At Kotra Pharma, we believe that everyone deserves a healthier tomorrow. It's every individual's right to live a healthy life to the fullest, and thus, we are committed to bring top-notch health products to the world. By humanising healthcare, we see beyond instruments and medicines for the general well-being of everyone. If you want to make a difference in this industry, begin with us.

1.Senior Chemist (Method Development) **Level II**	**<u>Key Responsibilities:</u>** * To report to R & D Manager on all matters related to analytical method development or improvement for existing starting materials and finished products. * Establishing, managing, planning, scheduling and executing analytical method development or improvement programs for existing starting materials and finished products following regulatory requirements. * Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia. * Responsible to train and qualify R & D chemists and lab technician on development or improved analytical methods for existing starting and finished products. * Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required. * To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. * To work towards achieving the R & D department KPI. * Comply and work towards meeting the company's quality, health safety and environment objectives and policies. * Responsible for executing method transfer from R&D to QC. **<u>Job Specifications:</u>** * At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old. * At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department.

	* Able to handle analytical procedures pertaining to all dosage forms (solids, liquids, semi solids etc). * Strong working knowledge in products development and familiarity with quality assurance procedures. * Knowledge in new products developed compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. * Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia. * With good command of spoken and written English. * Core competency should be method development and method troubleshooting. * Must be able to review and interpret analytical results. * Self starter and needs to lead the Method Development group. * Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.
2.Senior Chemist (Method Validation) **Level II**	**<u>Key Responsibilities:</u>** * To report to R & D Manager on all matters related to analytical method validation. * Establishing, managing, planning, scheduling and executing analytical method validation as per latest regulatory guidelines. * Responsible to train others R & D chemists and lab technicians on activities pertaining to method validation. * Should be a strong reviewer and must be able to review the protocol and reports. * Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required. * To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. * To work towards achieving the R & D department KPI. * Comply and work towards meeting the company's quality, health safety and environment objectives and policies. * Responsible for executing method transfer from R&D to QC. **<u>Job Specifications:</u>** * At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old. * At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department. * Able to handle analytical procedures and validation pertaining to all

	dosage forms (solids, liquids, semi solids etc). ∗ Strong working knowledge in products development and familiarity with quality assurance procedures. ∗ Knowledge in new products developed compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. ∗ With good command of spoken and written English. ∗ Core competency should be method validation (inclusive of protocol writing to executive and report general. ∗ Must be able to review and interpret analytical results. ∗ Self starter and needs to lead the Validation group. ∗ Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.
3.Senior Chemist (Raw Mat Testing) **Level II**	**<u>Key Responsibilities:</u>** ∗ To report to R & D Manager on all matters related to analytical raw material testing/material qualification method for existing starting materials and finished products. ∗ Establishing, managing, planning, scheduling and executing analytical raw material testing/material qualification method or improvement programs for existing starting materials and finished products following regulatory requirements. ∗ Responsible to review the DMF and other analytical procedures. Establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia. ∗ Responsible to train and qualify R & D chemists and lab technician on development or improved analytical methods. ∗ To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. ∗ To work towards achieving the R & D department KPI. ∗ Comply and work towards meeting the company's quality, health safety and environment objectives and policies. **<u>Job Specifications:</u>** ∗ At least Master in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old. ∗ At least 3 to 5 years working experience in analytical pharmaceutical healthcare or analytical testing house. The experience should be in Formulation Analytical Department and in a Research and Development Department. ∗ Able to handle analytical procedures pertaining to all dosage forms. ∗ Strong working knowledge in products development and familiarity with quality assurance procedures. ∗ Knowledge in new products developed compliance to cGMP, National

	regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. * With good command of spoken and written English. * Core competency should be raw material testing including API, Excipient and packaging material. * Must be able to review and interpret analytical results. * Self starter and needs to lead the raw material group. * Hands on analytical equipment such as GC, HPLC, dissolution, Auto titration is a must.
4.Senior Chemist (Method Development/Validation) **Level II**	**<u>Key Responsibilities:</u>** * To report to R & D Manager on all matters related to analytical method validation and analytical method development or improvement for existing starting materials and finished products. * Establishing, managing, planning, scheduling and executing analytical method validation and analytical method development or improvement programs for existing starting materials and finished products following regulatory requirements. * Responsible to review and establish finished product and starting material test procedures, specification and COA in accordance with latest official monographs/pharmacopoeia. * Responsible to train and qualify R & D chemists and lab technician on development or improved analytical methods for existing starting and finished products. * Direct assistance to the Validation Team in process validation, cleaning and other qualification or validation, in which laboratory testing support is required. * To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. * To work towards achieving the R & D department KPI. * Comply and work towards meeting the company's quality, health safety and environment objectives and policies. **<u>Job Specifications:</u>** * Master/PHD in Analytical/Organic Chemistry, Pharmacy or equivalent. Below 35 years old. * At least 6 to 10 years working experience in analytical pharmaceutical, healthcare. 2-3 years of supervisory experience is mandatory. The experience should be in Formulation Analytical Department and in a Research and Development Department. * Besides being hands on HPLC, GC, UV, Dissolution, IL should have worked on GC-MS, HPLC-MS/MS. * Able to handle analytical procedures pertaining to all dosage forms. * Strong working knowledge in products development and familiarity with quality assurance procedures.

	* Knowledge of new products development compliance to cGMP, National regulatory Guidelines and other law regulating the manufacturing and commercialization of medical products. * Excellent communication skill, good command of spoken and written English. * Core competency should be method development and method validation. * Must be able to review and interpret analytical results. * Should be able to work independents and leads team members. * Knowledge of extractable/leachable studies is highly recommended.

1.R&D Formulation (parenteral)	**Key Responsibilities:** * Development of new Formulation for Parenterals products (Powder, liquid and suspension Injectables). * Literature search and background analysis of the allocated products. * Sourcing and Material qualification of new raw material and packaging materials for new parenterals product. * Initiate Trail batch, Pilot batch for Stability study of formulated Parenterals products. * Ensure proper management of data and documents generated during product development and stability studies in accordance to the Good Documentation Practices. * Assist in the investigation and resolution of designated product complaints related to formulation and stability issues as captured by CAPA issued by QA. * Monitoring and updates on the project's progress/status. * To ensure that the final product for product launch complies with the input requirements and Market Authorization requirements. * Prepare Registration Dossiers for the new Parenterals products for NPBC submission and follow up on the correspondence & queries. * Assist and liaise with other departments in coordinating the Scale up batch/Process Validation of new Parenterals products upon NPCB approval prior to Commercial Batch. * To participate as an auditor in internal and external quality audits, including vendor audit, when requested. * Responsible for parental product development from R&D till commercialization stage which requires excellent communications skill

	and liaising with all departments. **Job Specifications:** * At least Master in Pharmacy or equivalent. Below 35 years old. * At least 5 to 7 years working experience in handling of sterile formulation (liquid injectables form, powder for analytical etc) in a R&D department in pharmaceutical. * Familiar with sterile environment manufacturing process and clean room technology. * Knowledge of GMP, PICs, ICH guidelines and other law regulating the manufacturing and commercialization of the medicinal product. * Knowledge of process validation, scale up and analytical testing will be an added advantage. * Should have a very good knowledge on sterilization techniques. * Should possess good knowledge of QBD, PAT and Risk Assessment.
2. .R&D Formulation Scientist	**Key Responsibilities:** * Reports to the R & D Manager on matters pertaining to New Product Development (NPD). * Responsible for the development of new formulations and dosage forms as requisitioned. * To ensure products are developed and launched in accordance to Marketing requirements and that project completion are within agreed timelines. * To ensure that, in carrying out product research and development, adherence to Good Laboratory Practice and Good Manufacturing Practice is observed at all times as necessary. * To ensure that the final product for product launch complies with the input requirements and Market Authorization requirements. * To coordinate Material Qualification for new starting materials and primary packaging materials. * Assist in the improvement of product quality for current products under the Product Quality Improvement (PQI) program. * Ensure proper management of data and documents generated during product development and stability studies in accordance to the Good Documentation Practices. * Assist in the investigation and resolution of designated product complaints related to formulation and stability issues as captured by CAPA issued by QA. * Ensure that the department properties such as machines and instruments as designated, are properly used at all times.

	* Assist QA and Production Department in product and process validation by establishing the appropriate process flow and process parameters. * To participate as an auditor in internal and external quality audits, including vendor audit, when requested. * Responsible for the preparation, maintenance, confidentiality and safe keeping of Product Design Files. * Ensure strict compliance to the Company's policies on Quality, Safety, Health and Environment * Responsible for parental product development from R&D till commercialization stage which requires excellent communications skill and liaising with all departments. **Job Specifcations:** * At least Master in Pharmacy or equivalent from a reputable university. Below 35 years old. * At least 5 to 7 years working experience in handling of formulation and development of various dosage forms. * Should have worked in research and development of reputed pharmaceutical. * Knowledge of GMP, PICs, ICH guidelines and other law regulating the manufacturing and commercialization of the medicinal product. * Knowledge of process validation and analytical testing will be an added advantage. * Should have a very good knowledge of process scale up and process validation. * Should possess good knowledge of QBD, PAT and Risk Assessment.

Research Assistant	**Key Responsibilities:** * To report to the R&D Manager or designate on all matters related to the scope of responsibility. * Responsible to plan and ensure the smooth running of all activities in Medical device laboratory. * Responsible to perform Quality control testing on every existing and new product before product release. * Responsible to present and compile results of research that has been conducted and to report all the results and findings to the R&D Manager. * Responsible to plan and conduct stability study for the manufactured or new products.

	∗ Work in liaison and in cooperation with various departments in Kotra Pharma. ∗ Ensure compliance to cGMP, GLP and GSP. ∗ Formulation of New Product Development projects for Sterile Potentials (powder, liquid and suspension). ∗ Initiate Trail batch and Stability study of formulated Parenteral products. ∗ Prepare Registration Dossiers for the new Parenterals products. ∗ Sourcing and Material qualification of new raw material and packaging materials for new parentals product. ∗ Initiate Process Validation of new Parentals products upon NPCB approval prior to Commercial Bath. **Job Specifications:** ∗ Minimum 2 years working experience in Pharmaceutical manufacturing environment ∗ Good leadership and communication skill with the ability to interact well with all parties concerned ∗ Able to work under pressure to meet tight deadline with minimum supervision

Analytical Chemist	**Key Responsibilities:** ∗ To develop and validate analytical test methods for pharmaceutical products Quality controls. ∗ To plan and execute all analytical testing for starting materials and finished pharmaceutical products for Quality Improvement and routine testing ∗ To prepare the protocols for inter-department transfer of approved analytical test methods and qualification report for new Product Quality Improvement (PQI) projects. ∗ To check, monitor record and maintain designated analytical instruments in accordance with the Instruments, Machine and Equipment Maintenance Procedure. ∗ Ensure strict compliance to the company's policies on Quality, Safety, Health and Environment. ∗ To guide and supervise Laboratory Technicians in the analytical department in either R&D or QC departments. **Job Specifications:** ∗ 28 years old and above. ∗ Bachelor's Degree or Master's in Chemistry/ Food Science/ Pharmacy or equivalent. ∗ At least 5 years working experience in pharmaceutical, healthcare or cosmetic manufacturing industry.

	* Strong working knowledge in HPLC and other spectrophotometric equipment and familiarity with quality assurance procedures. * Hands-on experience in validation of analytical test methods. * Familiar with compliance to GLP, cGMP and other National Regulatory Guidelines regulating the manufacturing and commercialisation of medical products. * Good communication skill and good command of written & spoken English.

Interested candidates are encouraged to apply. Kindly send your resume to:

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Kotra Pharma (M) Sdn Bhd (90082-V)
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75250 Melaka, Malaysia

Or

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