THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ALLRITE PHARMACEUTICALS (UNIT - 1), SOLAN, HIMACHAL PRADESH, INDIA

PUBLIC GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Allrite Pharmaceuticals (Unit 1)
Corporate address of manufacturer	Plot No. 77, 78, 79-B & 116, EPIP, Phase-II, Village - Thana, Tehsil - Baddi, District Solan -173205, Himachal Pradesh, India Email address: vivek@allrite.in Telephone number: +91-9316093601
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Plot No. 77, 78, 79-B & 116, EPIP, Phase-II, Village - Thana, Tehsil - Baddi, District Solan -173205, Himachal Pradesh, India
Unit/ block/ workshop number	Not Applicable
Inspection details	
Date of inspection	03rd - 04th February, 2025
Type of inspection	Pre-registration GMP Inspection
Introduction	
General information about the company and site	The facility was situated in Himachal Pradesh, at Plot No. 77, 78, 79-A, 79-B & 116, Export Promotion Industrial Park, Phase-II, Village Thana, Tehsil approximately 9 km from Baddi Bus Stand, 55 km from Chandigarh International Airport and 300 km from Delhi International Airport. The facility was engaged in manufacturing of a wide range of general pharmaceutical products, in form of tablets, capsules, cream, ointment, and lotion as well as cosmetic products.
History	The plant was established in 2015.

	The facility was inspected and licensed by the Local National Regulatory Authority but had not been inspected by any foreign other National Medicines Regulatory Authorities
Brief report of the activities undertaken	
Areas inspected	Inspection focused on the following GMP systems; Inspection covered: • Pharmaceutical Quality System • Production System • Facilities and Equipment System • Laboratory Control System • Material System • Packaging and labelling System
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	General pharmaceutical products in the form of tablets, capsules, cream and lotion.
Abbreviations	**Meaning**
AHU	Air Handling Unit
BMR	Batch Manufacturing Records
CAPA	Corrective Actions and Preventive Actions
EDI	Electrode ionization
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
SS	Stainless steel
TMDA	Tanzania Medicines and Medical Devices Authority

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had a sufficient number of personnel with appropriate qualifications and experience to perform production and quality control activities.

They were aware of the principles of GMP which proved that they were provided with basic principles of GMP training and on job training relevant to their needs. The procedure and selected records for some personnel were reviewed and found to meet requirements.

The procedure for medical checkup was in place. Pre-employment health check was done for new employee and all other personnel were checked annually.

Moreover, personnel hygiene and hygienic practices were observed such that, in all areas personnel were observed wearing clean uniforms and maintain good hygienic practices.

2. Premises

a. Layout and Design

The facility was properly constructed, adapted and maintained to suit the manufacturing operations carried out. It consisted of two (2) main production blocks, the tablets & capsules block, and cream & lotion block, along with other subsidiary blocks for utilities, scrap yard and storage of drums, solvents, packaging materials and inflammable materials.

The building was made of reinforced concrete cement (RCC) structure. Outside walls were plastered and painted with suitable water proof enamel paint to provide a hard smooth finish. Walls in both warehouse and manufacturing areas were made of clean modular panels which were easy to clean, and in addition, SS panel cladded in all core processing areas (i.e., sampling, dispensing and manufacturing) and washing areas. Floor was epoxy coated and where applicable, kota stones were used in the warehouse. Covings were properly built

between walls and floor and between walls to ceiling to permit effective cleaning and minimize dust accumulation.

Generally, the facility was designed, located, constructed and maintained to minimize error, avoid cross-contamination, permit effective cleaning and provide a unidirectional flow of materials and personnel.

b. Sanitation and Hygiene

High levels of sanitation and hygiene were generally observed in all areas, including the surroundings.

The plant was provided with adequate change rooms which 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.

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

3. Production

The facility was dedicated for manufacturing of general pharmaceutical products, in the form of tablets, capsules, cream, ointment, and lotion as well as cosmetic products. The facility was provided with three (3) dispensing areas in the tablets & capsules block and five (5) dispensing areas in the cream & lotion block, each provided with separate entries for materials and personnel. Dispensing was carried under the laminar air flow (LAF) cabinets. Access to production area was restricted to authorized personnel only.

There was a Standard Operating Procedure (SOP) for receiving of materials and all incoming materials were generally controlled (quarantined, sampled, tested, released or rejected). Production areas were spacious enough and well designed to enable orderly placement of equipment and provide a unidirectional flow of materials and personnel to minimize mix-up and cross-contamination. Pressure differentials, relative humidity and temperature were monitored as per procedures and records were in place.

a. Tablets and capsules production Line

Manufacturing process of tablets involved wet granulation, which included the following steps; materials sifting, granulation, drying, milling, blending and lubrication, compression, coating and packaging. For capsules same processes as tablets followed by capsule filling. Measures were in place to minimize the risk of cross-contamination and microbial contamination of materials and products during manufacturing processes. In addition to air control systems, dust extractors were provided in all compression areas to prevent generation and spread of dust.

b. Manufacturing process of creams and lotion

Manufacturing process of creams and lotion simply involved bulk manufacturing prior transferring to storage tank. Bulk manufacturing involved preparation of the aqueous phase, the non- aqueous phase, emulsification, dispersion and final mixing. Critical process parameters i.e mixing speed and time, temperature and pH were monitored during manufacturing records were in place. To minimize the risk of particulate or microbial contamination of the materials and products, manufacturing operations were carried out in closed vessels vacuum piping system in the classified areas. All the manufacturing and storage vessels were made of SS material.

Generally manufacturing processes were initiated as per the BMR and sequence of manufacturing process was followed and recorded in the BMR. Line clearance and in process quality checks were performed at appropriate stages as per respective products manufacturing process and laid down procedures, records were in place.

4. Quality Control

The facility had a quality control (QC) laboratory which was divided into different sections such as chemical laboratory, instrumentation rooms, microbiology section, stability room, and retained sample room. It was responsible for analysis and release of raw materials,

intermediates, packaging materials, finished products, water, stability samples, as well as conducting environmental monitoring. The QC laboratory had sufficient number of trained personnel with appropriate qualifications and experience. Modern analytical instruments were available, the same were found qualified/calibrated. The facility performed both accelerated and long-term stability studies in line with the respective procedures and protocols. Products were properly arranged in the chambers and were easily traceable. Reference and working standards were properly stored and easily retrieved.

5. Equipment

The facility was provided with sufficient number of equipment and instruments, appropriately for the manufacturing and quality control operations 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 schedules. Equipment was adequately cleaned and sanitized as per validated cleaning and available sanitization procedure; records were verified. Preventive maintenance, calibration and cleaning status labels were in place.

6. Water Treatment System

The facility had installed water treatment plant for the generation of Purified Water (PW). Water Treatment Plant was found to be properly designed, maintained, and monitored.

The facility sourced water from the bore well which was treated at different stages including chlorination, filtration, softening, RO, and EDI. From EDI purified water was stored in a 5 KL storage tank. Before being distributed to user points, PW passed through UV sterilizer and was maintained in continuous circulation loop at ambient temperature.

Performance of PW generation plant was monitored online through PLC system for flow rate, pH, conductivity, routine sampling and testing for chemical and microbiological attributes and records were maintained. Preventive maintenance, sanitization, and re qualification was performed as per procedures in place, records were verified.

7. Heating, Ventilation, and Air Conditioning

The facility was equipped with an HVAC system designed to provide filtered air, maintain proper temperature, relative humidity, and pressure differentials, while minimizing the risk of cross contamination between processing areas. The system comprised of 73 air handling units (AHUs) for the tablets & capsules block, and 56 AHUs for the cream & lotion block.

The procedure was in place for daily monitoring of the performance of the filters and records were maintained. Cleaning, change, storage and destruction of' filters were perfomed in accordance with respective blocks procedures. 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 of documents proved that, the company had a good documentation system as documents were designed, prepared as per the GMP requirements. The same were prepared, approved, signed and dated by appropriate responsible personnel and were distributed with care. During inspection, various documents were reviewed and were found to be in line with the respective SOPs. SOPs were presented at vantage areas in and were properly followed. Records were observed to be up to date; document review was done in timely manner as per the procedures.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in Part 2 above, **Allrite Pharmaceuticals, Unit 1, Plot No. 77, 78, 79-B & 116, EPIP, Phase-II, Village - Thana, Tehsil - Baddi, District Solan -173205, Himachal Pradesh State, India**, was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicines for production of general pharmaceutical products in the form of tablets, capsules, cream and lotions.

This TPIR will remain valid for three (3) years from the date of approval for GMP compliance provided that the outcome of any inspection conducted during this period is positive.

Part 4: References

1. Allrite Pharmaceuticals (Unit - 1), Site Master File AKH3/SMF/01 Effective date 24/02/2025.

2. The Tanzania Medicines and Medical Devices Act, Cap 219.

3. The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulations, GN No. 295.

4. The Tanzania Medicines and Medical Devices Authority Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities (Second Edition, January 2025).