THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

DR. REDDYS LABORATORIES LIMITED, TELANGANA-INDIA

PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Dr. Reddy's Laboratories Limited
Corporate address of manufacturer	Formulation Tech Ops – II, Survey No 42p, 43, 44p, 45p, 46p, 53, 54&83, Bachupally Village, Bachupally Mandal, Medchal Malkajgiri District - 500090. Telangana State, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Survey No 42p, 43, 44p, 45p, 46p, 53, 54&83, Bachupally Village, Bachupally Mandal, Medchal Malkajgiri District - 500090. Telangana State, India
Unit/ block/ workshop number	Not applicable
Inspection details	
Date of inspection	26th - 27th September, 2024
Type of inspection	GMP pre-registration inspection
Introduction	
General information about the company and site	Dr Reddy's Laboratories Limited was commissioned on 1997 to manufacture solid dosage forms sch as tablets, capsules and pellets. It is located at Bachupally, 30km from the north-west of Hyderabad city and approximately 65km from Rajiv Gandhi International Airport, Shamshabad.
History	The facility has been licensed by the Drug Control Administration of Telangana, India with license No. 63/RR/AP/96/F/R to manufacture and sell general tablet, capsules and pellets. The site has been inspected by several medicine regulatory authorities and was issued GMP Certificates including Government of upper Bavaria, Eurasian Economic Union, Brazilian Ministry regulatory authority and Ukraine

Brief report of the activities undertaken	
Areas inspected	The inspection focused on external surroundings, production areas starting from incoming raw material warehouse, manufacturing and packaging areas to the finished goods warehouses, quality control laboratory and utilities including water treatment plant and HVAC system. The inspection also verified the qualification of personnel involved in various lines of production, premises layout and design, sanitation and hygiene, and equipment used in various manufacturing, packaging and quality control operations and review of documentation.
Restrictions	The inspection focused on the production lines for general solid dosage in form of tablets and capsules.
Out of scope	None
Production lines inspected by TMDA	General solid dosage in form of tablets and capsules
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating Ventilation and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TMDA	Tanzania Medicines and Medical Devices Authority

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of qualified personnel in different operational activities at the facility. Review of the facility organogram confirmed that the key positions were occupied by fulltime, qualified and experienced personnel. Head of Quality Assurance (QA), Production and Quality Control (QC) were independent of each other as evidenced in their job description and supported by organogram.

Personnel received induction training and on job training on cGMP as per company procedure and training program; interviews and records indicated that they were aware of cGMP, company policy and procedures. Medical examination was performed for newly employees and on routine basis for all working employees annually.

2. Premises

a. Layout and Design

The premises was properly located, designed, constructed and qualified to ensure unidirectional flow of the manufacturing operations carried out at the site. The production block was found in between the warehouses for raw and packaging material and the finished goods warehouse. The premise was constructed with reinforced cement concrete and the walls, floors and ceiling were constructed by using hard non-porous and non-shedding material with smooth finish to ensure effective cleaning.

The facility was designed in such a way that it allowed for a unidirectional flow of materials and personnel to minimize the possibility of contamination.

Generally, the premises were suitably located, designed, constructed and maintained to suit the operations which were carried out.

b. Sanitation and Hygiene

The premise was situated in an environment which presents minimal risk of contamination of raw materials and finished product. The premises and its external surrounding were cleaned and adequately maintained to prevent dust and contaminants. It was designed such that it prevents entry of insects and rodents through provisions of insects and rodents traps located at various points of the building,

To maintain the hygienic condition of manufacturing areas, change rooms were provided at each entry point from warehouses, sampling rooms, dispensing rooms and production areas to primary and secondary change room. The rooms were furnished

with washing areas/toilets, lockers for personnel belongings, stepover benches, hand sanitizing solution and relevant Standard Operating Procedures (SOPs) including SOP for entry and exit and pictorial demonstration for gowning and de-gowning. All workers were observed to be neat and wearing clean garments according to the area of operation.

Cleanness of the manufacturing area and equipment were maintained as per the procedure in place. In order to facilitate effective cleaning, disinfectants were used for area cleaning in rotation bases as per the defined frequency and cleaning records were maintained.

3. Production

Manufacturing operations were carried out in the designated and well segregated areas equipped with all necessary equipment to facilitate production operations and to prevent mix- up and cross contamination. Personnel change rooms were equipped with step over bench, cabinet for keeping garments, caps and shoes covers, hand sanitizer and dustbins.

To prevent cross contamination sampling and dispensing booth were provided with separate material and personnel entry. Manufacturing processes were initiated as per the BMR, sequence of activities was followed and properly recorded. In process control was performed in the production area. Packaging lines were also equipped with automatic machines and proper separations between the packaging lines was provided to avoid mix-ups.

Generally, the manufacturing processes followed unidirectional flow, thus minimizing the risk of cross contamination and mix ups.

4. Quality Control

The facility had Quality Control laboratory located at the administration block and had enough space and found to be properly maintained. It was sub- divided into instrumentation room, raw material testing room, in process and finished goods testing room, wet chemistry sections, stability chambers and microbiology section.

The laboratory was responsible for testing of raw materials, excipients, packaging materials, intermediates, finished products, stability samples, water and environmental monitoring. It was also responsible for preparation of specifications, reagents and volumetric solutions. Calibration of instruments and performance qualification of equipment was done and records maintained.

Laboratory had sufficient number of qualified personnel with appropriate knowledge and experienced to carry out quality control activities, analyst qualification records were availed.

5. Equipment

The facility had provided with all necessary equipment for production which were generally located, installed, designed, constructed and maintained to fit the purposes of the operations to be carried out. The layout and design permitted effective cleaning thus preventing the risk of cross contamination build - up of dust or dirty. Calibration and preventive maintenance were performed according to the established schedule.

6. Purified water System

Water Treatment Plant was found to be suitably designed, maintained and periodically monitored. Water was produced, stored and distributed in a manner that prevented unacceptable microbial, chemical or physical contamination.

The facility used water sourced from municipal as feed water to generate Purified Water (PW). The collected water was chlorinated and pumped through multigrade filter, softener, ultrafiltration and soft water was then pumped through RO I plant, 5-micron filter then RO II plant, electro-deionization unit to generate PW which collected in 1000L and 3000L SS 316 L storage tanks. Before being distributed to user points, PW passed through UV sterilizer and was maintained in continuous circulation at room temperature.

Cleaning and sanitization of storage tanks and distribution loop was done as per the procedure. Online monitoring for conductivity and TOC, routine sampling and testing for chemical and microbiological attributes were performed and records were maintained.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air-conditioning (HVAC) system was suitably designed, installed and qualified to maintain adequate temperature, relative humidity and pressure differential within the facility to prevent contamination and/or cross contamination. The system had a total number of 32 Air Handling Units (AHUs) designed to have air changes depending upon process requirement. The process operations have their own AHUs and dedicated AHUs were proved to function properly and supply filtered air to various manufacturing areas. Pressure differentials, temperature and humidity were also maintained within the limits as per respective area, design, criteria to avoid cross contamination. Temperature, relative humidity and pressure differential across rooms were controlled by Building Management System (BMS) and Environmental Monitoring

System (EMS). Relevant records for preventive maintenance and performance qualification were all reviewed and proved the suitability and functionality of the system.

8. Document Review

The review indicated that, facility had a documentation system to include procedures, records, specifications and policies to support quality management and quality assurance. Documents were verified to be developed, prepared, approved, distributed as per procedure for developing, approving and managing documents. Records were maintained.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, **Dr Reddy's Laboratories Limited Formulation Tech Ops - II Survey No 42p, 43, 44p, 45p, 46p, 53, 54 & 83, Bachupally Village, Bachupally Mandal, Medchal Malkajgiri District - 500090, Telangana State, India** was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicines for production of general solid dosage in form of tablet and capsules.

This report shall be valid for 3 years from the date of approval unless forms and operations herewith are changed or the site is no longer considered to be in compliance with current GMP requirements.

Part 4: References

1. TMDA, (2003)., Tanzania Medicines and Medical Devices Act, Cap 219, Tanzania Medicines and Medical Devices Authority, Government Printers, Dar es Salaam, Tanzania
2. TMDA, (2018), Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295. Tanzania Medicines and Medical Devices Authority. Government Printer, Dar es Salaam, Tanzania
3. TMDA (2023)., Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Dar es Salaam
4. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority Dar-es-Salaam, Tanzania.
5. SMF, (2024)., Dr Reddy's Laboratories Limited Formulation Tech Ops - II (FTO 2), India
6. TMDA, RIMS 2.0