

# KASHIV PHARMA LLC.

## Job Description

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<b>Job Title</b>	<b>Senior Scientist I / II</b>
<b>Business Unit</b>	Analytical
<b>Department Name</b>	AR&D
<b>Function</b>	AR&D
<b>Reporting Relationship</b>	Supervisor/Manager, Analytical R&D
<b>FLSA</b>	Exempt
<b>Date</b>	May 1, 2017

### **Essential Duties & Responsibilities**

Key responsibilities of the position include, but are not limited to –

- Develop and validation analytical method for drug substances, drug products, and excipients
- Conduct routine and advanced analytical tests in accordance with SOPs and regulatory guidance.
- Write protocols, reports, methods, standard operation procedure, and submission documents.
- Provide analytical support for formulation and process development.
- Perform independent scheduling and coordination of activities
- Conduct instrument troubleshooting.
- Analyze analytical data, identify trends and provide recommendation.
- Review laboratory notebooks, raw data and technical documentation (e.g. test method, validation protocol, or validation report) in support of regulatory filings
- Train and provide technical guidance to junior scientists.
- Conduct laboratory investigation and prepare laboratory investigation report.
- Proactively provide Lab management with suggestions on how to improve the methods, lab practice or lab system.
- Evaluate and improve existing test methods
- Review and evaluate drug substance supplier's technical documents and provide recommendation in API vendor selection.
- Performs other functions as required or assigned
- Complies with all company policies and standards

### **Position Requirements and Qualifications**

- Ph.D. in analytical chemistry or related discipline with minimum 5+ years' US pharmaceutical experience or M.S. with minimum 8+ years experience.

### **Specialized Knowledge and Skills**

- Posses broad analytical chemistry knowledge in HPLC, GC, UV, FTIR and other related analytical technologies
- Good understanding of USP methodologies, ICH Guidelines, cGMP and FDA regulations.
- Hands on experience in wet chemistry techniques.
- Good verbal and written communication skills.
- Attention to details and accurate record keeping.
- Ability to plan, schedule and work independently in a fast pace environment. Self-motivation, adaptability, and a positive attitude.
- Working knowledge of applicable safety and standards guidelines, such as SOP, cGMP, GLP, DEA regulations and/or MSDS.
- Ability to work under pressure and meet deadlines

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### **Work Environment & Physical Demands**

General work environment and physical demands as required to successfully perform the essential functions of this job. Ability to work flexible hours as needed. Some travel may be involved.

**Supervisory Responsibility, if any:** No

***This position description is not a complete list of all responsibilities, duties or skill required for the job and is subject to review and change at any time, with or without notice, in accordance with the needs of the organization.***