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| **Abhishek Kumar Shukla** | Phone- 08889687232, 7021197589 |
| Assistant Manager Quality Control | Email: [abhishek.0802@rediffmail.com](mailto:abhishek.0802@rediffmail.com),  che.abhishek@gmail.com |
| **Present Address:**  Near Swahid Bedi, Mirza, Kamrup,  Assam (Guwahati)-781125. | **Permanent Address:**  Village-Chhipiya, PO-Phool,  Tahsil Naighari, Rewa,  Madhya Pradesh-486331. |

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| * **Career objective:** I am looking forward for a position in **Quality Control department.** I expect a career which is different yet unique, my intelligence is continuously nourished by challenges and constant quest for knowledge is honed on the newest of technologies. * **Educational Qualification**:  |  |  |  | | --- | --- | --- | | **M.Sc. Chemistry:** | Vinayaka Missions University Salem Tamlnadu - 2010 | :68 % | | **B.Sc. Biology Group :** | [Awadhesh Pratap Singh University, Rewa](http://apsurewa.ac.in/) MP - 2006 | :56% | | **Higher Secondary (12th):** | Higher Secondary School Mauganj Rewa (M.P. Board)-2003 | :61% |  * **Work Experience:** 12 year 11 month. * **AJANTA PHARMA LTD GUWAHATI**, **ASSAM** (28 Dec 2016 to till Date):- TFDA, WHO approved site. Tablet, Capsule, Cachets-jelly, Creams, Ointments, Gel, Eye Drops formulation plant from Guwahati, Assam.   **Designation:** Assistant Manager Quality Control   * Handling of Finish Product section and assurance the completeness of the activity Finish Good sample, In-processed sample processed validation sample and Hold time study sample. * Ensure the timely transfer and verification of analytical method from analytical development laboratory. * Approval of LIMS master test Plan for In-Process samples finished Products, raw material and working standard. * Approval of In-Process sample, Finished Products, processed validation sample test reports. * Review and approval of specification, test methods and other Quality Control Procedures in LIMS. * Review and approval of analyst qualification report. * Review Cleaning validation and Method validation protocol and report. * Review of process validation protocol and report. * Review of process qualification report (PQR). * Approval and review testing data of raw material, stability sample and packing material in LIMS. * Prepare and Review of specification, standard test procedure and General test procedure. * Verification of standard operating procedure (SOP) and its implementation. * Handling the investigation of incidents and OOS/OOT. * Handling of laboratory deviation, change control and CAPA in QMS. * Follow Audit trail requirements electronic record, 21CFR PATR 11 and ALCOA. * Follow 21 CFR Part 210- Current good manufacturing practice in manufacturing, processing, packing, or holding of drugs. * Follow 21 CFR Part 58\_Good laboratory practice for nonclinical laboratory studies. |

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| * Planned, directed, coordinated and assigned manpower to efficiently meet production requirements, approx 20 manpower handling. * To report to QC Asst. General Manager on all matters related to processed validation, In-processed sample and Finish Product. * To ensure a safe working environment at QC Department. * Evaluate the laboratory needs\ requirements (New instrument\ Equipments, sufficient manpower, appropriate working environment etc.) * Responsible in ensuring that all the laboratory equipment are always in an idle status for use. * Responsible to train and qualify QC 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 and other qualification or validation, in which laboratory testing support is required. * To participates in troubleshooting laboratory equipment failure and provide proposals for improvements. * **SUN PHARMA LABORATORIES LTD GANGTOK, SIKKIM** (29 May 2015 to 24 Dec. 2016):- WHO approved site. Tablets, capsules formulation plant from Sikkim.   **Designation:** Sr. Executive Quality Control   * Handling of stability section and assurance the completeness of the activity stability sample. * Planning and work allocation of the activity **Stability Section.** * **Review of Stability protocol and report.** * Review of analytical documents Stability sample in LIMS. * Receipt and charging of stability sample, withdrawal, testing and release of sample as per schedule. * Review of instrument calibration document and IQ, OQ, PQ document. * Review and checked of instrument and equipment logbook. * Preparation of worksheet along with Specification and STP’s in Laboratory Information Management System (LIMS). * Handling the investigation of incidence and OOS/OOT. * **IPCA LABORATORIES RATLAM, M.P.** (01 Sep 2014 to 15 May 2015):-USFDA, MHRA, TGA approved site, Manufacturer & Supplier of API.  **Designation:** Executive Quality Control. * Review data of Finish Active Pharmaceutical Ingredients (APIs) / Drug. * Handling of Pre-evaluation incidences, System suitability incidences. * Reporting of day to day activities immediately to QC Head. * Learn new skills/techniques in order to progress to the next level. * Participate in OOS and OOT investigations as directed. * Follow Audit trail requirements electronic record, 21CFR PATR 11 and Data integrity in the analytical laboratory is an area of increasing focus for regulators such as FDA. |

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| * **CIPLA LTD. INDORE, M.P. (May 23 2011 to 30 Aug 2014):-** USFDA, MHRA, TGA approved site. Tablets, capsules formulation plant from Indore. **Designation:** Officer Quality Control. * Working in Chromatography Section. * Analysis of Finish good and stability sample. * Calibration of HPLC. * Handling of Pre-evaluation incidences, System suitability incidences. * Reporting of day to day activities immediately to superiors. * **UNICHEM LABORATORIES LTD BADDI, H.P.** (14 Jun 2010 to 17 May 2011**):-** MHRA, WHO approved site. Tablets, capsules, injection formulation plant from Baddi.   **Designation:** Officer Quality Control.   * Analysis of Finish good sample Capsule, Tablets & Injection. * Operation & Calibration of HPLC. * Operation & Calibration of UV-VIS Spectrophotometer * Operation & Calibration of Dissolution. * Operation & Calibration of FTIR Spectrophotometer. * Operation of Tablet Hardness Tester. * Operation of Tablet Friability Tester. * Operation & Calibration of Disintegration Time Apparatus. * Operation & Calibration of Karl Fischer Apparatus. * **ANKUR DRUGS & PHARMA LIMITED BADDI, H.P. (**29 April 2008 to 25 May 2010):- WHO approved site. Tablets, capsules, syrup, suspension formulation plant from Baddi.   **Designation:** Jr. Officer Quality Control.   * Sampling and Analysis of Raw material Sample. * Operation & Calibration of HPLC. * Operation & Calibration of UV-VIS Spectrophotometer * Operation & Calibration of Weighing balance. * Operation & Calibration of pH meter. * Operation of Viscosity meter. * Operation & Calibration of Polari meter  |  | | --- | | * **KILITCH DRUGS (INDIA) LTD. PAONTA SAHIB, H.P.** (11 Dec. 2006 to 17 April.2008.):- WHO approved site. Injection formulation plant from Paonta Sahib.   **Designation:** Chemist Quality Control. |  * Chemical Analysis of Water Sample. * Sampling and Analysis Packaging Materials Sample. * Analysis of packaging sample Shipper, carton, PVC, label, Ampoule and injection vial. * Handling of Bursting strength instrument |

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| * **Certification:** Approved as Quality Control Analytical Chemist, Indian FDA (Assam Govt.). * Audit and visit faced: **In my Years Experience. I have do working with GLP, cGMP, Safety, as per Guidelines and with discipline and faced  audits like WHO, USFDA, MHRA & other small audits.** * Unichem Laboratories Ltd Baddi (H.P.) -*MHRA-UK.(6 Sept. 2010)* * Cipla Pharma Ltd Indore (M.P.)-USFDA ( 2 November 2012) * Ajanta Pharma Ltd (Guwahati Assam)- TFDA ( 5 May 2019)  |  | | --- | | * **Computer skills:** I am having the sufficient knowledge of computer; I can work on Laboratory Information Management System LIMS, MS Office, MS Word, MS. Excel, Internet and also onNon -chromilon, TRIMS and QMS. |  * **Personal Details**  |  |  |  | | --- | --- | --- | | Name | - | Abhishek Kumar Shukla | | Father Name | - | Sh. S. P. Shukla | | Date of Birth | - | 08- 02- 1985 | | Nationality | - | Indian | | Languages | - | Hindi and English | | Marital status | - | Married | | CTC | - | 9.96 Lac/year | | Expected Salary |  | Negotiable | | Preferred Location | - | Anywhere in India | | Hobbies | - | Shopping, Cricket. |   **Declaration:   I hereby declare that, the above given information by me are true and correct to the best of knowledge.**  **PLACE:**  **DATE- (ABHISHEK KUMAR SHUKLA)** |