Available online on 15 Jun, 2026 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article Open Access

An Analytical Study of Selected Bulk Drug Manufacturers in Andhra Pradesh and Telangana: SEZ Status, Regulatory Framework, Compliance, Oversight, and Workforce Welfare and Safety

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Abstract

Introduction: India's bulk drug manufacturing industry has witnessed rapid growth over the past two decades, driven by supportive government policies, financial incentives, and regulatory reforms such as the Special Economic Zones (SEZ) Act 2005 and Rules 2006. Encouraged by these initiatives, several major pharmaceutical companies established manufacturing units across Andhra Pradesh and Telangana, particularly in industrial clusters and SEZs. Although this expansion significantly strengthened India's pharmaceutical sector, it was also accompanied by multiple industrial accidents resulting in loss of lives and raising concerns about workplace safety and employee welfare.

Methods: This research paper evaluates ten selected bulk drug manufacturing companies using publicly available documents, regulatory reports, and media sources. The analysis is based on four key parameters: regulatory compliance, regulatory oversight, employee welfare, and workplace safety, along with a review of reported accidents.

Results and Discussion: The findings indicate that listed pharmaceutical companies generally perform better across all evaluated criteria. In contrast, certain SEZ-based unlisted companies, including Hetero SEZ Infrastructure and Escentia, appear to show weaker commitment toward employee welfare and occupational safety.

Summary: The study emphasizes the need for stricter regulatory enforcement, regular safety audits, greater transparency, and stronger accountability to ensure safer and more sustainable growth of the bulk drug manufacturing industry in India.

Conclusion: The review highlights the growth of India's bulk drug industry and evaluates regulatory compliance, employee welfare, and workplace safety among selected companies. It emphasizes the need for stricter regulations, regular safety audits, transparency, and stronger accountability to ensure sustainable and safe industrial development.

Keywords: Bulk drug manufacturers, SEZs, Regulations, Accidents, compliance, oversight, employee welfare, workplace safety

Article Info: Received 21 Apr 2026; Review Completed 10 Jun 2026; Accepted 11 Jun 2026

Cite this article as:
Jayanti VR, Mandavilli SR, Battu H. An Analytical Study of Selected Bulk Drug Manufacturers in Andhra Pradesh and Telangana: SEZ Status, Regulatory Framework, Compliance, Oversight, and Workforce Welfare and Safety. Int. J. Drug Reg. Affairs [Internet]. 2026 Jun 15 [cited 2026 Jun 15]; 14(2):60-75. Available from: http://ijdra.com/index.php/journal/article/view/906

DOI: https://doi.org/10.22270/ijdra.v14i2.906
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1. Introduction

The last two decades have seen an accelerated growth of the bulk drug industry in India, inspired by incentives and special schemes, by the state and central governments. A study of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India, (May 2023), found that there are 118 pharma clusters, all over India, and that there are 7673 pharma industries in operation, 87.6 % of these being MSMEs. MSMEs form the heart of the supply chain for the large industries. (1) The present study intends to analyse API manufacturing companies, including units from the list of companies given in the survey report, and some units that suffered accidents in recent years. They would be studied by accessing their documentation and certification available in public domain and would be rated on regulatory compliance, regulatory oversight, commitment to employee welfare and workplace safety. It further aims to come out with some suggestions that ensure the safety of the employees and accountability of the managements. Production Linked Incentive (PLI) scheme for Pharmaceuticals, is one of the central government schemes, in which, it came out with guidelines, dated, 29th October 2020, to promote companies manufacturing a

targeted set of pharmaceuticals. (2) The central government also came out with guidelines for promoting the setting up of bulk drug parks by several state governments, dated 27th July 2020. (3) Evaluation criteria for the selection of a state's proposal for the formation of a cluster are given in Appendix I of this document and include, the extent of financial incentives that a state can offer and the state's rank in "Ease of doing Business".

Agencies, like the Confederation of Indian Industries (CII), and eminent pharmaceutical industrialists called upon the Indian government to take decisive and progressive steps to encourage entrepreneurs to start and operate bulk drug industries. The Government was called upon to show financial incentives, reduce regulatory burden and participate in development of clusters of pharma units, to save on the expenditure by individual companies, to create common facilities for a number of companies in a single place, to provide good infrastructure like supply of water, electricity and all other essential supplies. The CII report of 2017 advised the central government to promote bulk drug manufacturers through single window clearance, policy reforms, and skill development programmes. (4) In another report (2020), the CII reviewed the initiatives taken up by the GOI and recommended promoting ease of doing business, financial assistance and setting up joint infrastructure in clusters (5). Dr. Gurpreet Sandhu, President, Council for Healthcare and Pharma (CHP) suggested starting clusters of API pharma units with common facilities (common testing, R&D, effluent treatment, electricity supply). (6) Shefali Singh and Harvinder Popli suggested that the GOI must have a unified vision for the API sector and resolve policy issues. (7) Katoch Committee recommended the development of large manufacturing zones for APIs, with water, electricity and common state-of-art facilities such as effluent treatment plants (ETPs), steam, and testing laboratories. (8) The Special Economic Zones Act, 2005 (9) and The Special Economic Zones Rules, 2006 (10) were brought out by the GOI, which paved the way for the development of SEZs. SEZs provided for a single window clearance and for the constitution of a single authority in the name of a Development Commissioner to handle all the issues of the SEZ. The GOI issued guidelines to assist states in developing bulk drug parks. (3) These guidelines gave a list of essential pharmaceuticals to be targeted for manufacture by the API manufacturers. They also laid out the eligibility criteria for selection of a state for promotion of the parks. The bulk drug manufacturers needed statutory and environmental clearances, and needed to be producing some of the targeted pharmaceuticals. Only states that would ensure single-window approvals and have strong ease-of-doing-business rankings would be prioritised by the central government. (3)

2. Regulations

Bulk drug companies must comply with numerous central laws and voluntary workplace safety standards, such as:

Factories Act, Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989, Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996, Air (Prevention and Control of Pollution) Act, 1981, Schedule M of the Drugs and Cosmetics Rules, 1945, IS 14489:2018 (Occupational Health and Workplace safety Audit Code of Practice), Industrial Disputes Act, Minimum Wages Act.

The major regulations that API units have to follow, laid down norms for them to meet. The two standards, ISO 9001 and ISO 45001 require documented competence and training within certified systems; certification itself is voluntary.

Some regulations of the central government, and Acts or GOs or policies issued by the governments of Andhra Pradesh and Telangana, (API manufacturering companies discussed in this paper, are all situated in these two states) are discussed below.

The Special Economic Zones (SEZ) Act, 2005 was introduced to boost exports and investment. This Act provides for the constitution of a Development commissioner (Chapter IV), Single Window Clearance (Chapter V), and certain facilitation in "agency to inspect" (Section 20). It is mentioned in Section 20 "the Central Government may, by notification, specify any officer or agency to carry out surveys or inspections for securing compliance with the provisions of any Central Act". Section 49 is about power to modify provisions of this Act or other enactments in relation to SEZs. This Section mentions "nothing contained in this section shall apply to ---- matters relating to trade unions, welfare of labour, old age pensions, maternity benefits---". The Special Economic Zones Rules 2006 give procedures for the establishment of SEZs and for the establishment of units. SEZ Act (S.49) does not permit changes to core labour-welfare laws. But when some API units were inspected, post accidents, certain lapses were observed. There were many lacunae in their systems, like employment of underqualified people, lack of training to employees, employees working without protective gear and most important of all, lack of alarm systems. (97)

Andhra Pradesh: The Government of Andhra Pradesh brought in "Policy framework for Special Economic Zones (SEZs) in Andhra Pradesh" by Industries and Commerce (INF) Department G.O.Ms.No.151, dated, 09.04.2002 to utilise the concept of SEZs, introduced by the central government in March 2000. (11) Further, on 31.5.2016, the labour department of Andhra Pradesh launched an online portal for "Ease of doing business" for the purpose of "simplification, transparency and accountability of inspections and ease of compliance of law by the industry". (12) This GO proposed risk- based assessment and categorised risk by three criteria; by the number of workers, by the number of contract workers employed and on the basis of the type of activity carried out in the establishment. Chemicals and Fertilisers was categorised into the high-risk category. Section 9 of this GO, gives the list of establishments exempted from online inspections, and "Establishments under SEZs / EPZs" come in this list. So, SEZ based companies of bulk drug manufacture are exempted from online inspections only, not statutory inspections.

The Central Pollution Control Board (CPCB) has been established as a regulatory authority for implementing various pollution control laws. The Ministry of Environment, Forest and Climate Change (MoEFCC),

Government of India has started its own "online consent management and monitoring system". (13) The government of Andhra Pradesh has its own State Pollution Control Board, which is tasked with monitoring different industries in the state and with giving Consent for Establishment for different varieties of industries, such as red, orange, green and white (colour coded by the type of activity that is carried out in the industry). (14) The Andhra Pradesh Single Desk Policy 2015 was declared and a GO was released on 14.06.2016. (15) Under this policy the state government created state level and district level mechanisms to give approvals to different types of industries. The aim of the policy is to create a system whereby all clearances required to set up an industry can be obtained within 21 working days. These policy initiatives helped Andhra Pradesh in gaining an advantage in setting up different industries, including bulk drug manufacturing industries, in and outside SEZs. There are eight pharma clusters in Andhra Pradesh as per the survey of the Government of India. (1)

Telangana: Industrial Policy Framework for the state of Telangana was brought out by the state govt in 2014 with the objective to facilitate industrial growth. (16) Some of the components of this policy are minimum inspection and maximum facilitation, self- certification and automatic renewals and a system called Telangana State Industrial Project Approval and Self- Certification System (TS-iPASS). Bulk Drugs is one of its thrust areas and development of Common Facility Centres is one of its proposed programmes.

There is an updated version of the same policy document which outlines some specific incentives being implemented in the year 2016-2017 (page 24). (17) It proposes the development of a new pharma city and chemical city with well- developed infrastructure, including waste management. The Telangana State Industrial Project Approval and Self Certification System (TS iPASS) Act, 2014 Act 3 of 2014, provided for speedy processing for issue of various licenses, clearances and certificates required for setting up of industrial undertakings. (18) There are 7 pharma clusters in Telangana. (1)

There are two Government of Telangana abstracts dated 21.4. 2017and 20.7.2017. The first one is from Labour, Employment, Training and Factories Department, regarding inspections under various labour laws. (19) It prescribes that there shall be a single joint inspection under all the labour laws, to facilitate Ease of Doing business. The second one was from the Industrial and Commerce Department, which proposed action points, like, setting up a central inspection system responsible for taking up compliance inspections, designing and developing an online inspection system for scheduling inspections and developing computerised risk assessment methods to carry out inspections; all these methods are meant to facilitate the ease of doing business in the state of Telangana. (20) The Telangana Pollution Control Board (TGPCB) is a statutory authority entrusted to implement Environmental Laws and Rules within the jurisdiction of the State of Telangana, India. (21) The CPCB has a national OCMMS Dashboard, which lists state pollution control boards' online consent portals. (22)

3. Methods

We studied ten API manufacturing companies operating in Andhra Pradesh and Telangana and evaluated them, using a four-criteria framework (compliance, oversight, commitment to employee welfare, workplace safety). Evidence was gathered exclusively from public sources (company/regulator portals, court/tribunal orders, media). Evaluation depended upon documented certifications, inspection history, and disclosures. Annual reports or BRSRs of large companies having multiple units were taken into consideration, when they mentioned the address of the unit under study, in their content. For companies with multiple units, only the unit whose address was clearly identifiable in annual reports or BRSRs was evaluated. The scores therefore apply strictly to the specific unit under study. In the case of Hetero, however, media reports do not mention the unit number and official documents are addressed to "Hetero SEZ infrastructure". To maintain accuracy and consistency, we treated three closely located units as a single SEZ-linked infrastructure, aligning with how regulatory filings themselves refer to the cluster. Cluster-level documents—such as investigative reports covering the broader Visakhapatnam and Hyderabad API clusters—were also considered where relevant. The final results are presented in Table 1.

Regulatory compliance was assessed based on the availability or not, of certifications like International and national approvals (USFDA, EMA, MHRA, TGA, WHO GMP, CDSCO), ISO 9001 quality management, timely corrective actions after notices, strong GMP/SOP documentation, transparent disclosures (annual/ sustainability reports. Regulatory oversight was assessed based on how much inspection the company received from Indian regulators (State Drug Control, Labor Dept, Pollution Control Board) and international regulators (USFDA, EMA, MHRA, EDQM), and how it responded to observations from the regulators. Commitment to employee welfare was assessed based on Statutory compliance (PF, ESI), employee facilities (canteen, health check-ups, housing/transport), internal workplace safety committees, and grievance redressal. Commitment to workplace safety was assessed based on how much is shown by them regarding safety SOPs for hazardous processes, frequency of mock drills, regulatory verification by PCB/Factories Dept, on-site/off-site emergency plans, certifications such as OHSAS 18001 / ISO 45001, process workplace safety audits, dedicated EHS teams. In each case the grading goes from very poor to excellent, depending on the extent of certification or documentation available, the occurrence of accidents, the response to the occurrence of adverse events and the display of commitment to welfare and safety of workers and communities. **ChatGPT AI 5** and **Google Gemini AI** were used as research assistants, to locate and retrieve documentary proof; they helped in finding certifications, reports and materials, and also in accessing web sites; all the references were studied and interpreted by the authors**.** The ratings reflect the extent of accessibility that common citizens have to documents of manufacturers and the understanding and judgement of the authors, and are hence necessarily subjective. There is no conflict of interest or

bias on the part of the authors towards any manufacturer. **The results are shown in Table1 and in Figure 1.**

4. Study of Certifications, web sites, Annual reports, of companies and media reports:

a). Aurobindo Pharma Unit XIV (Apitoria 6): The Integrated Annual Report, 2023-2024, of Aurobindo Pharma lists the Unit XIV of Aurobindo (now Apitoria 6) in page no. 230, giving its address. (23) Its Annual report and its BRSR, 2023-2024, explain several procedures like safety training programmes, monitoring and improving safety performance, technical skill development programmes, its policy on quality and compliance, and the policy to adhere to stringent regulatory standards. (24) Thus, all the policies and assurances kept in the annual report and in its BRSR, are applicable to this unit also. This unit received WC from CDSCO and Environment Clearance from the central government and international certifications. (25-29) There was a show cause notice by the Central Pollution Control Board but there is no publicly available response from the company in public domain. (30)

An accident occurred in Aurobindo Pharma Unit XIV (Apitoria 6), and one worker died, (information by Aurobindo to the Stock Exchange Limited, on 7th April 2024). (31) Joint Chief Inspector of Factories suggested that the accident occurred during leak testing by applying nitrogen, and the applied pressure might have exceeded the safe limit, causing the door of the vacuum tray dryer (VTD) to detach and strike two technicians. (32) Public reports (The Hindu, 27th June 2024) state that Apitoria Pharma Limited hiked the workers' wages and allowances in June 2024. (33) Two reports, on the effects of pharmaceutical pollution present many harsh facts, with proofs in the form of photos, regarding how, API manufacturers in VSP, in Pydibhimavaram and in Hyderabad are damaging the environment, the lakes and the surrounding communities, by their effluents. Aurobindo Pharma (not specifically Apitoria 6) is also named in one of these reports. (34,35) Aurobindo Pharma Unit XIV emerges as a very responsible, internationally visible organisation with transparency and accountability. But the happening of an accident and the allegation of pollution (not the unit under study but the entire cluster is accused of this by reports), bring down its rating. That there was an accident, in spite of all the training programmes of the company, affects the employee score and the workplace safety score. Aurobindo Pharma Unit XIV, or Apitoria 6, may thus be considered as good in compliance, excellent in regulatory oversight, good in commitment to employee welfare and average in workplace safety.

b) Gland Pharma: The Annual Report of Gland Pharma (plot 49 and50, JNPC, Vizag) explains the various steps they take to ensure regulatory compliance and workplace safety and well- being of their employees. (36) In page 85 of Annual Report 2022- 2023 and the last page 243/244 of Annual Report 2021-2022, Gland Pharma, Plot no. 49 and 50, JNPC SEZ is listed, hence, it is assumed, that all the policies described in the Annual reports are relevant to this API unit also. (36, 37) The positives are: Benefits like health, insurance, maternity, paternity, nursery to their employees, training the employees, risk assessment procedures, and internal audits, active engagement with employees and communities.

Plans under EHS, CSR and risk management, ISO 45001:2018, ISO 14001:2015, ISO 9001:2015, and WHO-GMP certifications, environment friendly measures like replacing furnace oil with piped natural gas (thus reducing its CO_2 output) and installing solar panels in their Hyderabad facilities, determination to expand this programme to their plants in Vizag. (38)

USFDA Pre-approval Inspection (PAI) for sterile Active Pharmaceutical Ingredients (APIs) at the site happened from 19th t0 25th February, 2025 and Receipt of the Establishment Inspection Report (EIR) from the USFDA, was received indicating a closure of the inspection at its facility at JNPC, VSP. (39) Gland Pharma is listed as no.3 in the WHO- GMP Manufacturing Units for Certificate of Pharmaceutical Products (COPPs), (40) it has Written Confirmation from CDSCO, international cell, on 22nd June 2023. (41)

Gland Pharma is excellent with respect to regulatory compliance and regulatory oversight (because there are proofs in terms of certifications and successful inspections) and very good in Commitment to employee welfare and in Workplace safety (proof for these two are the companies own annual reports and BRSRs, in addition to the fact that there are no adverse reports from media or from any agencies).

c) M/s Porus Laboratories Pvt Ltd (Unit-IV): M/s Porus Laboratories Pvt Ltd (Unit-IV), Village Akkireddygudem, Musunuru Mandal, Eluru district, (Andhra Pradesh) has the following documentary proofs for certifications and oversight/positives: Proposes plans for expansion to the (MoEFCC)(IA-II Division) and gets environment clearance, (42) files a six-monthly EC compliance (Jan 2019), (43) and receives APPCB Consent for Establishment and Consent for operation in order dated 17th September 2019, (44) applies twice for expansion of its Unit to theMoEFCC, GOI; once in January 2016 and next in March 2018, (45, 46) submits a risk assessment report in 2018. (47) Declares (in the proceedings of the NGT, after the accident in April 2022) that it has an onsite emergency plan, updated in June 2021, and also that it carried out a mock drill on 18.11.2021. (48) So, Porus labs has the necessary certifications for the manufacture of APIs subject to its meeting the regulatory standards, in the aspects of environment, commitment to employee welfare and workplace safety. A major accident happened in Porus labs on 13th April 2022. (49) A runaway chemical reaction occurred in Reactor SSR-D01, in Porus labs, as methylamine gas was being added to molten phthalic anhydride. A hazard and operability study (HAZOP) was carried out by a third party in May 26, 2017. Suggestions by the audit: interlocking of temperature with MMA gas feed, provision of pressure relief systems, and provision of alarm systems with regard to high temperatures. Stage 1 production of 4-NPI involving phthalic anhydride since April 2020, was started in February 14, 2022, without compliance with HAZOP recommendations and without Pre Start-up Safety Review (PSSR).On the day of the accident, the employee who was supposed to monitor this

exothermic reaction was not there in his place, for thirty minutes; as the reaction was unmonitored and as there were no automatic controls, temperature and pressure rose uncontrollably; the reactor burst violently, the manhole blew off, hot chemical mass spilled, ignited, and the reactor collapsed, causing severe burns and injuries to workers, multiple fatalities and injuries occurred. (48) After the accident all the media, Human Rights Forum, APPCB, NGT and others inspected the company, interviewed the villagers in Akkireddygudem, where the company is situated and reported on releasing harmful effluents into the village "since years". (49) The company was fined and was ordered to shut down. (50) Media reports speak about failure in compliance with workplace safety protocols. (51) The accident itself speaks of failures of workplace safety protocols and deaths and injuries to workers imply failure of workplace safety.

So, Porus labs, Akkireddygudem is rated as average in regulatory compliance and in regulatory oversight and poor in commitment to employee welfare and in workplace safety.

d) Hetero Group Units at Nakkapalli SEZ (Anakapalli District, Andhra Pradesh): Hetero has three units, labelled as Hetero drugs Ltd- Unit IX at plot 1, Hetero labs Ltd- Unit III at plot no.4, and Hetero Labs Ltd- Unit IX at plot no.2; all three units are located at Narasapuram, Nakkapalli Mandal, Anakapalli District and are API manufacturers (Unit III is no. 13, Hetero Drugs Unit IX is no. 16 and Hetero Labs, unit IX is 11 in the list of COPPs of WHO, May 2019. (40) All three units have certifications. In the case in NGT, the reference is to "respondent 11, which is M/s. Hetero Infrastructure SEZ Ltd & Hetero Laboratories Ltd". Hetero labs Unit IX, plot 2 has certifications from national regulators (CDSCO) and from international institutions (WHO), (52, 54) Hetero Drugs Ltd, Unit IX, plot 1 has WC. (53) Hetero labs Limited, Unit III has environment clearances from the MoEFCC. (55, 56, 57) Hetero's reports claim certification as per ISO 50001 and ISO 45001 for all its units (page 43 of its Sustainability Report), (58) its plans for sustainable environment, health, well-being, skill development and workplace safety are all presented in the sustainability report, 2021-2022, (59) it has permissions for expansion and two six monthly compliance plans to the MoEFCC. (60, 61) All these certifications and oversight seem to be ineffective in ensuring the safety of their workers as the company sustained three major accidents and one minor accident in the last decade; one in 2013, another in 2016 and the last major one in 2022. The media reports which report them do not mention the units. One article says all three accidents which happened (up to that point in time) happened in the same company. (62) Hence, the three units are being considered as part of the same Hetero SEZ infrastructure (as referred to in NGT documents and in EC documents) for the purpose of this study. There was a reactor blast in January 2013, in which two workers died and some workers sustained injuries. (63) It was reported that the DGM of Hetero drugs was held, for this accident. (64) Vizag collector, speaking to news persons, said, "*one of the reasons is that the steam that is to be used for the reaction has to be supplied in a regulated manner, but excess steam was supplied the reaction got accelerated and there was a blast*." On 22nd June, 2016, there was another accident and one worker died. (65) A blast occurred in the scrap yard while workers were cutting empty chemical plastic drums; one drum still contained isobutyl formate, which is highly flammable, and it exploded. Two workers were injured and were treated in a hospital. There was a reactor blast on February 23rd, 2022, which injured five workers, one of whom died during treatment. (66) According to the Deputy Inspector of Factories, after neutralizing material in one reactor with nitric acid, the material was transferred to another reactor and some material got stuck in the bottom pipeline—causing a temperature rise (this material should be stored at minus 20 °C), which may have triggered the blast. When this accident happened, people from nine neighbouring villages, led an agitation and complained against Hetero, Nakkapally. They said that the company had installed a 4 km effluent pipeline into the sea, and had discharged harmful effluents into it "for years", which caused environmental damage. (67) Media said that Hetero stopped the operations in the plant immediately after the tragedy, transported the injured workers to hospitals.The minor accident, where twelve workers were hospitalised happened in 2025. (68) On 4 February 2025 (night) at the Hetero unit in Nakkapalli, a chemical-fume or gas leak occurred. These accidents suggest that practically, some issue is there with respect to SOPs or workplace safety drills to employees. There is no transparency in the way the company is responding to accidents. A case was filed against Hetero Nakkapally in NGT, Chennai accusing it of marine pollution. The MoEFCC confirmed the allegation. Its affidavit stated that monitoring of Hetero Infrastructure by the Integrated Regional Office (Vijayawada) found partial non-compliance with several EC conditions and elevated chloride and TDS levels in groundwater near the site. In *Kambala Ammoriya v. Union of India and Ors., OA No. 23 of 2022 (NGT Southern Zone, Chennai)* case, the MoEF and CC affidavit (2023) recorded "*11 of 52 conditions partially complied, ground-water contamination beyond limits, and monitoring deficiencies*". The NGT did not impose a fine, but the affidavit established ongoing environmental-compliance deficiencies at Hetero's SEZ complex. The NGT proposed action after an ATR review. (69) So, the claims in the Sustainability Report do not seem to be justified when held against the record of accidents and pollution cases. Hetero (Nakkapally)'s rating has to be high if its certifications and international visibility is considered but because of its record of accidents and pollution charges, it is poor in compliance, good in oversight and poor in commitment to employee welfare and in workplace safety.

e) Escientia Advanced Sciences Pvt. Ltd: Escientia Advanced Sciences Pvt. Ltd, has the following certifications, oversight or positives:WCs from CDSCO, a NAI from the USFDA, a CTO and HWA renewal from the APPCB, (70-72, 75, 76) an EC letter was issued by the MoEF of India on February 13, 2012. (73) This and the "Initial Environment Examination, (Dec 2022)" apply to the entire cluster in which this manufacturer is located and it implies that its obligations on compliance are met at cluster level. (74) It can be inferred from all these certifications that Escentia Advanced Sciences has multi-level regulatory oversight and hence a good level of

regulatory compliance. A major accident occurred in this company in August 2024, resulting in deaths of some workers and injuries to many others. (77) A highly inflammable solvent leaked through piping, formed a vapour cloud, and ignited, probably on touching a hot surface or spark or static, (78) *The Hindu* reported the Director General, State Disaster Response and Fire Services Department as saying that there are basic defects in the design of the building (a reactor over an electrical panel and a closed building). (79) The Hindu also reported how Scientists for People, an NGO based in Hyderabad as criticising the report of the high- level committee, appointed by the state government, for lacking details and for failing to point out regulatory lenience. (80) A question was asked in the Rajyasabha on this incident, and in a written answer it was reported that three inspections (2.2.2018, 17.11.2021, 19.10.2022) were carried out by different agencies and non - compliance issues, such as, *"(1) lack of adequate condition monitoring of plant and equipment; (2) inadequate risk assessments; (3) inadequate standard operating procedures; (4) inadequate emergency response plan; (5) ventilation systems improvement; and (6) inadequate fire workplace safety systems*" were pointed out, to the company. In this same answer, it was revealed that a compensation of 32 crores was given to the families of the victims and that the company claimed it has 93.5 % compliance, and that it has conducted workplace safety drills. (81)The media and scientists (NGO), opine that the ease of business doing concept, permitted and actually encouraged in SEZs by the central as well as state governments, is responsible for a possible laxity in regulatory control. (80)

Escientia Advanced Sciences (Atchyutapuram SEZ) is a typical example of a company with required certifications but having multiple practical issues and is rated as poor in regulatory compliance, poor in regulatory oversight, poor in commitment to employee welfare and very poor in workplace safety.

f) Sahithi Pharma (Atchyutapuram SEZ): Sahithi Pharma is a five-year old API manufacturing company, formerly known as Sruthi Chemicals. Publicly visible Certifications:Sahithi has two inventories of the CPCB, National Inventory on Generation and Management of Hazardous and Other Wastes (2022–23) and the same inventory of 2023-2024. They list Sahithi Pharma, the former in page 82 and the later in page 86. (82, 83) A safety audit was carried out by the factories department on this unit in April 2023 (two months prior to the accident) and the auditors gave 70 recommendations to this company to be complied with. (84) However, it did not give any compliance report, at least till the date of the accident in 2023 as evidenced by a newspaper article.

An accident happened in June 2023, in which there were multiple deaths and injuries to many workers. There was a government ordered probe by five members, there was a case in the NGT and the APPCB ordered a closure of the company (closure notice was submitted to the NGT). A compensation of 25 lakhs rupees was granted to each of the kin of the workers who died in the accident, but, as per the newspaper report, after about a month of the accident, only 1 lakh was given to each of them, by the company. If any amount was paid at a later date to them, it is not publicly known. (85, 87, 88) The important points about this accident: an unqualified person as a supervisor for a chemical unit (a B.Com degree holder for a distillation unit), operational failure (vacuum pump of the distillation unit was shut off- led to build up of pressure- led to explosion), blast happened near to a flammable solvent, non-compliance in spite of multiple improvement notices, and the presence of 107 safety lapses. (82) There were two statements that are applicable to all API companies in SEZs of Andhra Pradesh, one is that a safety audit was done before July 2023, not only in Sahithi Pharma but in a total number of 186 hazardous units. (89) Another statement was given by the government of AP that the Vizag unit of SEZ is going to get an off-site workplace safety plan. (90) Taking all these points into consideration, Sahithi Pharma's performance can be rated as good in regulatory oversight, very poor in compliance, poor in the other two criteria.

g) Sainor pharma: Sainor pharma has the following certifications: a Consent to Establish order from APPCB Vijayawada and a Consent and authorization order, from APPC Board Zonal, Visakhapanam [91], a WC from CDSCO (International Cell) (page 58/71), (92) listed in the WHO GMP (COPPS) as an API manufacturing unit in Andhra Pradesh (No.103 in the list), (93) consent and authorisation letter from the APPCB. (90) Its web site claims it is compliant by cGMP and USFDA norms and that it has quality audits to ensure all its products are of the highest quality. The company suffered a serious accident in 2015 and then another in 2022. (95, 96) There are multiple national and international level references that point out the negligence towards workplace safety and quality in this company. (34) Two workers were charred to death and five others were injured after a reactor blast rocked the active pharmaceutical ingredients manufacturing plant of Sainor Life Sciences Private Limited, in 2015. (95) Two persons died due to inhalation of H_2S gas at M/s. Sainor Life Sciences Private Limited, on June 29, 2020. (96)A joint committee inspected the premises after the accident and submitted a report to the NGT. (97) In this report, the committee pointed out several faults, such as improper handling of the process, lack of SOPs, personnel not wearing protective gear, negligent handling of hazardous equipment, employees being underqualified for the job they were doing, among others. NGT directed that safety audits be conducted for the pharma city in Vishakhapatnam along with other locations in the State. (98) The district collector of Visakhapatnam, explained to the media, that workmen, who were working without any protective wear, were transferring mother liquor from one reactor to another, directly by inserting a hosepipe into a 2- inch nozzle, which had no nipple arrangement. (99) The report also mentioned that some workmen working there, joined their jobs on that day only, one workman had a service experience of 12 days, and that there were neither SOPS nor any alarm systems. (97) Swedish financial services group Nordea, in a report following its investigation on pharma pollution in Hyderabad and Visakhapatnam, severely criticised pharma companies and the Pollution Control Boards (PCB) of both states for spoiling the environment in Visakhapatnam and in Hyderabad. (100) Media reports criticised the API companies for failing to comply with the safety or GMP

rules and for causing harm to the environment. (101, 102) Considering all these issues, Sainor may be graded as poor in all the four domains, i.e., regulatory compliance, regulatory oversight, commitment to employee welfare and commitment to workplace safety.

h) Synergene Active Ingredients Pvt. Ltd, Unit III: Synergene Active Ingredients Pvt. Ltd, Unit III, Plot no 59 A, JN Pharma City, Parawada has a production capacity of 380 KL, and employee strength of 250. Certifications: WHO GMP certification, ISO 90001, 140001 and 45001, (103) certifications from the APPCB to operate and it has GMP and GLP from the CDSCO, (104-106) proposal to manufacture hazardous APIs. (107) It displays on its website, WHO GMP certificate (it is no. 111 in the list of Andhra Pradesh companies in the list given in December 22) (9) given by the DCA of Andhra Pradesh and its ISO certifications. All these taken together mean that it has plans to handle its pollution load, effluent treatment, emission control, and hazardous wastage treatment. WHO GMP and GLP certificate holding and the ISO certifications mean that it has process understanding and SOPs, quality management policies and environment friendly policies. But an accident happened, resulting in death of three workers and injuries to some workers. A flash fire occurred in the early hours of August 23rd, at this unit, while workers were charging losartan potassium in the reactor, which was pre-charged with methanol. (108, 109) Media reports attribute this to a lack of closed transfer systems for solvents and workers not wearing protective gear (poor employee training, lack of safety awareness of employees). (108, 110) All these documentations attest to the following statement, followed by assessment: All the rules are being followed on paper, but practically limitations are there. So, the rating is average in regulatory compliance, good in regulatory oversight, and poor in commitment to employee welfare and in workplace safety.

i) Ms Laurus Labs Limited (Unit-III): Ms Laurus Labs Limited (Unit-III), Plot No.18, Jawaharlal Nehru Pharma City, Parawada (M), Visakhapatnam 531021, Andhra Pradesh received several certifications which are as following: WHO Certifications in 2017, and in 2020 (107, 115) Establishment Inspection Report from the USFDA in 2015 and 2024, (116, 119) and Consent for Establishment from APPCB, (110) Written Confirmations from the CDSCO in 2019, 2020, 2022, and 2024. (115-118) Its integrated reports of 2020-2021 and 2022-2023 give data and information to substantiate their claims that they have in place SOPS, and procedures for all their positive and progressive policies that they profess. Key words in their integrated reports include transparent, ethical and accountable governance, risk management, compliance with regulations, workplace safety, employee benefits, reducing waste, green chemistry, health and wellness programmes, employee engagement, and service awards to employees. (112, 113) The key words in the BRSR are renewable energy, emission reduction, employee safety, welfare measures, ethical governance, and community engagement. (121, 122) All these positives make Laurus Labs the ideal API manufacturer, and yet an accident happened. As per the disclosure of Laurus Labs to the Stock Exchange and as per media reports, a fire accident happened in Laurus Labs Unit III, on 27th December 2022. (124,125) The fire was caused by the leakage of toluene solvent. When the workers were trying to arrest the leakage of toluene, the solvent caught fire. Media reported some leaders saying that the management was not following the workplace safety norms to a satisfactory level. (116) The evidence in the form of all the documents and media reports help us in making the following assessment: We can give ratings as good in regulatory compliance, excellent in regulatory oversight, average in commitment to employee welfare and average in commitment to workplace safety.

j) SB Organics Ltd: SB Organics Ltd is incorporated as a public limited company in Telangana. Unit I at Chandapur village, Sangareddy District, Telangana is listed on their site as producing guanidine nitrate and guanidine carbonate. The company is unlisted, i.e., it is a public company but not listed on a recognised stock exchange. This company is not a part of any SEZ. In the list of companies operating under the consent management of TSPCB SB organics is listed at no.191. (127) Its certifications: environment clearance from State Environment Impact Assessment Authority (SEIAA) Telangana, (124) a Consent for Operation renewal from the Board via order dated 21.06.2021, which is valid until 31.07.2026, and a proposal for the production of intermediates. (129) on 3rd April 2024, a major explosion occurred at this unit while it was producing guanidine nitrate; six employees died and many were injured. (130, 131) It was found that the reactor lacked an active cooling system for an exothermic reaction and depended on a system of natural cooling. Hot oil leaked from the reactor's jacket and contacted the reaction mixture (guanidine nitrate) triggering the explosion. (128) Media reports cited experts from NGOs to say that SB organics obtained approval only for guanidine nitrate but not for ammonium nitrate (which was also being used in the process and also was an explosive material), and giving permission by way of a CFE order to SB Organics without checking this point, is a fault on the part of the state PCB. (133) Investigations by the state PCB, after the accident, revealed that the company's operations compromised on the workplace safety of workers and environment. State PCB levied a fine of 31 lakh on the company. (134) Media reported that "*it was an accident waiting to happen*", because of the poor process design, and lack of trained and properly qualified personnel. (135) Considering all this documentary evidence, SB organics has to be graded as very poor in all four categories.

5. Results and Discussion

Three companies (S.Nos. 1, 2, and 9) have all ratings as above average or excellent. All the three are listed on stock exchanges and are parts of pharma clusters. Five companies (S.Nos.4,5, 6,7, and 10) (4 and 5 are parts of SEZs and are not listed) are rated as poor or very poor, (Nos.4 and 6 are good in oversight). One company (S.No. 3) (No. 3 is not in SEZ or in a cluster) is unlisted) is rated in a mixed way, getting good or average in one domain and poor in others. This is because it suffered accidents in spite of their visibly strong oversight.

Table 1. Regulatory Compliance, Regulatory Oversight, Commitment to employee welfare and Workplace safety Ratings for Ten companies

Company & Unit No.	Listing Status	Factory Address	SEZ Status	Compliance	oversight	Employee welfare	Workplace safety
Aurobindo Pharma Ltd (Unit XIV – now Apitoria 6)	Listed – NSE/BSE filings & BRSR 2023–24 submitted to NSE (Aurobindo Pharma Ltd., 2024).	Plot No. 17 E, Bonangi Village, JN Pharma City, Parawada Mandal, Visakhapatnam Dist., Andhra Pradesh 531019 (CDSCO WC 7-5/2013/EU/WC-0461 dated 18 Sep 2023).	Could not confirm (JN Pharma City cluster; WC does not specify SEZ/DTA).	good	excellent	good	average
Gland Pharma Ltd (Vizag API Facility)	Listed – NSE/BSE filings; Annual Report 2023–24.	Plot Nos. 49 & 50, JN Pharma City, Parawada Mandal, Visakhapatnam 531019 (AP) – CDSCO WC 0427 dated 22 Jun 2023.	Could not confirm (JN Pharma City cluster; no SEZ designation).	excellent	excellent	Very good	Very good
Porus Laboratories Pvt Ltd (Unit IV)	Unlisted private company – APPCB CFO 2019.	Akkireddigudem (V), Musunuru (M), Krishna District (AP) – APPCB Consent Order No. APPCB/VIA/VIA/14347/HO/CFO/2019 dated 17 Sep 2019.	Not in SEZ – outside any notified SEZ area (per MoEFCC EC J-11011/265/2015).	average	average	poor	poor
Hetero Drugs Ltd (Unit IX)	Unlisted company (Part of Hetero Group).	Plot No. 1, Hetero Infrastructure SEZ Ltd., N. Narasapuram Village, Nakkapalli Mandal, Visakhapatnam Dist., AP – CDSCO WC 75/2013/EU/WC-0066 dated 3 Sep 2019.	SEZ – Confirmed ('Hetero Infrastructure SEZ Ltd.' in official address).	poor	good	poor	poor
Hetero Labs Ltd (Unit IX)	Unlisted company (Part of Hetero Group).	Plot No. 2, Hetero Infrastructure SEZ Ltd., N. Narasapuram Village, Nakkapalli Mandal, Anakapalli Dist., AP 531081 – CDSCO WC 7-5/2013/EU/WC-0065 dated 23 Jun 2023.	SEZ – Confirmed ('Hetero Infrastructure SEZ Ltd.' in address).				
Hetero Labs Ltd (Unit III)	Unlisted – Part of Hetero Group.	Plot No. 4, Hetero Infrastructure SEZ Ltd., N. Narasapuram Village, Nakkapalli Mandal, Visakhapatnam Dist., AP – MoEFCC EC No. J-11011/398/2010-IA II (1), 2022–2023 compliance filings.	SEZ – Confirmed (Environmental Clearance explicitly covers Hetero Infrastructure SEZ).				
Escientia Advanced Sciences Pvt Ltd	Unlisted private company.	Plot Nos. 11, 11A, 12 & 12A, Andhra Pradesh Special Economic Zone (APSEZ), Atchutapuram, Visakhapatnam – CDSCO WC 7-5/2021/EU/WC-0501 dated 15 Jun 2022.	SEZ – Confirmed (address includes 'APSEZ Atchutapuram').	poor	poor	poor	Very poor
Sahithi Pharma Pvt Ltd (Unit I)	Unlisted private company.	Anakapalli District (Atchutapuram area) – address as per NGT/APPCB case filings.	Could not confirm (SEZ/DTA not stated; Atchutapuram industrial cluster only).	Very poor	good	poor	poor
Sainor Life Sciences Pvt Ltd	Unlisted private company.	Jawaharlal Nehru Pharma City, Parawada (M), Visakhapatnam – CDSCO WHO-GMP list.	Could not confirm (JN Pharma City cluster only).	poor	poor	poor	poor
Synergene Active Ingredients Pvt Ltd (Unit III)	Unlisted private company.	Plot No. 59-A, JN Pharma City, Parawada (V & M), Visakhapatnam – Govt. of AP DCA certificates.	Could not confirm (JN Pharma City cluster only).	average	good	poor	poor
Laurus Labs Ltd (Unit III)	Listed – NSE/BSE filings, BRSR and Integrated Report 2023-24.	Plot No. 18, JN Pharma City, Parawada (M), Anakapalli Dist. 531021 – CDSCO WCs (2022 & 2024 series).	Could not confirm (JN Pharma City cluster only).	good	excellent	average	average
SB Organics Ltd (Telangana)	Unlisted private company.	Sy. Nos. 350-352, Chandapur Village & GP, Shankarampet-R Mandal, Medak/Sangareddy Dist., Telangana – TSPCB OCMMS listing.	Not in SEZ (no SEZ designation in state PCB record).	Very poor	Very poor	Very poor	Very poor

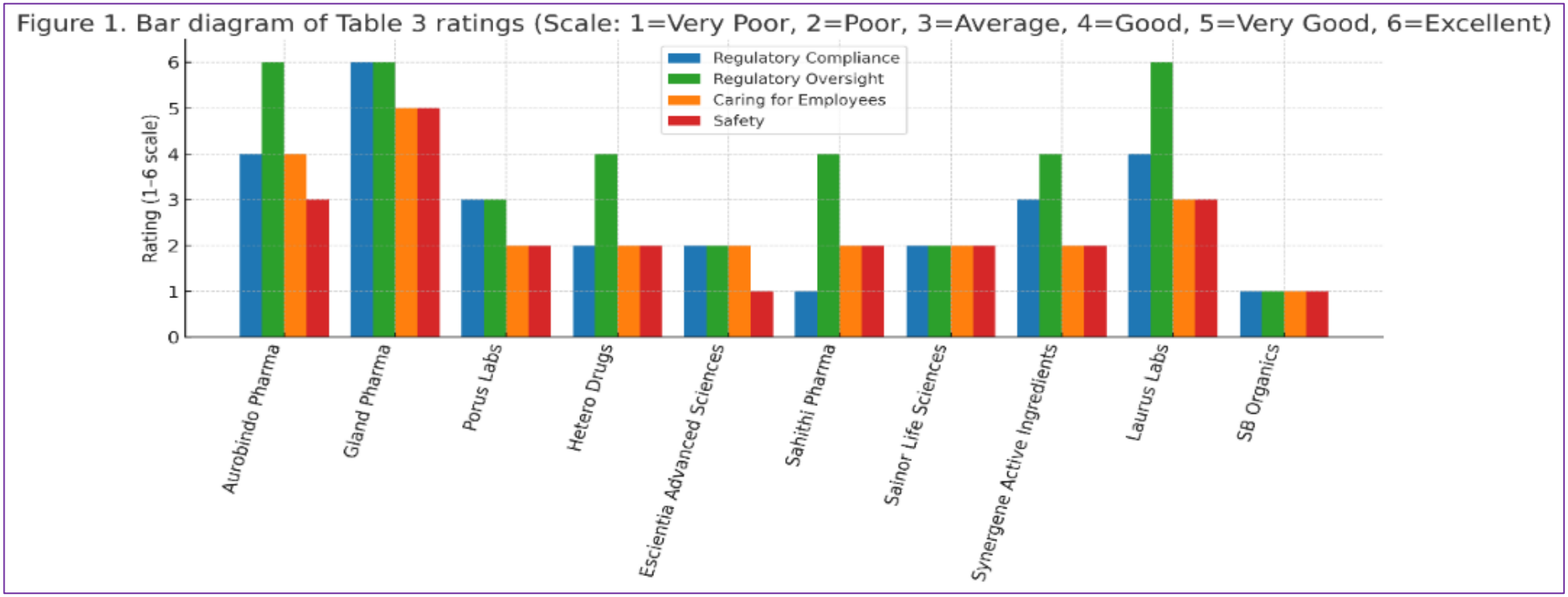

Figure 1. Comparative performance of 10 API manufacturing companies in regulatory compliance, regulatory oversight, employee welfare and workplace safety

Overall pattern: Listed companies tend to perform better across all four criteria. SEZ-based unlisted companies, studied in this work, (Hetero SEZ infrastructure and Escentia) seem to perform poorly, especially on commitment to employee welfare and workplace safety.

Inspections: Since December 2022, a total of 905 drug manufacturing and testing units have been inspected by CDSCO and State Drug Regulators, resulting in 694 enforcement actions (such as stop-production/testing orders, suspensions, cancellations, and show-cause notices) — Lok Sabha Unstarred Question No. 2226, answered on 1st August 2025 by the Ministry of Health and Family Welfare. (136) The number of factory inspections carried out, all over India, fell from 1,18,952 in 2014 to 67,674 in 2023; from 4607 in 2014 to 2982 in 2023 in Andhra Pradesh. The number rose slightly in Telangana, from 3849 in 2014 to 4623 in 2023.This data and the small number of CDSCO inspections clearly indicate a reduced regulatory oversight. This fall in the number of inspections could have had an effect on the fall in performance of the API manufacturers in criteria like compliance, commitment to employee welfare and in workplace safety.

6. Summary and Discussion

Several accidents happened in API manufacturing industries in Andhra Pradesh and in Telangana. In this context media, NGOs, academics and regulatory bodies reacted and called the API manufactures for accountability. Investigation report of "Scientists for people", an NGO which was reported by https://www.joiff.com/, suggested "*lack of proper process management as the cause of the accidents, unscientific inquiry methods, regulatory weaknesses, secrecy in reports, and poor enforcement by APPCB and Factories Dept*" as reasons for the accident in SB Organics (2024), in addition to poor reactor designing, lack of a cooling system and lack of workplace safety culture. (135) An engineer, observed on CCTV footage, supervising the reactor that exploded, was an electronics engineer. As per the joint committee report to the NGT, there was a gap of 21 minutes between release of decomposition from the reactor and the final explosion. This time should have been used for the evacuation of the staff. Huge clouds rose from the reactor and 30 seconds later, the explosion happened. Had they evacuated even in those 30 seconds, some lives would have been saved. But the MD and the employees that gathered around him, stayed close to the plant and died. (139, 140) They just did not know that they were facing danger. Several studies examined causes of industrial accidents, noting that bulk drug units are especially vulnerable due to their use of hazardous chemicals. A survey of 365 managers, in Iran, identified unsafe acts, poor working conditions, and weak workplace safety regulations as primary causes, emphasizing the need for regular safety training. (141) Indian researchers urged a unified national policy for the API sector. (6) The NGT committee on the Sainor (Vizag) accident found operational negligence, inadequate training, and absence of SOPs and protective gear, as responsible for the accident. (93) Media also reported that inspections of hazardous factories have sharply declined even as their numbers increase. (142) T.C. James, (2020), asserted that MSMES lack proper infrastructure, and suffer from non-compliance with environmental and regulatory laws. (139) Studies highlight highly centralized authority under the Development Commissioner and poor conditions of labour which collectively reduce accountability and worker protection in hazardous industries in SEZs. (144-146) The suggestions given by the committee (in page 18/28 of the judgement of the NGT) (report is reference 97, judgement is given in reference no. 142) which investigated the accident in Sainor life sciences and which were endorsed by the honourable National Green Tribunal are valid for every API manufacturer. (147) They said, every manufacturing unit shall: Manufacture only those products for which they received consent from the authorities, prepare SOPs for all products they are manufacturing, train all their employees on the SOPs of the manufacturing process and also on the workplace safety steps, prepare for emergencies, conduct mock drills, install sensors for gases and alarm systems, give personnel protecting equipment to all employees, and recruit qualified and experienced staff.

7. Conclusions

Bulk drug manufacturers must show a commitment towards workplace safety of the workers and pure and clean environment and display steps taken by them towards these ends and these measures must be verifiable by common public. Workplace safety rules must have no exemptions. All inquiry reports (district, APPCB, NGT-appointed committees) must be published within a fixed timeframe. Inspection frequency must be tied to hazard potential. Units with repeated violations or major accidents should face license suspension or capacity cap until workplace safety upgrades are demonstrated. It should be ensured that the same defaulter company does not manage to obtain a fresh license under a different name. Regulators need training in chemical engineering and process workplace safety (HAZOP, runaway reaction analysis. Creation of a specialized Chemical Workplace safety Cell in every state PCB, with mandatory annual audits of high-hazard units. Indian SEZs and pharma clusters need strong workplace safety rules, transparency, risk-based oversight, periodic review mechanism of their performance, an accident database and emergency planning to prevent accidents and loss of precious lives.

Limitations: This work based its rating (rating conceptualised by the authors) and its discussion on evidence available in public domain. There may be evidence available that is not publicly documented.

Acknowledgments

We would like to express our sincere gratitude to the editorial team and reviewers of the International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of the article.

Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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