KVK Tech	**Employee Job Description**

1. Employee details:

First Name		Middle Initial		Last Name			
Hire Date		Department	Quality Control				
Location	110 Terry 100 Campus	Job Title	QC Chemist		FLSA Status:	Exempt	
Role	N/A						
Sub role (If any)	N/A						

2. Role Purpose:

Primary responsibility is to complete documentation and analytical testing of raw materials, in-process materials, stability samples, finished products and product development in a timely manner, while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

3. Key Duties & Responsibilities:

- Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.
- Follow all DEA (Drug Enforcement Agency) regulations per laboratory SOPs.
- Perform analytical testing of raw materials, in-process materials, stability samples, finished products and product development products using different analytical techniques in compliance with written, approved methods.
- Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines. Maintain laboratory records including notebooks, logs, and other pertinent documentation in compliance with cGMP, SOPs, and good laboratory documentation guidelines.
- Operate, Calibrate, Qualify, or perform Preventive maintenance and routine trouble shooting on analytical instruments such as UPLCs, HPLCs, GCs, AAS, UV/Vis spectrophotometers, Dissolution apparatus, Laser Diffraction Particle Size analyzers, etc. as assigned (if trained).
- Ensure all instruments are qualified, and calibrated before each use.
- Ensure all instruments are maintained, cleaned and used appropriately.
- Evaluate existing, as well as verify and validate new analytical methods of drug products and drug substance as per FDA, USP and ICH guidelines.
- Research and gather information in a timely manner.

- Prepare, label, organize and maintain files.
- Follow all SOPs.
- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as assigned or delegated

4. Typical Supervisory Responsibility:

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Working knowledge of HPLC, UPLC, GC Dissolution, AA, UV spectrophotometers • Aptitude for application of analytical methods • Skilled in laboratory techniques • Good verbal and written English • Excellent interpersonal and communication skills
Education/Certifications/Licenses/Other	• Must have a BS Chemistry or related science field • Experience in Pharmaceutical industry a plus

6. Physical Demand and Work Environment:

a. Physical demands:

While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

b. Work environment:

N/A