PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Management of GC Column	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for management of GC Column.

2.0 SCOPE:

This SOP is applicable to all the GC Columns received in the Quality Control Department.

3.0 RESPONSIBILITY - Execution - Executive QC

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Receipt of New Column

5.1.1 Upon receipt of the column, Analyst shall be verified the details like Batch No. / Column serial No., make, size, type against the purchase requisition and certificate of column and allocate the column no as per current version of SOP "Numbering System".

5.1.2 Respective column no. shall be written on its certificate and to be filled accordingly.

5.1.3 Column details shall be filled in the "Column inventory / Index" as per annexure - I i.e. " Column No.", "Column Type" (Stationary phase or Brand Name), "Make", "Column Serial no." (Available on Column or in certificate), "Date of purchase"," Reference page no. of Column usage log" and "Dedicated for"(name of product) in the "Column inventory / Index" (Annexure - I).

5.1.4 Details of Column shall be filled in "Column label" for "type", "Particle size", "Dimension", "Column No." and "For"(Name of product) as per Annexure - II and label shall be affixed on it.

5.2 Usage of The Columns

5.2.1 **Column Installation and Precaution**

5.2.1.1 Install the column to GC oven column hanger. Take care the column tube does not touch the sides of the oven and sharp edges of column tags do not rub to column.

5.2.1.2 Unwind enough column to obtain a smoothly curved of tubing connected to inlet.

5.2.1.3 Do not apply extra force to tight the nut, which can be a cause of tube breakage.

5.2.1.4 Check the leakage at the joint with three / four drops of 50% .v/v solution of IPA in water prior to use.

5.2.2 **Column Conditioning**

5.2.2.1 Purge the column with carrier gas for 15 minutes.

5.2.2.2 Increase the temperature gradually to below 25 ºC of the column maximum temperature for about 30 minutes. Set the required temperature and condition for about 30 minutes. After obtaining stable baseline this shall be used.

5.2.3 **Column Efficiency Check**

5.2.3.1 For any new column, analyst shall check the column performance as per "GC COLUMN EFFICIENCY CHECK PROTOCOL" (Annexure - IV) prior to use.

5.2.3.2 For any specific make column where in – house method of column efficiency does not give satisfactory results, consider manufacturer's column efficiency report and take the authorisation of QC Manager for the usage of the same. Check the system suitability parameters by analysing the product, for which column is to be use. If system suitability parameters found satisfactory, reject the column for that particular product. Attach the system suitability raw data of product along with the manufacturer's column efficiency report.

5.2.3.3 Upon satisfactory column performance check data shall be given along with raw data for checking to designated person and for the final approval shall given to QC Manager.

5.2.3.4 Upon satisfactory column performance check, column shall be issued for the respective analysis by QC Manager or designee and "Date in use", column shall be filled in"Column inventory / Index".

5.2.3.5 In case of column performance not found satisfactory then reject the column.

5.2.3.6 In case of system suitability is not achieved after the required changes then analyst shall carryout reconditioning of column, perform the column efficiency and check the and the system suitability against the criterion.

5.2.3.7 After reconditioning if, column performances found satisfactory continue the usage for analysis. If, column performance found unsatisfactory then discontinue the usage and discard the column after the Authorisation of QC Manager.

5.2.4 After satisfactory column performance check QC Manager or designee shall issue column for analysis. Enter the details like "Date in use", "Column inventory / Index". (annexure - I)

5.2.5 In case a different make or manufacturer (i.e. Other than dedicated make) proper Authorisation of QC Manager shall be taken in remarks column of "column inventory / Index" prior to use.

5.2.6 Column shall be conditioned prior / after the analysis as per the above procedure.

5.2.7 Make necessary entries on every usage of the column in respective column usage log for "Date", "Product / Sample", "Batch No. / AR No.", "No. of injections", "Cumulative Injections", "usage time"(Start time and End time of column flushing), "flushed with (Name of gas)", "Sign"(Analyst's initials) and" Remarks" (if column performance is found as per requirement than use "Satisfactory".

5.2.8 If column performance is not found as per requirement mention specific reason (Like: Theoretical plates or Tailing factor or Resolution are not comply) (Annexure - III).

5.2.9 After completion of conditioning of column, open the door of column oven and allow cooling to room temperature, disconnecting the column, fixing column ends tightly and keeping the column at designated place.

5.3 Discarding of The Columns

5.3.1 Discard the column, in case of non-compliance of system suitability parameters against the criterion for the column efficiency check and product system suitability.

5.3.2 QC Manager or designee shall make entry of "DISCARDED ON", "NO. OF CUMULATIVE INJECTIONS ", and "REASON FOR DISCARD" in "COLUMN INVENTORY / INDEX"., also in "GC Column Usage log" for" Remarks" Column.

5.3.3 Discard the column, in case a loss of packing material is found in the ccolumn and take the Authorisation of QC Manager or designee.

5.3.4 Discard the column if it gives high backpressure even after conditioning; take the Authorisation of QC Manager or designee.

6.0 SAFETY & PRECAUTIONS:

Not applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

SOP of "Numbering System"

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10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

Annexure - I : Column Inventory / Index

Annexure - II : Column Label

Annexure - III : GC Column Usage Log

Annexure - IV : GC Column Efficiency Check Protocol

Annexure - V : GC Column Reconditioning Protocol

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ANNEXURE - I

COLUMN INVENTORY / INDEX

Column No.	Column Type	Make	Column No.	Date of Purchase	Ref. Page No. of Column Usage Log	Dedicated For	Date in Use	Discarded on	No. of Cumulative Injections	Reason For Discard	Remarks

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ANNEXURE - II

COLUMN LABEL

Type : _____

Particle size: _____µm

Dimension: _____

Column No. : _____

For :_____

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ANNEXURE - III

COLUMN USAGE LOG

COLUMN NO. : _____ **MAKE :** _____

COLUMN TYPE :_____ **DEDICATED FOR:** _____

Date	Product /Sample	B.No./A. R.No.	No. of Injection	Cumulative Injections	Usage Time		Conditioning Time		Sign	Remarks
					Start	End	Start	End		

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ANNEXURE - III

COLUMN USAGE LOG

COLUMN NO. : _____

Date	Product /Sample	B.No./A. R.No.	No. of Injection	Cumulative Injections	Usage Time		Conditioning Time		Sign	Remarks
					Start	End	Start	End		

Remarks: For each column, First page of GC column usage log shall be as per Page no. 1 of 2 of Annexure - III and second to ten pages shall be as per Page no. 2 of 2 of Annexure - III.

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ANNEXURE - IV

GC COLUMN EFFICIENCY CHECK PROTOCOL

Column Type:			
Column No.:		No. of Cumulative Injections:	
Reason for Efficiency check :			
Test mixture preparation: Take about (1 ml)____ml of methanol and (1 ml)____ml of acetone in a 100 ml volumetric flask, mix well and make up the volume with water, mix well.			
Procedure: Make single injection of water blank and triplicate injections of test mixture preparation. Record the chromatogram, check the peak shape of methanol and calculate the system suitability for methanol peak. The order of elution is Acetone (first) and methanol (second). Attach the chromatogram with the protocol.			
	Test Condition	Applied Condition	
1.0 GC Set up:			
a. Flow Rate	About 3 ml / min		
b. Carrier	Nitrogen		
c. Column Temperature	About 90 º C		
d. Injector Temperature	About 150 º C		
e. Detector Temperature	About 180 º C		
f. Injection volume	0.5 µl		

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ANNEXURE - IV

GC COLUMN EFFICIENCY CHECK PROTOCOL

	Test Condition	Applied Condition
2.0 Integration Parameters		
a. Width		
b. Threshold		
c. Other (if any)		
3.0 System suitability for methanol peak		
a. Theoretical plates / meter	NLT 500	
Conclusion: The column is Satisfactory / Not Satisfactory for the analytical use.		
Remarks:		
Analyst: **Checked by:** **Approved by:**		
Date: **Date:** **Date:**		

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ANNEXURE - V

GC COLUMN RECONDITIONING PROTOCOL

Column Type:		
Column No.:		
Reason for Regeneration:		
Procedure: • If material found dirty or coloured than discard the portion of that packing material. • Attach the column in column oven • Purge the column with carrier gas for 15 minutes. • Increase the temperature gradually to below 25º C of the column maximum temperature for about 30 minutes. Set the required temperature and condition for about 30 minutes. After obtaining stable baseline this shall be used.		
	Column maximum temperature	Applied temperature
1.0 GC Set up:		
a. Flow Rate		
b. Column Temperature		
Remarks:		
Analyst: Date:	Checked by: Date:	Approved by: Date: