STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Handling of GC Column	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Receipt, issuance, usage, Storage, Performance, Regeneration, and destruction of GC column in the Quality Control laboratory.

2.0 SCOPE:

This procedure is applicable to Receipt, issuance, usage, Storage, Performance, Regeneration and destruction of GC column in the Quality Control laboratory.

3.0 RESPONSIBILITY:

Officer, Executive – Quality control

Head – Quality Control

4.0 PROCEDURE:

4.1 Receipt of GC Column:

4.1.1 On receipt of new GC column, check the pack of column physically as per indent and check the performance report of the manufacturer.

4.1.2 Record the date of receipt, Name of Column, Batch/Sr. No, Cat. No, dimensions, Make/ Suppliers and column destruction date in “Column Inward Record” as per Annexure-I.

4.1.3 The manufacturer’s column performance certificate shall be filed by Responsible QC Officer and retained for future reference

4.2 Issuance of GC Column

4.2.1 Record the name of column, Column ID. No., Product Name/ Raw material, Test, Date of issuance and Issued by in “Column issuance record” at the time of Column issue as per annexure-II

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4.2.2 Assign GC column Id. number

GCC/XXX/YY

Where,

GCC : Gas Chromatography Column

XXX : Serial number

/ : Slash

YY : Year (i.e. 15 for the year 2015)

4.3 Usage of GC Column

4.3.1 Record for usage of column in the respective column usage logbook as per Annexure-III

In case the product analysis requires the same column for two different tests at a time, then

4.3.2 additional column shall be issued and used for carrying out the

analysis

4.3.3 In case the product analysis requires the same column for two different tests at a time, then additional column shall be issued and used for carrying out the analysis.

4.3.4 For the same products having multiple columns, analyst shall use the column based on the FIFO (First In First Out).

4.3.5 Only If the system suitability of the column is meeting the system suitability requirement for the test performed, then the analysis shall be continued. Otherwise the column regeneration has to follow as per 4.6 or 4.7 depends upon type of chromatography otherwise new column has to issue

4.4 Performance of GC Column

4.4.1 At the time of first analysis GLP Person has to ensure to receive the System suitability chromatogram from analyst, fill System suitability criteria on the annexure-IV as per respective STP and attach the chromatogram with manufacturer's column performance certificate.

4.4.2 Accept the column only if all the system suitability parameter is within limits.

4.5 Usage of the columns:

4.5.1 **Column installation for capillary column: For Injector end:**

For any new column cleave off 1-2 cm from the injector end of the column.

Insert the injector end of the column in to the injection port, making sure to

insert it at the appropriate distance.

Tighten the ferrule until the column no longer slides up or down the fitting. One fourth of a turn past finger tight is usually.

Apply carrier gas pressure at least 5psi (1kpa = 0.145psi) for 0.53 mm ID, 10psi for 0.32 mm ID, 20psi for 0.25 mm ID and 30psi for 0.20 mm ID columns.

4.5.2 **For Detector end:** For any new column cleave off 1-2 cm from detector end of the column. Wait 1 minute, then check the gas flow by dipping the

Detector end of the column in to a vial of non-toxic solvent (Water: IPA, 50:50) and check for carrier gas bubbles.

Install the detector end of the column in to the detector port making sure to insert it at the appropriate distance and follow the remaining procedure as per step-4.5.1 to

Check the leakage from injector end and detector end by using Water: IPA, 50:50.

4.5.3 **Column installation for Packed column:**

For Injector end: Insert the injector end of the column in to the injection port, making sure to insert it at the appropriate distance.

Tighten the Nuts and ferrule until the column no longer slides up or down the fitting.

Apply carrier gas pressure and purge the column for at least 15 minutes.

For Detector end: Check the gas flow by dipping the detector end of the column in to a vial of non-toxic solvent (Water: IPA, 50:50) and check for carrier gas bubbles.

Install the detector end of the column in to the detector port making sure to insert it at the appropriate distance and follow the remaining procedure as per step-4.5.1 to 4.5.2

Check the leakage from injector end and detector end by using Water: IPA, 50:50.

4.6 Column conditioning:

For any new column purge the column with carrier gas for 15 minutes keeping detector end open.

Increase the temperature gradually from 25°C or ambient at the rate of 10°C/min. or suitable rate to reach the column temperature below 25°C of the maximum temperature of the column.

Maintain the achieved temperature for about 2-3 hrs. or till the baseline gets stabilized.

In the case of thermally stable methyl- and phenyl-substituted polysiloxanes, a special sequence increases inertness and efficiency; maintain the column at a temperature of 250° for 1 hour, with helium flowing, to remove oxygen and solvents. Stop the flow of helium, heat at about 340° for 4

hours, and then reduce the heating to a temperature of 250°, and condition with helium flowing until stable or condition the column as per column specification/manufacture specification.

4.7 Discarding of the Column

Discard Column, in case of Non- compliance of system suitability parameters against the material / product system suitability.

Head QC or designees shall make an entry of "DISCARDED ON", and "REASON FOR DISCARD" in "Column Inventory/Index" also in "GC Column Usage Log" in "Remarks" column.

5.0 ANNEXURE(S):

Annexure –I : Column Inward Record.

Annexure –II : Column Issuance record.

Annexure –III : Column Usage Record.

Annexure –IV : Column Performance Report

6.0 REFERENCE (S):

USP <621> / BP Appendix III / Ph. Eur. 2.2.46/IP 2.4.13 & 2.4.14

SOP: Preparation, approval, distribution, control, revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S)/ DEFINITION (S):

GC: Gas chromatography

µl : micro liter

NMT : Not more than

NLT : Not less than

RT : Retention Time

USP : United States Pharmacopoeia

BP : British Pharmacopoeia

Ph. Eur. : European Pharmacopoeia

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IP : Indian Pharmacopoeia

STP : Standard Test procedure

° : Degree

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE I
COLUMN INWARD RECORD

S.No.	Date of Receipt	Name of Column	Batch No. / Sr. No	Cat. No.	Column Dimension/ Material	Make/ Suppliers	Received by	Destruction date	Destructed by	Remarks

ANNEXURE II
COLUMN ISSUANCE RECORD

S.No.	Name of column	Column ID. No.	Name of Product/Raw material	Test	Date of Issuance	Issued by Sign

PHARMA DEVILS

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ANNEXURE III

COLUMN USAGE RECORD

Name of Column:			**Column ID No.:**		**Dimension:**	
S.No.	**Date of Analysis**	**Name of product**	**No. of Injection**	**Cumulative Injection**	**Analyst**	**Remarks**

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ANNEXURE IV
COLUMN PERFORMANCE REPORT

Observation: For

System Suitability Criteria	Observations	Limits
Theoretical Plate		
Tailing Factor		
Resolution		
% RSD		

Conclusion: The column is satisfactory/ Not satisfactory for analytical use.

Analyzed By:
Date:

Checked By:
Date:

Approved By:
Date: