



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Chemical Analysis of Nitrogen	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Chemical Analysis of Nitrogen.

2.0 SCOPE:

This procedure is applicable for Chemical Analysis of Nitrogen.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control.

Head – Quality Control.

4.0 PROCEDURE:

4.1 Instrument:

Gas Chromatograph

4.1.1 Gas to be examined:

4.1.1.1 Reference gas (a): Use Ambient air.

4.1.1.2 Reference gas (b): Use Nitrogen R1.

4.1.3 Chromatographic condition :

Column: Stainless steel column 2m long and 2mm in internal diameter packed with an appropriate molecular sieve for chromatography (0.5 μ)

4.1.4 Procedure:

4.1.4.1 Collect the sample for Nitrogen Purity through Rubber Balder.

4.1.4.2 Inject reference gas (a). Adjust the injected volumes and operating conditions so that the height of the peak due to nitrogen in the chromatogram obtained with the reference gas is at least 35 per cent of the full scale of the recorder.

4.1.5 System Suitability :

4.1.5.1 The Chromatograms obtained show a clear separation of oxygen and nitrogen.

4.1.5.2 Inject reference gas (b) and the gas to be examined and calculate to content of N₂ the gas to be examined.

4.2 Test for Carbon monoxide:



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- 4.2.1.1 Select the specific Gastec tube for the testing of Carbon monoxide.
- 4.2.1.2 Carefully break both the ends of the detector tube.
- 4.2.1.3 Then insert the detector tube into MCAS sampler with the arrow G on the tube pointing towards the sampler.
- 4.2.1.4 Adjust the knob of pressure gauge so that the flow rate of air is 300ml/minute.
- 4.2.1.5 Sampled for the four minute of Nitrogen.
- 4.2.1.6 Then read and record the indication at end of the color change layer. The indicator change should not correspond to more than 10 ppm.

4.2.2 GASTEC TUBE CODE DETAILS

S.No	Name of Gastec Tube	Code No.
1.	Carbon monoxide	1LC

4.3.7 Determination of Oxygen content:

- 4.3.7.1 The concentration of oxygen is determined using Oxymeter.

4.4.8 Calibration of Oxymeter

- 4.4.8.1 The concentration of oxygen is determined using an Oxymeter. Refer to SOP.
- 4.4.8.2 Record the value as % the Oxygen content not more than 1.0 %.

4.4.9 Frequency:

Validation: Consecutive three days.
Revalidation: Once in Six Month for one day.

4.4.10 Limit

Nitrogen Purity –Not less than 99.0%
Carbon Monoxide – Not more than 10 ppm.
Oxygen Content - Not more than 1.0%

5.0 ANNEXURE (S):

Annexure-I: Inward Register of Nitrogen Sampled.
Annexure-II: Gastec Tube Sampling log sheet.
Annexure-III: Test Report for Nitrogen.

6.0 REFERENCE (S):

SOP: Operation and calibration of Oxymeter



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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SOP: Cleaning and Operation of MCAS ECO Compressed Air /Nitrogen Gas Sampler

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

7.0 ABBREVIATION (S)/ DEFINITION (S):

V/V- Volume/Volume

SOP- Standard Operating Procedure

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 III
TEST REPORT FOR NITROGEN

Date:	Sampling Point:
A.R.No.:	Sampled by:
MCAS ID. No.:	Oxymeter ID. No.:

CHEMICAL TEST

Test	Observation	Limits
Purity (%)		Not less than 99.0 %
Carbon monoxide (ppm)		Not More than 10 ppm.
Oxygen Content		Not more than 1.0 %

Remarks: The above sample complies / Does not Comply as per above limit.

Analyzed By
(Signature & Date)

Checked By
(Signature & Date)

Approved By
(Signature & Date)