

OUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Control SOP No.:				
Title: Instrument usage log	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

1.0 OBJECTIVE:

To lay down procedure for instrument usage log.

2.0 SCOPE:

This SOP is applicable Quality Control Department.

3.0 RESPONSIBILITY: Execution - Executive QC

Checking - Assistant Manager QC

- **4.0 ACCOUNTABILITY -** Manager Quality Control
- **5.0 PROCEDURE:**
- 5.1 GENERAL PROCEDURE:
- 5.1.1 "Instrument usage log" shall be issued as per "Issuance and retrieval of formats SOP".
- 5.12 If instrument operation carry out satisfactory then analyst shall write "satisfactory" in Remark column.
- 5.1.3 If the instrument used for calibration purpose then after satisfactory results analyst shall write "calibrated" in Remark column.
- 5.1.4 If instrument operation in between is discontinued then analyst shall write "discontinued" in Remark column with a reason for discontinuation.
- 5.1.5 Instrument usage log shall be verified for any incomplete entry or for erroneous entry by Manager QC or Designee randomly and put initial / date against the entry .
- 5.1.6 Instrument usage log shall not be mentioned for the instruments like Ultra cleaner, water bath, centrifuge and instruments which are not used directly for the measurement of product.
- 5.2 INSTRUMENT USAGE LOG FOR BALANCE (Refer Annexure –I)
- 5.2.1 Analyst shall make entry in "Instrument usage log" at the time of balance usage for "Date", "Product/ material" "B.No. / AR No.", "No. of sample", "Started at (time)" and put initial in "Analysed by" column.
- 5.2.2 After the completion of instrument usage analyst shall make entry in "Completed At (Time)"
- 5.2.3 In case of balance used for the weighing of reagent / test solution preparation then analyst shall write "NA(Not applicable)" in "B.No. / AR No." column.
- 5.2.4 In case of balance used for the weighing of primary / secondary / WS/ impurity preparation then "Code No." of the same shall be mentioned in "B.No. / AR No.", column.



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5.3 INSTRUMENT USAGE LOG FOR GC (Refer Annexure –II)

- 5.3.1 Analyst shall make entry in "Instrument usage log" at the time of GC instrument usage for "Date", "Product/ material" "B.No. / AR No.", "Column No." "Started at (time)" and put initial in "Analysed by" column.
- 5.3.2 After the completion of instrument usage analyst shall make entry in "Completed At (Time)"

5.4 INSTRUMENT USAGE LOG FOR HPLC (Refer Annexure –III)

- 5.4.1 Analyst shall make entry in "Instrument usage log" at the time of HPLC instrument usage for "Date", "Product/ material" "B.No. / AR No.", "Column No.", "Flow rate", "Started at (time)" and put initial in "Analysed by" column .
- 5.4.2 After the completion of instrument usage analyst shall make entry in "Completed At (Time)"

5.5 INSTRUMENT USAGE LOG FOR OTHER INSTRUMENT (Refer Annexure –IV)

- 5.5.1 Analyst shall make entry in "Instrument usage log" at the time of instrument usage for "Date", "Product/ material" "B.No. / AR No.", "Started at (time)" and put initial in "Analysed by" column
- 5.5.2 After the completion of instrument usage analyst shall make entry in "Completed At (Time)"

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

Сору	Issuance Record					Withdrawal Record		Destruction Record	
No.	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	Ву	Sign/ Date	Ву	Sign/ Date	



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9.0 REFERENCES:

"Issuance and retrieval of formats SOP"

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance
QC : Quality Control

GC : Gas Chromatography

HPLC: High performance Liquid Chromatography

Annexure –I: Instrument Use Log For Balance

Annexure -II: Instrument Use Log For GC

Annexure –III: Instrument Use Log For HPLC

Annexure –IV: Instrument Use Log For Other instruments



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ANNEXURE – I INSTRUMENT USE LOG FOR BALANCE

MAKE: MODEL:

Date	Product /Item name	B.No. / AR No.	No. of samples	Started at (Time)	Completed at (Time)	Analysed by	Checked by	Remarks



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ANNEXURE – II INSTRUMENT USE LOG FOR GC

INSTRUMENT : INSTRUMENT CODE: MAKE: MODEL:

Date	Product / Item name	B.No. / AR No.	Column No.	Started at (Time)	Completed at (Time)	Analysed by	Checked by	Remarks



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ANNEXURE – III

INSTRUMENT USE LOG FOR HPLC

INSTRUMENT: INSTRUMENT CODE:

MAKE: MODEL:

Date	Product / Item name	B.No. / AR No.	Column No.	Flow rate	Started at (Time)	Completed at (Time)	Analysed by	Checked by	Remarks



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ANNEXURE – IV INSTRUMENT USE LOG FOR OTHER INSTRUMENTS

MAKE: MODEL:

Date	Product / Item name	B.No. / AR No.	Started at (Time)	Completed at (Time)	Analysed by	Checked by	Remarks