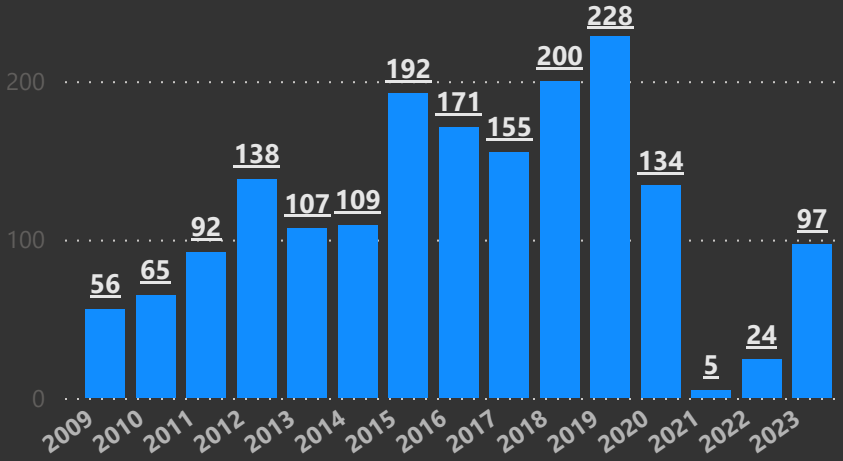


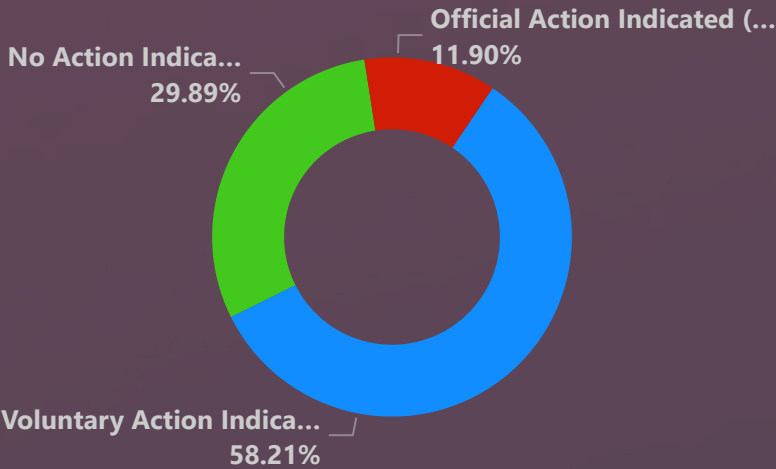
Analysis of FDA inspections in INDIAN Drug Firms

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

FDA inspections Yearwise

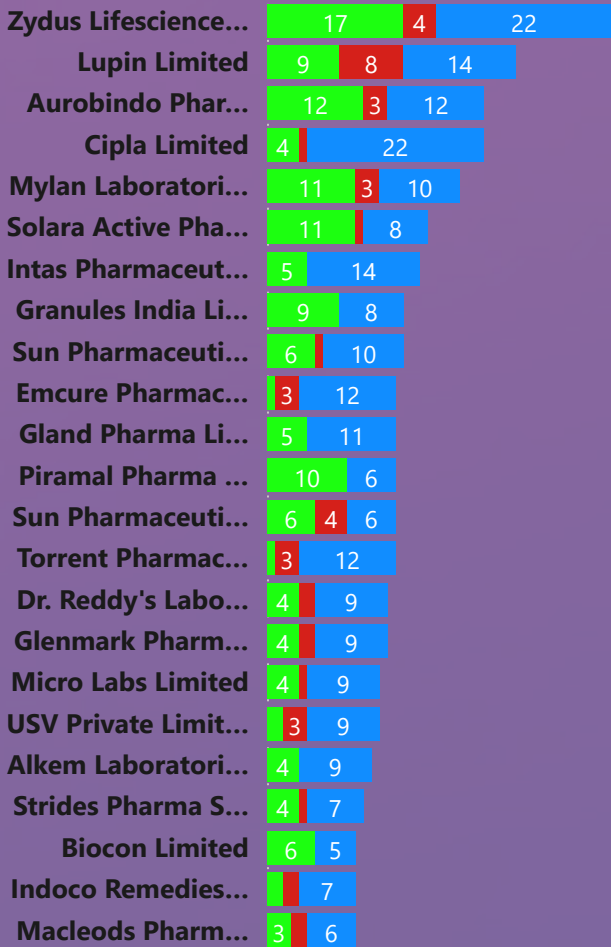


NAI, VAI, OAI



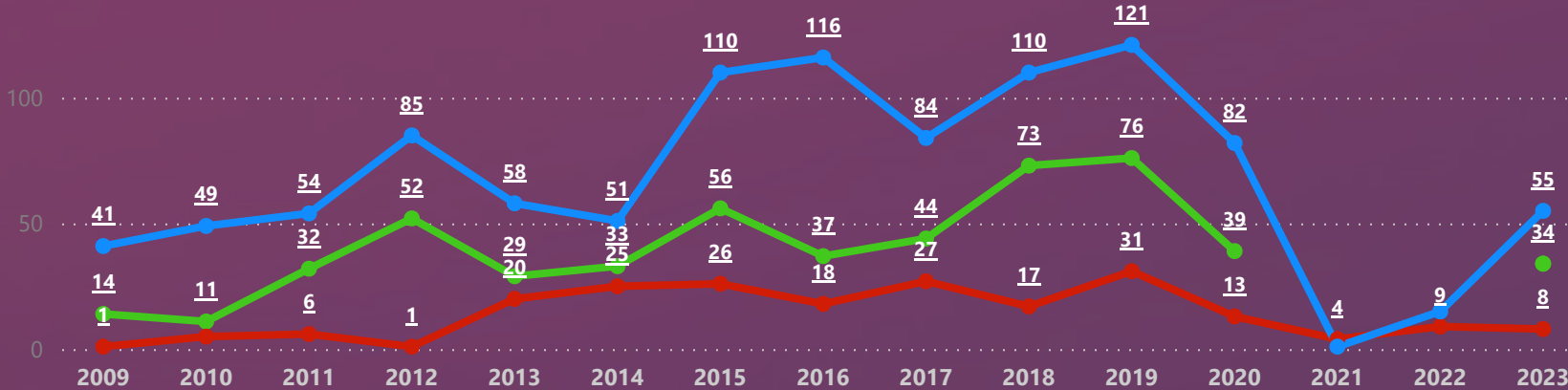
Classification by Legal Name and Classification

Classification ● No Action Indic... ● Official Acti... ● Voluntary ...



Inspections classification by Fiscal Year

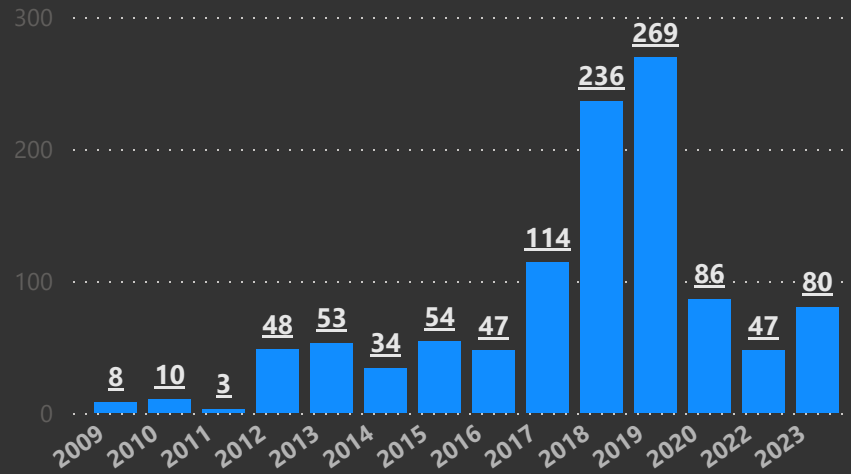
Classification ● No Action Indicated (NAI) ● Official Action Indicated (OAI) ● Voluntary Action Indicated (VAI)



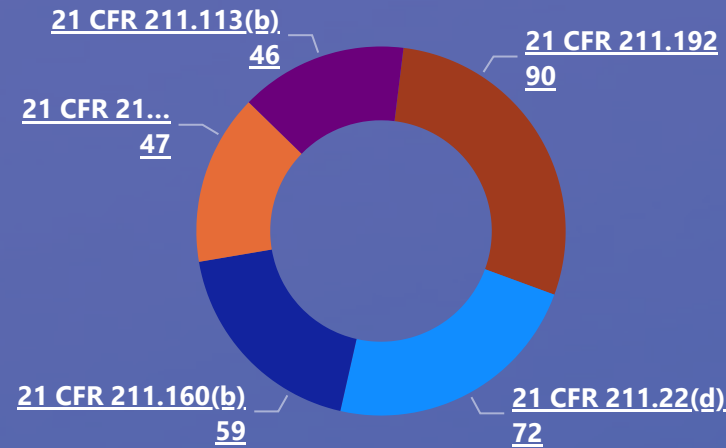
Analysis of FDA inspections Citations in INDIAN Drug Firms

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

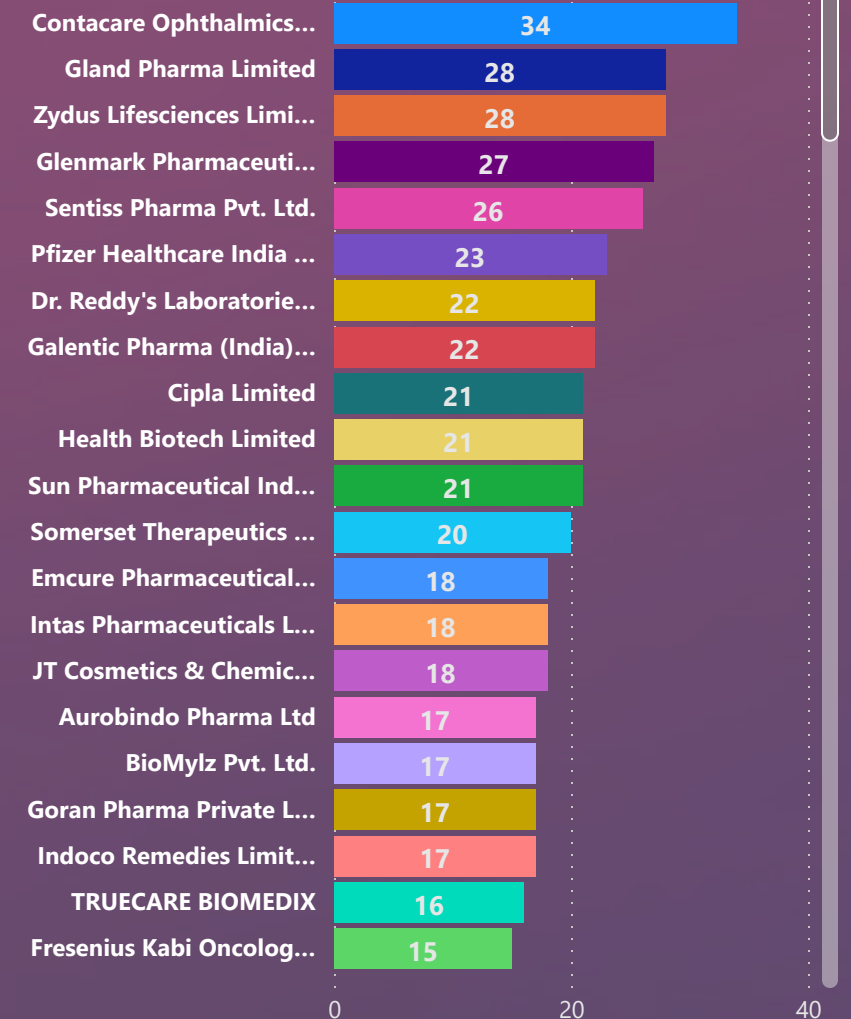
FDA Citations Yearwise



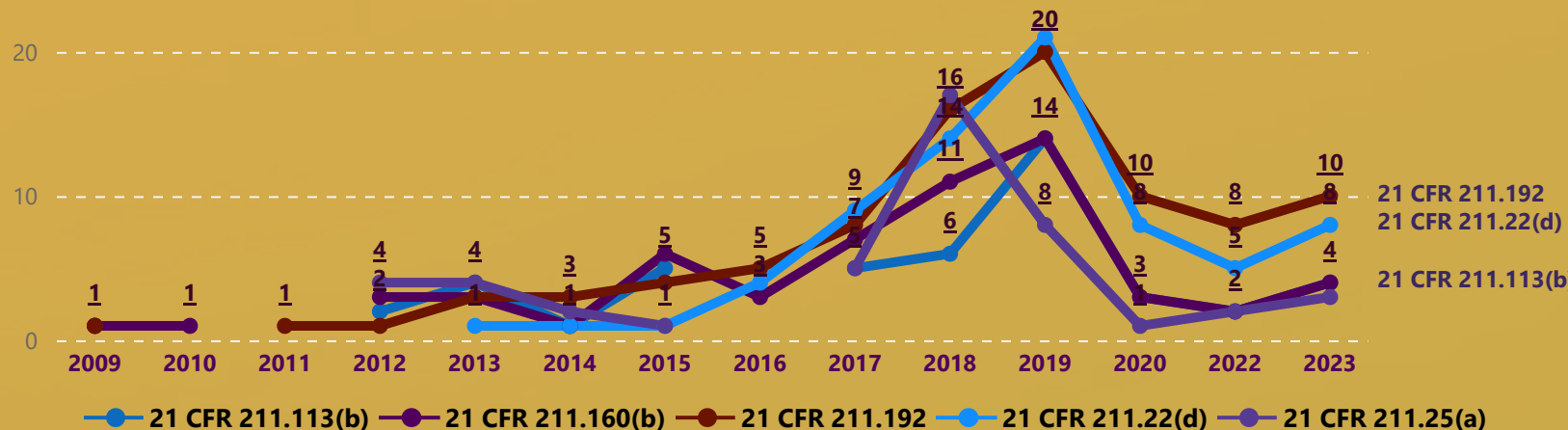
Top 5 Observations



Citations per firm



TOP 5 Observations yearwise



Analysis of FDA inspections Citations in INDIAN Drug Firms

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

Top citations and Observations

Act/CFR Number	Short Description	Count of Act/CFR Number
21 CFR 211.22(d)	Procedures not in writing, fully followed	72
21 CFR 211.160(b)	Scientifically sound laboratory controls	59
21 CFR 211.192	Investigations of discrepancies, failures	50
21 CFR 211.113(b)	Procedures for sterile drug products	34
21 CFR 211.25(a)	Training , Education , Experience overall	29
21 CFR 211.192	Written record of investigation incomplete	22
21 CFR 211.25(a)	Training--operations, GMPs, written procedures	14
21 CFR 211.192	Extent of discrepancy, failure investigations	13
21 CFR 211.113(b)	Validation lacking for sterile drug products	12
21 CFR 211.25(a)	GMP Training Frequency	4
21 CFR 211.192	Quality control unit review of records	3
21 CFR 211.192	No written record of investigation	2
Total		314

Analyzing Inspections:

- Analyzing FDA inspections and citations can help identify patterns or trends in the compliance history of regulated entities.
- It provides insights into their track record, recurring issues, and the effectiveness of corrective actions taken in response to previous inspections.
- FDA inspections and their outcomes have a significant impact on regulated industries and public health. They help ensure the safety and quality of products available in the market, build consumer trust, and maintain a level playing field for compliant companies.
- Inspections also drive continuous improvement and encourage companies to prioritize quality and compliance.