

**ENVIRONMENTAL AUDIT REPORT
(FORM – V)**

OF

**M/s. DANO VACCINES & BIOLOGICALS (P) LTD.
575, SHIVAREDDYGUDA
GHATKESAR MANDAL
MEDCHAL DISTRICT
TELANGANA STATE**

**FOR THE
FINANCIAL YEAR ENDING**

31ST MARCH 2024

(FORM - V)

**ENVIRONMENTAL STATEMENT OF M/s. DANO VACCINES & BIOLOGICALS PVT.LTD.,
575, SHIVAREDDYGUDA, GHATKESAR MANDAL, MEDCHAL DISTRICT, TELANGANA
FOR THE FINANCIAL YEAR ENDING MARCH- 2024**

Introduction:

Environmental Statement/Environmental Audit Report is a report that provides the complete scenario of the Environment Quality in and around the industry in operation. A gazette notification on Environmental Statement / Environmental Audit was brought out by the Ministry of Environment & Forests on 13th March 1992 and amended vide notification G.S.R. 386 (E) dated 28th April, 1993 under which every person seeking consents under Sec. 25 of the Water (Prevention and Control of Pollution) Act 1974 or under Sec. 21 of the Air (Prevention and Control of Pollution) act 1981, or Both or Authorization under the Hazardous Wastes (Management and Handling) Rules, 1989, issued under the Environment (Protection) Act 1986 shall submit an environmental statement for the year ending 31st March in Form - V to the concerned State Pollution Control Board on or before 30th day of September every year.

Definition of Environmental Audit:

The International Chamber of Commerce defines Environmental Audit as a Management Tool comprising of a Systematic, Documented, Periodic and Objective Evaluation of how well environmental organization, management and equipment are performing with the aim to regulate the environmental policy by:

1. Facilitating management control of environmental practices, and
2. Assessing compliance with company policies, which would include meeting regulatory requirement.

As a management tool, environmental audit would allow the management to look inwards and see as to whether cleaner technologies could be adopted which would avoid generation of wastes. The audit strikes a balance between the industrial unit and regulatory bodies by resolving the conflicts of their interests by assisting the industrial units to attain compliance with the prescribed standards and improve productivity. Preparation of such audits also help to bridge the gap by assuring optimum protection of environment and minimizing the insurance liability by better environmental management. There is hardly any management goal that is not served by environmental audit from prevention of waste and excessive consumption of resources, creation of an environment conducive to efficiency and optimum productivity and a harmonious relationship with common public and regulatory authority. Thus, environmental audit can help improve corporate environmental performance and also provide basis for reporting this performance to company stake holders.

Dano Environmental Statement

M/s. Dano Vaccines & Biologicals Pvt. Ltd., being conscious of its responsibilities towards Protection of Environment by minimizing the pollution load due to the project activities has undertaken preparation of Environmental Statement / Audit Report for their unit for the Financial year ending 31st March 2024.

THE COMPANY:

M/s. Dano Vaccines & Biologicals Pvt. Ltd. is in the line of manufacturing Tetanus Toxoid (Adsorbed) I.P., which is the only preventive medicine available for protecting the human beings from Tetanus infections. The unit is located on a 2.29 acre plot bearing plot No. 575, in Sivareddyguda, within the periphery of Ghatkesar Mandal of Medchal Dist, falling on the Hyderabad - Warangal State Highway at a distance of about 22Kms from the city of Hyderabad. The industry is in operation since 1985 onwards. The manufacturing of the Vaccine is based on the toxoid processed from *Clostridium tetani*, which is considered to be a hazardous microorganism and is categorized under risk group III under the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms / Genetically Engineered Organisms or Cells, 1989.

OBJECTIVES OF THE PROJECT:

- To make available the product at a very reasonable cost compared to imported product.
- To make available the product easily to the other units who develop this product for consumption by the end user.
- To adopt the best technology available for such product manufacturing.
- To make use of the resources available and thus strengthen the economy.
- To utilize the services of the local people and improve their standard of living.
- To manufacture the products under Environment friendly conditions there by protecting the Environment

LOCATION

The site has been selected on the basis of scientific evaluation of various environmental, production, financial and other aspects. The plant is located in a 2.29 acre plot at Shivareddyguda, Ghatkesar, Ghatkesar Mandal, Medchal District of Telangana at a distance of 22Kms from the City of Hyderabad on Hyderabad – Warangal State Highway.

The industry has been regularly applying for and obtaining the Consent for Operation under Air Act and under Water Acts respectively.

INDUSTRY AND ENVIRONMENT:

M/s. Dano Vaccines & Biologicals Pvt. Ltd., manufactures Tetanus Toxoid (Adsorbed) I.P using *Clostridium tetani* as the production system apart from chemicals like peptone, Sodium chloride etc., as raw materials. The handling and processing of *Clostridium tetani* and other chemicals carry limited risks to the people working on it and also to the environment, provided necessary precautions are taken while handling them. M/s. Dano Vaccines & Biologicals Pvt. Ltd., is conscious of its responsibilities towards the Environment and the Society in minimizing the pollution load due to the project activities and is following Good Laboratory Practices (GLP). It is also adhering to stringent environmental management practices. The industry has also applied for Environmental Approval to the Genetic Engineering Approval Committee (GEAC) under Ministry of Environment and Forests, New Delhi. An Environmental Clearance was accorded by GEAC, based on the application made by the industry. It has prepared an On-Site Emergency Plan for which the studies were carried out. The industry has also constituted an Institutional Bio-Safety Committee (IBSC) involving experts from different fields, including a main nominee from Department of Biotechnology, and has already conducted the meeting regularly twice a year. It is implementing all the suggestions put forth by the IBSC.

The industry has taken all necessary precautions to combat the above polluting factors. Air Pollution caused by the oil fired boiler is quite negligible as the boiler is operated only for a maximum of 6-7 hours per day as the industry operations are limited only to a single shift; Autoclaving the contaminated equipment, materials and killing the live organisms if any, by heat treatment for control of Water Pollution. The effluents generated are decontaminated and after treating in the ETP, it is used for the development of the Greenbelt inside the plant premises. The industry also intends to monitor regularly the pollution generated in Air and Water by appointing Consultants.

The solid waste in the form of broken / rejected ampoules and vials are discarded and disposed off as scrap. Other solid waste from the animal section is being disposed to third party biomedical waste service providers M/s Sattva Global Services Pvt. Ltd.

The industry has been exempted from obtaining GEAC Approval by Genetic Engineering Approval Committee vide Lr. No. 13/4/99-HSMD dated 3rd May 2000. However it is regularly conducting Institutional Bio-Safety Committee (IBSC) Meetings and is complying with the directions of the Committee.

The Environmental Statement in Form - V shows the Water Requirement, Water consumption for manufacturing one Single Dose, Raw Material Consumption for manufacturing the product, Quantity of Pollution generated in Air and Water, its control and discharge, Generation of Hazardous Waste and its Quantity, Quantity of Solid Waste Generated on daily basis, its treatment / disposal, Green Belt Development,

Dano Environmental Statement

Re-use / Recycling of the Waste water generated etc. The statement also provides the measures the industry proposes to adopt in controlling / abetting the pollutants generated from the project site, etc.