



IMPACT ASSESSMENT FOR DEVIATION IN CALIBRATION OF HPLC

Objective: The objective of this report is to evaluate and assess the deviation in calibration, regarding the impact on the performance of Instrument HPLC.

Justification of Deviation: Following points to be followed during.

1. Instrument HPLC gone under maintenance due to D2 Lamp is not working.
2. After review the Calibration calendar, it was found that calibration of HPLC has been due.
3. Calibration cannot be done as D2 Lamp is not received.
4. Planned Deviation has been raised as per deviation by user.

Impact Analysis: There is no any potential impact on the analytical performance of HPLC. Following point can be review-

1. Instrument HPLC has been gone under maintenance on **(Refer to Annexure-I)**.
2. Before going under maintenance last, analyzed. To check the performance of instrument system suitability has been reviewed and found OK **(Refer to Annexure-II)**.
3. D2 Lamp received on.....
4. Calibration is done on and completed on and found OK **(Refer to Annexure-III)**.
5. To check the performance system suitability is reviewed for and found OK **(Refer to Annexure-IV)**.

Conclusion: Based on the above it is concluded that the performance of instrument HPLC has been performed properly and produce the analytical results with respect to the quality of products.

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