TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

AUROBINDO PHARMA LIMITED – UNIT VII, INDIA
PUBLIC GMP INSPECTION REPORT

10th December,2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Aurobindo Pharma Limited Unit VII
Corporate address of manufacturer	The Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hi-tech City, Hyderabad-500084, Telangana State, India www.aurobindo.com +91(0)8542238450
Inspected site	
Name & address of inspected manufacturing site	Unit-VII (SEZ), Plot No. S1, TSIIC-SEZ, Green Industrial Park, Polepally (V), Jedcherla (M), Mahboob Nagar (Dist.) T.S. 509302, Telangana State, India
Unit	Unit VII
Inspection details	
Date of inspection	5th – 6th November, 2018
Type of inspection	GMP Re-inspection
Introduction	
General information about the company and site	Aurobindo Pharma Limited Unit VII is situated at plot No. S1 in green Industrial park area, Polepally, Jedcherla, Mahboob Nagar district, Telangana state, about 60km from Ravji Gadhi International airport Hyderabad, India. The facility is engaged in manufacturing of general pharmaceutical products in form of tablets, capsules and powder (sachet), ARV products and oral contraceptives. The facility was inspected by Drug Control Authority of Telangana and was issued with Manufacturing License Certificate No. 22/MN/AP/2009 / F/R.
History	The facility has been inspected and issued with GMP certificate No. 22/MN/AP/2009 / F/R from the Drug Control Authority of Telangana. Other regulatory authorities which have inspected and approved the facility include USFDA, FDA(Ghana), PPB (Kenya), NDA (Uganda), NAFDAC (Nigeria), TGA (Australia) and MCAZ (Zimbabwe)

	This report presents the TMDA renewal GMP inspection which conducted on 9th -10th February, 2018.
Brief report of the activities undertaken	
Areas inspected	External environment, utilities, raw materials and packaging materials warehouses, production areas, packing area, finished goods store and quality control laboratory .
Restriction	General pharmaceutical formulations (OSD) including ARVs
Out of scope	The manufacturing line for oral contraceptive
Production lines inspected by TMDA	Non beta lactam general formulations (OSD) including ARVs
Abbreviations	**Meaning**
AHU	Air Handling Unit
ARVs	Antiretrovirals
API	Active pharmaceutical ingredient
EAC	East Africa Community
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating Ventilation and Air Conditioning
OSD	Oral Solid Dosage
QC	Quality Control
RLAF	Reverse Laminar Air Flow
RO	Reverse Osmosis
SOP	Standard Operating Procedure
SS	Stainless steel
TMDA	Tanzania Medicines and Medical Devices Authority
TPIR	TMDA Public Inspection Report
UV	Ultraviolet

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had sufficient number of qualified and experienced personnel to carry out the manufacturing activities. All key personnel in production, quality assurance and quality control department were identified in company organization chart. The head of

production was independent form quality control head in fulfilling their responsibilities as evidenced in their job description reviewed.

Different types of training were imparted to personnel including induction training, on-job, refresher and GMP training. Training Management System (Nichelon5 CMS software) was used for planning, documentation, tracking and reporting of training. Personnel were subjected to medical examination prior to and during employment once in a year as per company SOP. Medical examination policy and records were availed and found to be implemented as per requirement.

2. Premises

The premises was properly designed, constructed and maintained to ensure compliance in manufacturing process. The design of the premises consisted of two block which were general block and oral contraceptive block. Each bock had dedicated warehouses, manufacturing area, packaging area, quality control laboratory and utilities.

i. Layout and Design

The layout of the premises was designed to provide unidirectional flow of production activities which help in minimizing the risk of cross contamination and mix-ups. The manufacturing units were constructed with clean room modular panels coated with epoxy coating materials.
Epoxy coving on angles between walls to floors and walls to ceiling were provided to prevent dust accumulation and allow effective cleaning. Dedicated air handling units, reliable electrical supply and sufficient lighting were appropriate for manufacturing process to be carried out and functioning of equipment. Storage areas were adequate in size and well equipped to allow systematic and orderly storage of materials and finished products.

ii. Sanitation and Hygiene

High level of hygiene was observed in personnel, premises, and equipment. Separate changing rooms for ladies and gents including visitors were provided with air showers, step over benches, gowning and de- gowning procedures, hand washing facilities and sanitizers. Sampling booth, dispensing booth and production area were provided with secondary changing rooms. Personnel working in production area were neat, properly dressed and provided with clean clothes, mask and gloves as safety gears.

Environmental monitoring inside production areas was conducted as per respective SOP and records were verified and found adequate. Production areas and equipment were observed to be clean and the cleaning SOP as well as records was in place.

3. Production

The block had three warehouses for storage of raw materials, packaging materials and finished good materials. Each warehouse had a receiving bay where materials were received, de-dusted, air showered and then stored. Different storage areas with adequate space were provided for storing quarantine, under-test and approved material. ERP system was used to issue status labels and material codes as well as approving sampled materials. Materials requiring controlled storage conditions were stored at cold storage condition of 2-8°C and NMT 25°C.
Sampling and dispensing booth were provided with separate material and personnel airlock, secondary gowning and reverse laminar air flow cabinet. Critical steps such as dispensing were performed under direct supervision of competent designated personnel. Manufacturing processes were carried out as per SOPs. Sequence of manufacturing activities was followed and found to be properly documented in batch manufacturing records (BMR). Holding time studies for semi – finished materials and in-process quality control checks were performed and found adequate. Packaging process was performed online and there was proper separation between packaging lines to avoid mix-ups.

Generally, the manufacturing activities followed the unidirectional flow to prevent mix ups and cross contamination. All the manufacturing units were adequate in size, ventilated, lightened, access controlled and labeled. Process validation, cleaning validation of manufacturing equipment and preventive maintenances records were availed and found adequate.

4. Quality Control

The QC laboratory was divided into chemical analysis laboratory and microbiology laboratory located in first and second floor respectively. The chemistry laboratory was further divided into wet chemistry section and instrumentation section. All the laboratories were provided with modern analytical equipment and instruments. The lab had sufficient number of personnel with appropriate qualification and experience for testing of raw materials, packaging materials, finished products as well as water and environmental monitoring samples. The facility utilizes both officials standard and validated in- house methods for testing of materials and products. Working standards and reference standards were also available and properly stored.

Stability studies were being carried out at zone IVB climatic conditions as per stability studies monitoring SOPs and records were found acceptable Retention samples room was available, properly handled and samples were stored at controlled storage condition.

The laboratory was suitably designed to suit the operations carried out. All equipment were found functional, calibrated and qualified. Equipment log books, SOPs, calibration records and qualification reports were verified and found to be satisfactory.

5. Equipment

The facility had sufficient number of GMP equipment to carry out the manufacturing activities. The equipment were well designed, installed, qualified, located and maintained to suit the operations and permit effective cleaning.

6. Water Treatment Plant

The facility had dedicated purified water systems for general block and oral contraceptives block each provided with dedicated distribution systems. The system was suitably designed, constructed, qualified and maintained.

In each block purified water was generated from bore well water which was subjected to chlorination, multi grade sand filter, sodium hydroxide dosing, softener, 50micron cartridge filter, on line dosing of sodium metabisulfite, double RO, electro deionization, and ultrafiltration. Purified water was then stored in a SS316L storage tanks and then passed through ultraviolet filtration in order to reduce microbial counts and continuously circulated to user points at ambient temperature. Sanitization of purified water storage tanks and distribution system were performed as per SOP.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air-conditioning (HVAC) system was suitably designed and installed to supply filtered fresh air and re-circulated air .The facility had dedicated AHUs for oral contraceptive block and general pharmaceutical block. All AHU were clearly labeled to show the direction of air flow and areas they supply. Each AHU was found to be equipped with return and fresh air mixing section, pre-filters, cooling coil, blowers, heater and finally HEPA filters. All critical areas were provided with AHU fitted with terminal HEPA filters. Appropriate pressure differentials were maintained in the processing areas which helped to prevent cross contamination. Preventive maintenance and performance qualification record of AHUs were reviewed and found to be adequate.

8. Document Review

Generally, the documentation system was functioning satisfactorily and documents were prepared, checked and approved by authorized personnel. All documents scrutinized were well written, detailed, updated as per master SOP and were traceable hence provide evidence of conformity to GMP requirements.

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 the report and CAPA assessment report, **Aurobindo Pharma Limited Unit-VII(SEZ), Plot No. S1, TSIIC-SEZ, Green Industrial Park, Polepally (V), Jedcherla (M), Mahboob Naggar (Dist.) T.S. 509302, Telangana State, India** was considered to be operating in an acceptable level of compliance with EAC compendium of GMP for the manufacturing of general Pharmaceutical products (tablets and capsules) and Anti-retroviral tablets lines .

This TPIR will remain valid for three years (3) 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. EAC- *Good* manufacturing *Practice Compendium, (2014), Technical Documents for Harmonization of Medicines Regulation in the East African Community*
2. TMDA *Good Manufacturing practices manual and SOPs,* Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania
3. Tanzania Medicines and Medical Devices Authority Act, Cap 219