REPORT ON VISIT TO AMNEAN THERAPEUTICS PVT. LTD.

Dt: 02-09-2022

Names of staff visited :
Dr.T.Mamatha
Dr.B.Haarika
Dr.P.Hyma
Smt.G.Srilalitha
Smt. Ch. Bhargavi,
Smt. R. Prashanthi,
Smt. P. Divya theja,
Smt. M. Swetha,
Smt. Sameera,
Smt. Azmeera Jyothi.
Smt.P.Ramya
Smt.Shilpa

- Dr. Srikonda Venkateswara Sastry, Director of Amnean therapeutics Pvt. Ltd. gave an introduction about industry and Kakatiya University.
- Sir discussed about biotechnological products and the advancement in the treatment of cancer by using CD4 & CD8 cells. He insisted that real science comes from the biology, chemistry & kinetics.
- Dr. Sastry wrote three NDA process.
- He suggested to think about applications & advanced pharmaceutics and to go for patents.
- In 2006 they started with manufacturing of small strips of Ondansetron orally disintegrating films (ODF). Now they are manufacturing 11 products of ODF.
- 12 staff have divided into 3 groups and moved to different departments (AHU,water plant, production, R&D, stability department, Q.C. & Q.A).
- Smt. Archana guided for R&D. She explained about various instruments & parameters that can be optimized for preparation of ODF and about the procedure for formulation:
    1. Design by using simple factorial design.
    2. Preparation of slurry.
    3. Pass the film on PE (Poly ethylene ester) film by using the casting machine.
    4. Drying – According to the FDA guidelines.
    5. Evaluation parameters like plasticization, thickness, folding endurance, weight variation etc.
- Then we headed to Q.A. department where they explained about the documentation procedure for the following:
    1. Vendor sample analysis to select the materials and agreement procedure(AHU).
    2. Method validation document.
    3. Q.C Analytical procedure documentation
    4. SPEC, STP & SOP documentation,MFR , BFR
    5. Stored samples of each batch for any future queries.
- Later we moved to stability department, where they explained about stability chambers and Zone 4 conditions which they are maintaining (Trial batch- 40°C± 2 & 75%RH, Commercial batch- 30°C± 2 & 75%RH) according to the ICH guidelines.

- Then we moved to Q.C. department. They explained about HPLC(Agilent technologies – Chemstation software), dissolution apparatus (VARIAN), Conductometer (ESICO), disintegration apparatus (VARIAN - VK100), DSC (Q100 – TA instruments), TGA (Q50), Millipore water purifier (Direct – Q), Karl fisher (ESICO), Casting machine, Nitrogen chamber for Vitamin D3 determination, Single beam UV (Agilent).
- We moved to water plant where they explained about water purification process.
  1. Chlorination
  2. Reverse Osmosis-1 and RO-2 (CSRO system)
  3. Automated NaOH dosing tank to adjust pH and conductivity (1.3mV).
  4. HSRO- Heating sensitization.
  5. Stored in water tank and circulated to all departments.
- Then we headed to Production area.
  1. Dynamic pass box to remove the dust particles of API & excipients. Before dispensing of the raw materials check for RH & temperature.
  2. Approved materials are dispensed.
  3. Manufacturing steps: All preparation steps they will do it in ISO 8 With NMT 1lakh ppm room maintained

     i) Mixing : Solution preparation tanks (USP) of SS and Homogenizers
     ii) Layering machine
     iii) Pumping of liquids for manufacturing by using peristaltic pumps.
     iv) Thickness 550-650 mm adjustment by doctor knife.
     v) Rolling of liquid film onto the PE roll and then passed to heating chamber.
     vi) Unwinding roll → Patch → Encoder roll → Coating roll → U- turn top roll → U- turn bottom roll → Drying chamber → Casing chamber → Linear motion roll assembly → Product unwinding roll

  4. Wash area.
  5. Slitting & packing.
  6. Packing with strips.
  7. Sealing.
  8. Cut the product film length.
  9. Secondary packing.
  10. IPQC

The solid dosage form formulations unit is being established with high end equipment like GLATT company RMG and FBD. The capacities being 60 kg and 120kg

The tablet compression machine is purchased from Japan Kikusi company and the zanasi 40E automatic capsule filling machine that can encapsulate 3 states of drug forms, solid liquid and semisolids.