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| **Abhishek Kumar Shukla** | Phone- 08889687232, 7021197589 |
| Assistant Manager Quality Control | Email: 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**:

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| **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

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| * **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)

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| * **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.
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* **Personal Details**

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| 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)** |