THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

JUBILANT GENERICS LIMITED, UTTARAKHAND - INDIA
PUBLIC GMP DESK ASSESSMENT REPORT

Date: March, 2025

Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Jubilant Generics Limited
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Name: Jubilant Generics Limited Physical address of the site: Village Sikandarpur Bhainswal, Roorkee, Dehdradun Highway, Bhagwanpur, Roorkee, District-Haridwar Uttarakhand, INDIA Tel: +91 1332235161-67 Email: *Varun.jha@jubl.com*
Name of Unit/ block/ workshop number inspected	The applicant has declared the facility to have one manufacturing blocks
1.3 Inspection details	
Date of desk review	2nd August 2024
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	This facility was last inspected by USFDA from 25th January to 2nd February 2024 valid till 31st December, 2025
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	The facility is involved in the manufacturing of non-sterile products for human use inform of tablets and capsules, primary and secondary packaging and Quality Control testing.
Production lines applied at TMDA	General pharmaceutical products in form of tablets

Part 2: Review of submitted documentary evidence

2.1. Site master file (*describe consistency of SMF as per requirements*)
Contents and layout of Site master file SMF001 R023 presented complied with requirements stipulated in TFDA GMP Regulations, 2018

2.2. Provide list of all regulatory inspections carried out in the past three years.

This facility was last inspected by USFDA from 25th January to 2nd February 2024 valid till 31st December, 2025
(https://dps.fda.gov/decrs/searchresult?type=Jubilant+Generics)

This facility was also inspected on 09-12-2023 by Federal Agency For Medicines And Health Products by a competent authority of Belgium,
GMP Certificate No. BE/GMP/2023/023 was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database

2.3. Manufacturing license and GMP permit granted by the local National Medicines Regulatory Authority (NMRA).

It was stated in the site master file that, this site holds manufacturing license numbers 58/UA/2007 and 81/UA/SC/P-2010 which were valid up to 13th August 2024. These manufacturing licenses were valid when the applicant applied for GMP inspection, hence the same will not be requested from the applicant.

2.4. Valid GMP certificate issued by WHO listed authority and/or that from WHO prequalification and Regional Harmonization Initiatives/AMA (whichever is applicable) for inspection carried out within the past three years for production line(s) applied at TMDA.

Not applicable, see section 2.2 of this report

2.4.1. Name of SRA/WHO-PQ/RECs

USFDA and Federal Agency For Medicines And Health Products - Belgium

2.4.2. Dates of inspection
2nd August 2024

2.4.3. Scope of inspection / List of compliant production line

General pharmaceutical products in form of tablets

2.4.4. A confirmation by the senior QA representative that a full WLA audit covering the product(s) has been performed and all matters dealt with and attest to the authenticity of the information

Not provided but this can be waived since the manufacturing facility was inspected both by stringent regulatory Authority USFDA and Federal Agency For Medicines And Health Products by a competent authority of Belgium and deemed GMP compliant in accordance with Art. 111(4) of Directive 2001/83/EC

2.5. Regulatory Actions against the facility that were taken in the past three (3) years.

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.

2.6. PQR(s) of the concerned product(s) (If products have not been registered).

Accepted since the product applied for registration was registered.

2.7. Real time and Accelerated Stability studies under Zone IVb conditions (*If products have not been registered*).

Accepted since the product applied for registration was registered

2.8. Review of Aseptic processing and filling validation protocols and reports (*for sterile products).*

This is waived because the manufacturing facility applied for and was GMP certified by SRA for manufacturing of General pharmaceutical products in form of tablets

2.9. Review of validation master plan; policy on validation qualification and calibration (If no product has been registered).

Accepted since the product applied for was registered

2.10. Market complaints in the last three years for products applied at TMDA

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.

Part 3: Conclusion

Based on the desk assessment and evidence(s) provided Jubilant Generics Limited, Village Sikandarpur Bhainswal, Roorkee, Dehdradun Highway, Bhagwanpur, Roorkee, District-Haridwar Uttarakhand, India is considered to be operating at an acceptable level

of compliance with the requirements of the Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, 2018 general pharmaceutical products in form of tablets.

This TPIR will remain valid until 01st August, 2027, provided that the facility will remain compliant following any inspections conducted in the period.

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 (2023)., Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Dar es Salaam
3. 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