Venkatesh Naidu

QC Chemist (HPLC)

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PERSONAL STATEMENT

Quality control chemist with 5 years of experience in USFDA- and EU-GMP-approved API and oral solid dosage plants. Hands-on with HPLC, GC, dissolution, Karl Fischer and UV under cGMP and ALCOA+ data-integrity practices, and experienced in OOS/OOT investigations and regulatory audits.

WORK EXPERIENCE

Executive, Quality Control · Godavari Lifesciences Ltd, Visakhapatnam — May 2023 – Present

- Perform assay, related substances and residual solvent testing on HPLC and GC using Empower 3 for 25–30 finished API batches a month.
- Investigated 6 OOS and 4 OOT results with QA, identifying root causes and closing CAPAs within agreed timelines.
- Faced USFDA and EU-GMP inspections as a QC analyst; the lab received no data-integrity observations.
- Cut HPLC run time for one impurity method by 35% after a validated method change, freeing about 40 instrument hours a month.

QC Chemist · Srikakulam Pharma Formulations Pvt Ltd, Srikakulam — Jul 2021 – Apr 2023

- Tested raw materials, in-process and finished tablets for dissolution, assay, KF water content and uniformity of dosage units.
- Calibrated HPLC, dissolution apparatus, UV and KF titrators as per schedule and kept logbooks inspection-ready.
- Prepared and standardised volumetric solutions and maintained working standards and reagent inventory.

EDUCATION

M.Sc in Analytical Chemistry · Andhra University affiliated college, Visakhapatnam — 2019 – 2021
Grade: 78%

B.Sc in Mathematics, Physics and Chemistry · Government Degree College, Vizianagaram — 2016 – 2019
Grade: 81%

SKILLS

HPLC (Empower 3) · Gas chromatography · Dissolution testing · Karl Fischer titration · UV-Vis spectroscopy · OOS / OOT investigation · Instrument calibration · cGMP and GLP documentation

CORE SKILLS

- Data integrity (ALCOA+)
- Audit readiness
- Root cause analysis
- Analytical accuracy
- Teamwork with QA and production

CERTIFICATIONS

Training on data integrity and ALCOA+ principles · Company GMP training programme — Feb 2024

LANGUAGES

English · Professional · Telugu · Native · Hindi · Conversational

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