

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Handling and Numbering System for GC Standards	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To provide guidelines for allotment of number to GC Standards.

2.0 SCOPE:

This SOP is applicable in Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control.

Responsible for allotment of number to GC standards.

Head – Quality control:

Responsible for implementation and compliance of SOP.

4.0 **PROCEDURE**:

4.1 Handling of GC standards:

- 4.1.1 Always use chromatographic grade solvents.
- 4.1.2 Procure the solvents along with Certificate of Analysis.
- 4.1.3 Maintain the 'COA' and Material Safety Datasheet of each solvent.
- 4.1.4 Enter the details of receipt GC standard solvents in format given as per Annexure-I.

4.2 Allotment of number to GC standards:

- 4.2.1 Assign the number of respective GC standard name as per format given in Annexure-II.
- 4.2.2 Each GC standard name shall be given number as below.

The number consists of six characters "GCS001"

Where,

 $1^{\mbox{st}},\,2^{\mbox{nd}}$ and $3^{\mbox{rd}}$ characters 'GCS' - Gas Chromatograph Standard

4th, 5th and 6th characters '001' - Assign the number of respective GS standard name.

characters

7th character '/' - slash

 $8^{th,}\,9^{th}$ and $10^{th}\,characters$



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4.2.3 Each standard at the time of opening give a version no. of the respective solvent standard no. which has been expressed as a "GCS001/15-00".

Where,

- 15 Current Year 2015
- 00 version no. of respective standard
- 4.2.4 If any GC standard, opening a new bottle version no. shall be changed.
- 4.2.5 Allot the number to solvent and enter the details in 'GC standard record' as per Annexure III.
- 4.2.6 The purity of solvent shall be taken from certificate of analysis or purity mentioned on label of the respective bottle.
- 4.2.7 The validity period for the GC solvents will be one year from the date of opening or the date mentioned by the manufacturer whichever is earlier.
- 4.2.8 Enter the details in 'GC standard' label as per Annexure-IV and paste it to the bottle.
- 4.3 Storage:

Keep the GC standard bottles tightly closed and away from the source of ignition and heat.

5.0 ANNEXURE (S):

Annexure - I : GC Standard Inward Record

Annexure - II : GC Standard List

Annexure -- III : GC Standard Record

Annexure - IV : Specimen Label for GC Standard .

6.0 **REFERENCE** (S):

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

7.0 ABBREVIATION (S)/DEFINITION (S):

GC – Gas Chromatograph

SOP - Standard Operating Procedure



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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	



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ANNEXURE I

GC STANDARD INWARD RECORD

S.No.	Date of Receipt	Solvent Name	Quantity Received	B. No./ Lot No.	Manufacturer	Remarks



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ANNEXURE II GC STANDARD LIST

S.No.	Solvent Name	GC Standard No.

				MA DEVILS ONTROL DEPARTMENT				
			STANDARD OPE	RATING PROC	EDURE			
Depart	ment: Quality Control	l					SOP No.:	:
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			ANNEXUR GC STANDARD					
S.No.	Date of Opening	Solvent Name	B. No./ Lot No.	GC Standard Number	Valid up to	% Pu	rity	Remarks



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE IV SPECIMEN LABLE FOR GC STANDARD

G	C STANDARD	
Name of the Standa	rd :	
GC Standard Numb	er:	
Date of Opening	:	
% Purity	:	
Valid upto	:	