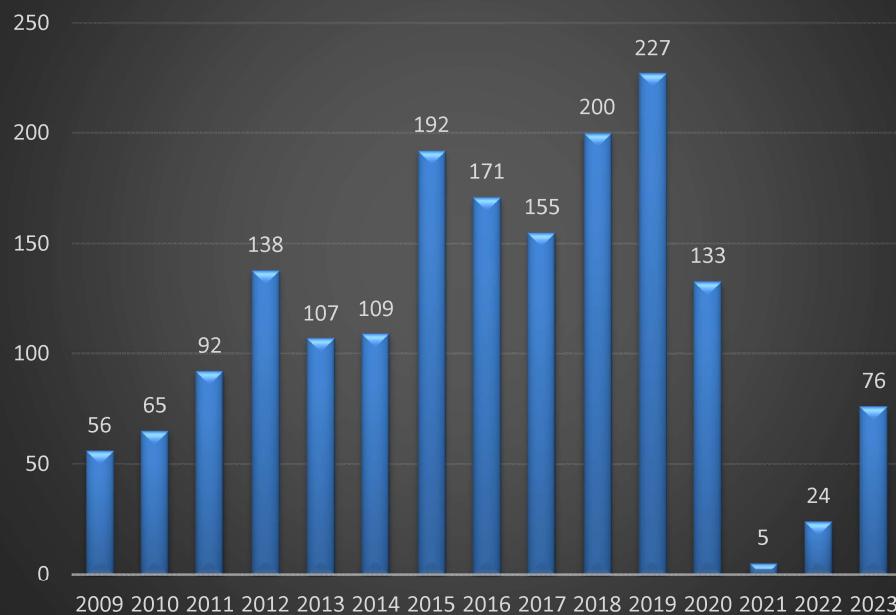
www.github.com/raviteja-padala

FDA Inspections (Year Wise)

Fiscal Year

2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

Total FDA inspections in INDIAN Drug firms



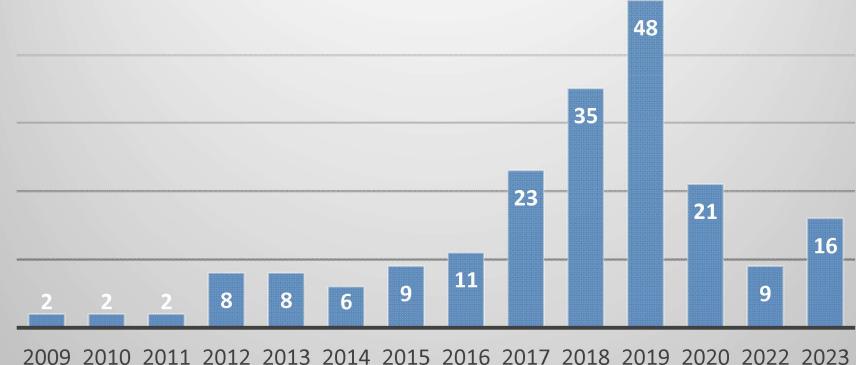
Total Inspections

1750

Inspections with Citations

200

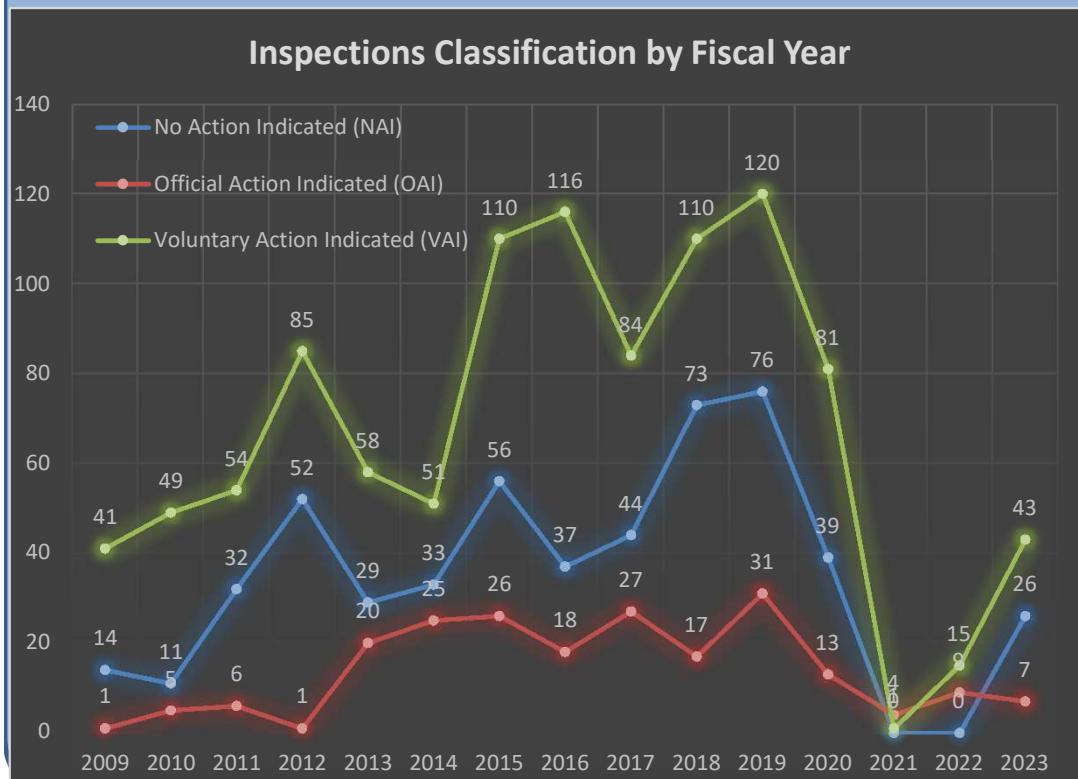
Inspections with Citations



Classification of Inspections(Year Wise)

Fiscal Year

2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
------	------	------	------	------	------	------	------	------	------	------	------	------	------	------



NAI
522

OAI
210

VAI
1018

Compliance Classifications

- **NAI - No Action Indicated**
Inspected firm is in compliance
- **VAI - Voluntary Action Indicated**
Deviation(s) from the regulations
Voluntary correction is requested
- **OAI - Official Action Indicated**
Because of serious non-compliance requiring regulatory or administrative action by FDA

VAI & OAI (Legal name Wise)

Fiscal Year

2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
------	------	------	------	------	------	------	------	------	------	------	------	------	------	------

VAI Legal name wise



▼ Zydus Lifesciences Limited

▼ Cipla Limited

■ Intas Pharmaceuticals Limited

■ Lupin Limited

■ Emcure Pharmaceuticals Limited

■ Torrent Pharmaceuticals Limited

■ Aurobindo Pharma Limited

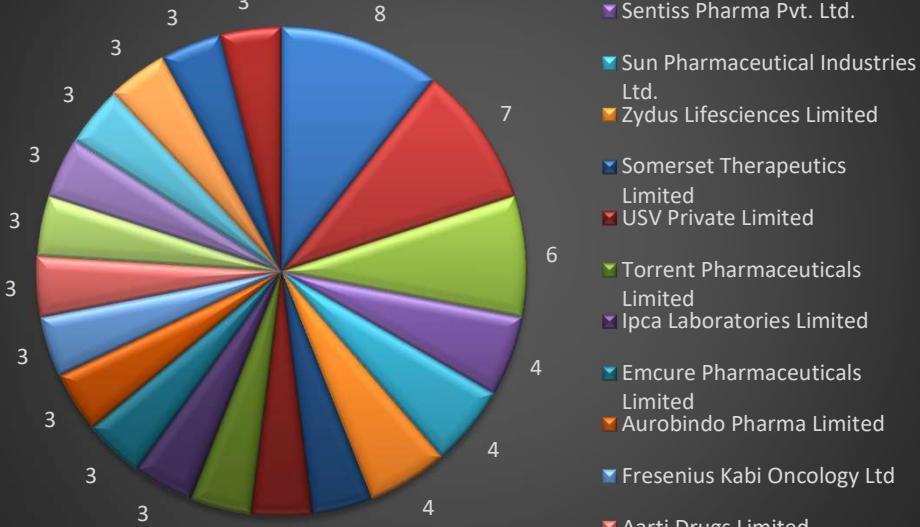
■ Gland Pharma Limited

■ Sun Pharmaceutical Industries Limited

■ Mylan Laboratories Limited

■ Pfizer Healthcare India Private Limited

OAI Legal name wise



▼ Lupin Limited

■ Wockhardt Limited

■ Megafine Pharma (P) Limited

■ Sentiss Pharma Pvt. Ltd.

■ Sun Pharmaceutical Industries Ltd.

■ Zydus Lifesciences Limited

■ Somerset Therapeutics Limited

■ USV Private Limited

■ Torrent Pharmaceuticals Limited

■ Ipca Laboratories Limited

■ Emcure Pharmaceuticals Limited

■ Aurobindo Pharma Limited

■ Fresenius Kabi Oncology Ltd

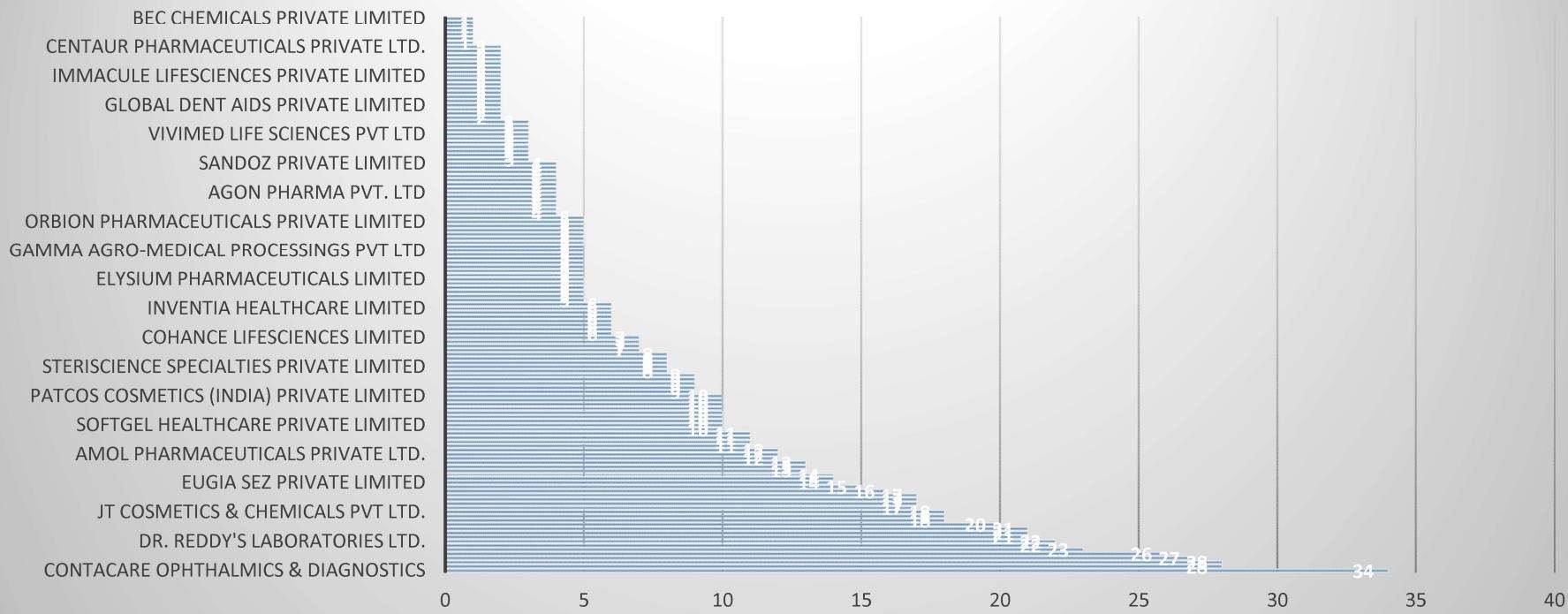
■ Aarti Drugs Limited

■ Unimark Remedies Limited

Citations (Year Wise)

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2022	2023
------	------	------	------	------	------	------	------	------	------	------	------	------	------	------

Citations by Legal Name

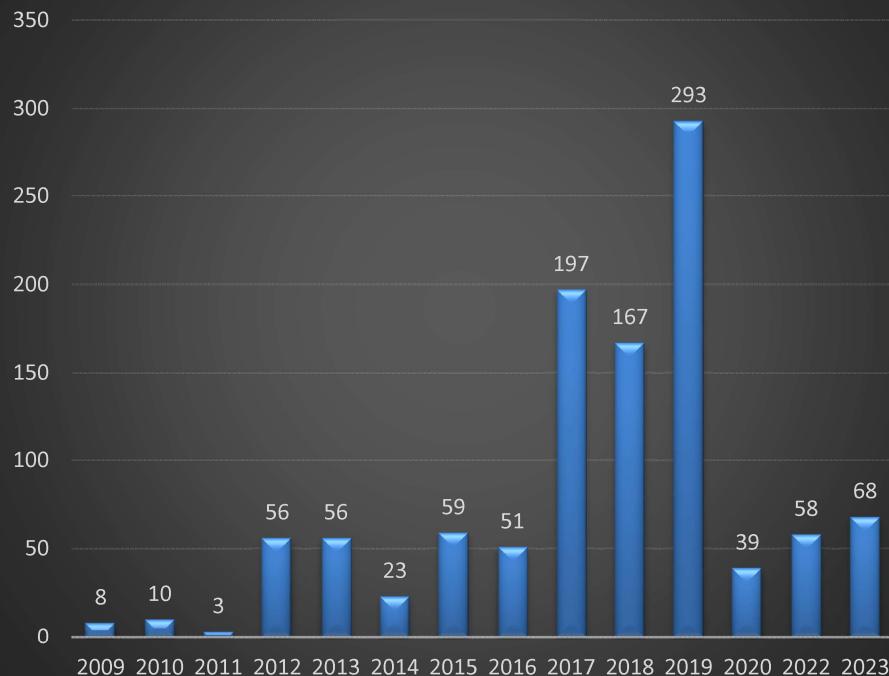


Citations (Year Wise)

Year

2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2022 2023

Citations



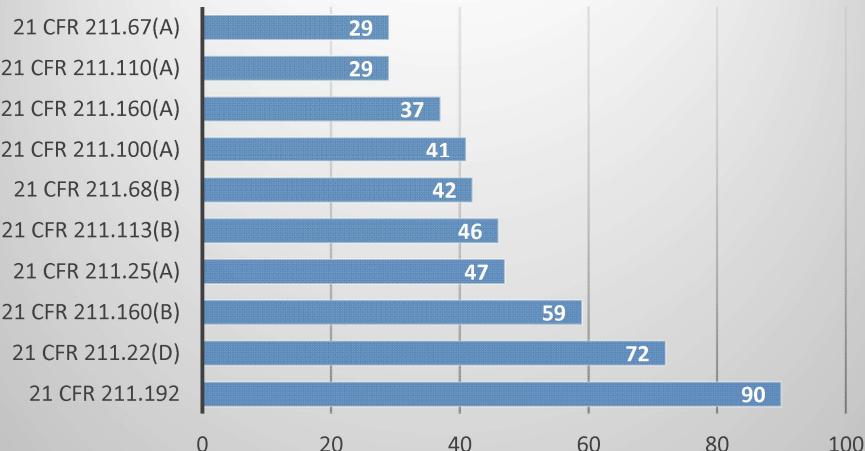
Total Citations

1088

Citation with High count

21 CFR 211.192

Top Citations by Count



Top Citations by FDA and Observations over Years

Year

2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2022	2023
------	------	------	------	------	------	------	------	------	------	------	------	------	------

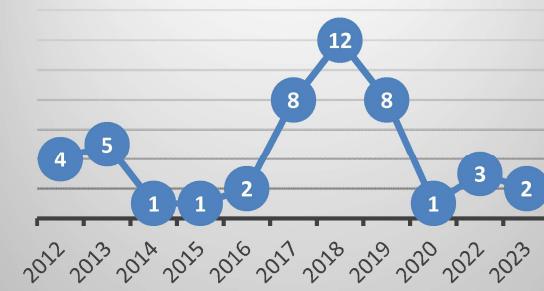
21 CFR 211.192



21 CFR 211.22(d)



21 CFR 211.25(a)



21 CFR 211.160(b)



21 CFR 211.113(b)



21 CFR 211.68(b)



Interpretation of Inspections

* Inspections with most number observations and citations are listed below:

21 CFR 211.192- Written record of investigation incomplete
21 CFR 211.22(d)- Procedures not in writing, fully followed
21 CFR 211.160(b)- Scientifically sound laboratory controls
21 CFR 211.192- Investigations of discrepancies, failures
21 CFR 211.100(a)- Absence of Written Procedures
21 CFR 211.113(b)- Procedures for sterile drug products
21 CFR 211.68(b)- Computer control of master formula records
21 CFR 211.67(a)- Cleaning / Sanitizing / Maintenance
21 CFR 211.25(a)- Training , Education , Experience overall
21 CFR 211.194(a)- Complete test data included in records



- * With most frequent observations listed out, firms can focus more on the related areas and full fill the lacunas and make the process more robust.
- * Firms can avoid obvervations by following appropriate procedures mentioned in the guidelines.
- * Upgrading and Being online with current Regulatory requirements.
- * Upgrading to advancements not only help organisation to be inline with standard practices, but also help enhance the productivity.

* For detailed description of CFR citations refer: www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211