**PRAFULLA N. MORE**

## RESIDENCIAL ADDRESS PHONE NO.& EMAIL ID

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Near Bharat College,

Badlapur (W)

Pin code: 421503

Dist.: Thane.

State: Maharashtra

## APPLIED POST FOR

**Manager / Assistant Manager Quality Assurance**

## OBJECTIVE

To pursue a challenging career in professionally managed, system driven pharmaceutical organization and contribute my best efforts towards the interest of the organization in a position that utilizes my skills while furthering my personal and professional goals.

## WORK EXPERIENCE

* TOTAL 13 YEARS OF EXPERIENCE.
* EXPERIENCED IN STABILITY SECTION FOR FARMULATION.
* SUCCESSFULLY ACHIEVED U.S. FDA AUDIT AT WATSON PHARMA.
* Presently working with **KORES PHARMACEUTICAL LTD.** at Roha, District Raigad, and Maharashtra State. As an Assistant Manager Quality Assurance department from 19th February 2018 to till date. (6 months)

(ISO 9001:2008, 2017 EDQM Surveillance.)

(i) Review and approval of master documents such as BMR, BPR, SOP, Log books, TDS and all the master records.

(ii) Review and Approval of executed BMR, BPR, Log books.

(iii) Preparation of audit compliance report.

(iv) Batch release before dispatch to the market.

(v) Preparation, review and approval of QA SOP, APQR, PRR.

(vi) Effective implementation of Changes, CAPA in the area.

(vii) Maintaining GMP environment in manufacturing area, QC, Engineering and ware house area

(ix) Handling of CC, Deviation and OOS observed and follow up for completion of documents.

(viii) Monitoring of activities as per GMP in the manufacturing, QC and ware house area.

(x) Effective Maintaining document archival room.

(xi) Support to RA providing documents as required

(xii) Support to BD/Sales providing documentary help.

(xiii)Support to P&A to maintain training documentation.

(xiv)Monitoring activities in all plant, warehouse, Engineering and other areas to maintain GMP

* Worked with **MEGAFINE PHARMA PVT.LTD.** Vapi, Gujarat State. As a Sr. Executive Quality Assurance department from 4th July 2016 to 15th February 2018. (1 year, 7 months, 1 week, 4 days)

(ISO 9001:2008, ISO14001: 2004, OHSAS1800: 2007 Certifications, 2008 first USFDA inspection then March 2013 and September 2016 USFDA Surveillance.)

Job Responsibilities:

1. Responsible for handling of Change control, Deviation, Incident Reports, OOS & OOT as per STP.
2. Responsible for review of Standard Operating Procedures pertaining to QC.
3. Responsible for review of Analytical Data and Electronic data.
4. Responsible for co-ordination and review of Analytical Method Validation and Analytical Method Transfer.
5. Responsible for preparation and review of Standard Operating Procedures pertaining to Quality Assurance.
6. Responsible for preparation and review of Annual Product Quality Review and Apex Documents.
7. Responsible for review of Raw Material, Intermediate, in-process and Finished product trend.
8. Responsible for review of document and records pertaining to Microbiology laboratory.
9. Responsible for IPQA in QC Dept.

* Worked with **ACHARYA PHARMA PVT. LTD**. Ambernath (w). as an Sr. Executive of Q.C. Dept. since 9th December 2014 to 29th June 2016 (1 year, 6 months, 2 weeks, 6 days)

( ISO 9001 – 2000 and W.H.O. approved pharmaceutical company of API division.)

Job Responsibilities

* + Present Profile:

1. Section wise distribution of work allocation to jr. analyst.
2. Checking of related documents i.e. in process slips, recover solvents, intermediate, finished product, raw materials GRN.
3. Maintain of sampling procedure, cleaning sample.
4. Preparation of working standard and documents.
5. Column performance.
   * Documents:
6. Review of documents of finished products, in-process, Intermediate, Raw material.
7. Maintaining all instrument related log book.
8. Maintain working standard log book and consumption record of it.
9. Review of impurity and chemical log books.
10. Review of S.O.P.s, S.T.P.s,
    * Instruments handled:
11. HPLC Quaternary (Agilent1200,Ezchrome Elite software Revision 3.3.2 V.04& Agilent 1260, Open lab software A.04.05)
12. GC (Shimadzu GC-2010 Plus gas chromatograph, Lab solution 6.31)

* Calibration of instruments.
* Maintaining service report and breakdown register.
* Maintaining log books
* Handling trouble shootings.
* Worked with **D.K. PHARMA PVT.LTD**. as s an Q.C. Sr. Executive Officer since 22st March 2011 to 01 March 2014. (total 2 year, 11 months, 1 week)

( ISO 9001 – 2000 pharmaceutical company of API division.)

Job Responsibilities

* + Working for Stability section, finished product, In process section.
  + Maintain all stability related data, trend charts.
  + Handling of all the instruments like HPLC.
* Worked with **AARTI INDUSTRIES LTD.** as an Q.C. Officer since 21st June

2010 to 14th March 2011. (Total 8 months, 3 weeks)

( ISO 9001 – 2000 and W.H.O. approved pharmaceutical company of API division.)

Job Responsibilities

* + Working in raw material, in-process section.
  + Handling of all the instruments like HPLC, GC, UV, KF.
* Worked with **“WATSON PHARMACEUTICAL INDIA PVT. LTD.”** as Q.C. Officer since 11th August, 2007 to 12th June 2010. (total 2 years, 10 months, 1 day)

(U.S. based Multinational company having USFDA,IMB and W.H.O. GMP approved and engaged in manufacturing of Tablet and Capsules)

Job Responsibilities

* + Working in Stability Section
  + Individual handling Stability section
  + Submission of ANDA Stability Data to USFDA.
  + Submission of Stability Data of Commercial product
  + Handling of SAP operation related departmental function :

Analytical work sheet print through SAP

Results submission though SAP

* + Handling of instrument HPLC, Dissolution apparatus, UV, IR, KF apparatus.
* Worked with **“GEO CHEM LAB PVT. LTD.”** as Q.C. Analyst from 26th April 2005 to 07th August 2007. (Total 2 years, 3 months, 1 week, 5 days)
  + Analysis of Stability Data for Formulation as per parties specification
  + Handling of instrument HPLC.
  + Results submission to the party along with Trend Chart as per party’s requirements.
* Worked with **“GEO CHEM LAB PVT. LTD.”** as Trainee from 25th Oct 2004 to 24th April 2005. (Total 6 months)
  + Analysis of tables capsule as per parties specification
  + Handling of instrument HPLC,UV,GC,IR,DISSOLUTION,D.T etc

## INSTRUMENT HANDLED

* HPLC –(Auto sampler)

Agilent 1200 series- Ezchrome Elite 3.2.1and

Shimadzu LC 2010A H-Lab solution 1.22SP1&1.22SP1.

* GC-Agilent 7890A –Ezchrome Elite 3.3.2 SP1, Ezchrome Elite 3.2.1.

Shimadzu GC 2010 - Lab solution 2.30.00SV3

Shimadzu GC 17A - Lab solution 2.30.00 (Manual)

* UV Spectrophotometer 1700– Shimadzu.
* Dissolution Tester – Electro lab, Lab India (Manual and Auto Sampler)
* IR Prestige21 (FTIR) –Shimadzu-IR solution 1.30
* Melting Range apparatus(auto)-Lab India-MR-VIS
* Density meter (Auto)-DMA-38
* KF Titrino plus 870–Metrohm
* Particle Size-Malvern-MastersizersV2.19
* Surface are analyzer –Thermo-Totalchrom navigator 6.3.1

## achievement

* Successfully achieved USFDA audit for Watson formulation plant

in 17th June 2008 for the submission of three months Stability data for A.N.D.A. product.

## OTHER ACHIEVEMENTS

* Method transfer of ANDA product form WATSON Ambernath division to WATSON Goa division for the month of August 2009.

## EDUCATIONAL QUALIFICATION

* Passed B.Sc. (Chemistry) from University of Mumbai in the Year 2003.
* Advanced Diploma in Technical and Analytical Chemistry from K.C. College in Year 2005. ( First class )
* M.Sc. Chemistry in Year 2012 from V.M.U University. ( First class )

## COMPUTER PROFICIENCY

* Computer Basic Knowledge with MS – Office.

## PERSONAL DETAILS

**Date of Birth :** 04th July, 1979.

**Marital Status :**  Married.

**Languages Known :** English, Hindi and Marathi.

**Nationality :** Indian.

**Strength :** Quick Learner & Hardworking.

**Gender** : Male

## INTERESTS

* Listening music
* Drawing & Singing.

## EXTRA CURRICULAR ACTIVITY

* Executive committee Member of Science Association in College.
* Executive committee Member of Marathi VangmayMandal in College.
* Achieved second price in Drawing competition for Mumbai Sakal at State level.
* Qualified in English and Math for Vidyabharati competitive exams.
* Achieved best price in Singing at School and College.

**Date: / /**

**Place: Badlapur (PrafullaNagnath More)**