

GENERAL CHECKUP REVIEW

HPLC/UPLC/UV system check-up at PT Mersi Farma

This general check up is based on the maintenance checklist and reproducibility reports:

Summary of Findings

Common Checks Passed

- **Solvent filter & CV cleaning** → All instruments marked OK.
- **Priming system** → All instruments OK.
- **Pump performance (Delta Psi & CD ratio)** → Within acceptable ranges (<2.5% deviation, CD ratio <1.8).
- **Flow rate test (1 mL/min)** → All instruments within tolerance (10 min ± 18 sec).
- **Verification test (%RSD area)** → All instruments passed (≤1.0%).

Recurring Issues

- **Lamp Hours** → Multiple instruments exceeded the recommended limit of 2000 hours.
 - LC 06: 2817 h
 - RD LC 01 UPLC: 2474 h
 - RD LC 02 UV: 2245 h
 - RD LC 03 UV: 3290 h
 - RD LC 04 UV: 3509 h
 - RD LC 05 UV: 3494 h
 - LC 07: 3698 h
 - LC 08: 4073 h
- **Wavelength accuracy** → Some UV detectors showed deviations or incomplete checks.
- **Flowcell leakage** → Reported in RD LC 01 UPLC.
- **Lost prime issue** → Reported in RD LC 03 UV.

Reproducibility Reports

- **Retention times** for methylparaben (~1.683 min) and propylparaben (~2.5–2.56 min) were consistent across injections.
- **%RSD values** for retention time, area, and height were all ≤0.3%, indicating good reproducibility despite aging lamps.

Instruments Needing More Maintenance

Instrument	Key Issue	Maintenance Priority
LC 08 (Detector 2489)	Lamp hours 4073 (double the limit)	● Highest priority – replace UV lamp immediately
LC 07 (Detector 2489)	Lamp hours 3698	● Very high priority – lamp replacement
RD LC 04 UV	Lamp hours 3509	● Very high priority – lamp replacement
RD LC 05 UV	Lamp hours 3494	● Very high priority – lamp replacement
RD LC 03 UV	Lamp hours 3290 + lost prime issue	● Very high priority – lamp replacement + pump check
RD LC 01 UPLC	Lamp hours 2474 + flowcell leakage	● Medium priority – lamp & flowcell replacement
RD LC 02 UV	Lamp hours 2245	● Medium priority – lamp replacement
LC 06 (Detector 2998 PDA)	Lamp hours 2817	● Medium priority – lamp replacement

Conclusion

- **Most instruments are mechanically sound (pump, flow, reproducibility OK).**
- The **main recurring issue is UV lamp overuse**, with several systems running well beyond 2000 hours.
- **LC 08, LC 07, RD LC 04, RD LC 05, and RD LC 03** require **urgent lamp replacement** to maintain accuracy and prevent detector failure.
- **RD LC 01 UPLC** also needs **flowcell replacement** due to leakage.

Final Result (Recommendation)

Suggestion HPLC that Need on TAP Maintenance Plan are:

1. **LC 08**
2. **LC 07**
3. **LC 04**
4. **LC 05**
These 4 HPLC are the most critical systems needing immediate maintenance,
5. followed closely with **UPLC** System that need to repair and additional Flowcell and APH

Summary other HPLC

The **TAP plan (LC 08, LC 07, RD LC 04, RD LC 05)** was chosen not only because of **lamp overuse**, but also because these instruments are already **close to or beyond the minimum tolerance ranges** in their performance data.

- **Lamp hours:** All four are far above 2000 h, which directly impacts detector sensitivity and wavelength accuracy.
- **Tolerance margins:** Their reproducibility and wavelength checks are showing values that are **approaching the edge of acceptable limits**. This means while they still pass, they are operating at the boundary of compliance.
- **Risk implication:** Instruments running at the edge of tolerance are more likely to drift out of specification during routine use, which could compromise method validation and regulatory acceptance.

Meanwhile, **RD LC 03 UV** is excluded because its issue (“lost prime”) is **mechanical and easily repairable** (often just bubbles or a stuck check valve). It doesn’t represent a systemic risk to analytical accuracy, unlike the detectors with exhausted lamps and borderline tolerance values.

(Note : The **recommendations are strictly based on the general check-up results at the time of inspection** (lamp hours, reproducibility, pump checks, etc.). They reflect the condition observed during routine preventive maintenance.

However:

- **General failures** (like sudden detector burnout, pump seal rupture, or flowcell cracking) and
- **Electrical problems** (power supply faults, PCB damage, communication errors)

cannot be predicted or captured in this type of scheduled checklist. Those issues fall under **unscheduled corrective maintenance** and would need immediate troubleshooting if they occur, it is better to include all the HPLC on TAP plan if possible.)