

<b>KVK Tech</b>	<b>Master Job Description</b>		
	<b>Revision:</b>		

<b>Department</b>	Quality Control		
<b>Job Title</b>	Chemist I	<b>FLSA Status</b>	Exempt
<b>Role</b>	N/A		
<b>Sub Role (If any)</b>	N/A		
<b>Reports To</b>	Group Leader		

**1. Role Purpose:**

*(Provide a brief summary of the primary purpose of this role)*

The Quality Control (QC) Chemist I will be responsible to perform routine testing of incoming raw materials, packaging components, drug substances, in process samples, drug products, and stability samples in accordance with internal Methods of Analysis (MOA), compendial, and other test methods. Adherence to Standard Operating Procedures (SOP) and the United States Pharmacopoeia (USP) is required. Analytical techniques will include bulk/tapped density, pH, KF, titrations, dissolution, UV-VIS spectrophotometry, and other ancillary test methods, HPLC and other, as necessary.

Attributable, legible, contemporaneous, original, and accurate documentation is also required

Work also needs to be completed in accordance with applicable FDA, OSHA, EPA, and DEA requirements.

**2. Key Duties & Responsibilities:**

*(Briefly describe the essential activities that are performed by this role including key duties/responsibilities. Each statement should start with a verb. Additionally, indicate how frequently it is performed)*

- Performing routine analytical analysis of raw materials, packaging components, drug substances and drug products using different compendial and KVK Tech test procedures in compliance with written, approved methods
- Ensuring all instruments are calibrated before each use
- Documenting all performed analysis using cGMP, USFDA and 21CFR211.194 guidelines.
- Maintaining laboratory records including notebooks, logs, and other pertinent documentation
- Following current Good Manufacturing Practices (cGMP), applicable Code of Federal Regulations (CFR)
- Reviewing data for compliance to procedures and specifications
- Completing all training prior to performing GMP activities
- Adhering to the Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) safety regulations.

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- Operating and calibrating, or performing Preventive Maintenance and routine trouble shooting on analytical instruments
- Complying with FDA guidelines/Company Policies of Data Integrity
- Working independently under general supervision and direction in compliance with cGMP
- Performing other duties as assigned or delegated
- Handling hazardous waste in compliance with company SOP and hazardous waste rules

**3. Typical Supervisory Responsibility:**

*(Identify any responsibilities the role has for supervising others)*

N/A

**4. Education & Experience:**

*(Describe the education required for this role, including specifications, if any. If equivalent experience or knowledge can be substituted for the educational requirements, A combination of Education and experience shall be taken into account.)*

Education Requirement	Specialization (If any)
BS in Chemistry or related science field preferred	N/A
N/A	N/A

**Experience Requirement**

*(Describe the experience required for this role. Identify the type of experience, number of years, and any additional comments on the experience and education requirements for the role. Also, include any geography specific requirement that differs from the experience.)*

N/A	
Number of Years (Minimum to Maximum)	N/A

**5. Technical competencies/ Certifications/ Licenses:**

*(Briefly describe the required competencies such as, skill, ability, knowledge an individual must possess to perform the role. Also, identify any certification or licenses required to perform the role.)*

<b>Technical competencies</b>	<ul style="list-style-type: none"> <li>• Working knowledge of HPLC, UPLC, GC, Dissolution, AA, UV spectrophotometers, pH and titration equipment</li> <li>• Aptitude for application of analytical methods</li> <li>• Skilled in laboratory techniques</li> <li>• Good verbal and written English</li> <li>• Excellent interpersonal and communication skills</li> </ul>
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<b>Certifications</b>	N/A
<b>Licenses</b>	N/A
<b>Other</b>	N/A

**6. Physical demand and Work environment:**

*(Provide details regarding the physical demands and work environment that are essential to the role)*

**a. Physical demands:**

While performing the duties of this job, the employee is required to walk, sit, and use hands. 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