

Rev.11	<b>METHANOL NF SPECIFICATION</b>		<b>Reference</b>
			<b>USP-NF-2021</b>
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Sr.No.	Test	Specification	Method of Analysis No.
1	Description	Methyl alcohol is a Clear, colorless, liquid, having a characteristic odour. Is flammable.	QC/PH-FG/SPEC/11-01
2	Solubility	Miscible with water, with alcohol, with ether, with benzene, and with most other organic solvents.	QC/PH-FG/SPEC/11-02
3	Identification a) By IR	The spectrum obtained with the substance to be examine corresponds in position & relative intensity to those in the spectrum obtained with that of Methanol USP CRS or its Working standard. (Purity index should not be less than 0.99)	QC/PH-FG/SPEC/11-03
	b) By GC	The retention time of the major peak of the test solution corresponds to that of the Standard solution, as obtained in the assay.	QC/PH-FG/SPEC/11-04
4	Acidity	Not more than 0.45 ml of 0.02N NaOH is required to produce pink color.	QC/PH-FG/SPEC/11-05
5	Alkalinity (As ammonia)	Not more than 0.20 ml of 0.02N H <sub>2</sub> SO <sub>4</sub> is required to produced Pink color (3ppm)	QC/PH-FG/SPEC/11-06
6	Water	Not more than 0.1%.	QC/PH-FG/SPEC/11-07
7	Readily carbonizable substances	No decolorization develops	QC/PH-FG/SPEC/11-08
8	Readily Oxidisable substances	The pink color does not completely disappear within 5 min	QC/PH-FG/SPEC/11-09
9	Acetone & Aldehydes (As acetone)	Any turbidity produced in the sample solution is not greater than that produced in the standard solution. (NMT 0.003%).	QC/PH-FG/SPEC/11-10
10	Non volatile residue	The weight of the residue does not exceed 2 mg (NMT 0.001% w/w)	QC/PH-FG/SPEC/11-11
11	Assay (By GC)	Not less than 99.5%.	QC/PH-FG/SPEC/11-04
12	Residual solvents		QC/PH-FG/SPEC/11-12
	Benzene	Not more than 2 ppm (v/v)	
	Ethanol	Not more than 5000 ppm (v/v)	
	Acetone	Not more than 5000 ppm (v/v)	

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	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C.	Q.C.	Q.A.
SIGNATURE	<u>R. Sarkate</u>	<u>Mrj</u>	<u>P. Pandit</u>
DATE	06/07/2021	07/07/2021	07/07/2021

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### GENERAL INFORMATION

**Structure:**

**Molecular Formula:** CH<sub>4</sub>O

**Molecular weight:** 32.04

**Desirable Pack:**

To be supplied in SS container/HDPE container/ Glass bottle, properly identified with a label having Name of the material, Name of the Manufacturer, Quantity, Manufacturer's Batch Number, Manufacturing Date, Expiry Date and or Retest Date.

**Storage Condition:**

Preserve in tight containers, remote from heat, sparks, and open flames.

**Handling precaution:**

Use PPE (Personal Protective Equipments) during handling of the material.

**Sampling SOP:**

As per the current approved sampling procedure. (SOP/CASE/01)

**Quantity to be sampled:**

Analysis Sample: About 720 ml

Control Sample: About 1440 ml

Stability Sample: About 300 ml

**Shelf Life:**

Three years from date of manufacturing.

**Note:**
**1. For Bullet Rinsing, Filter and Supporting equipments rinsing and filter cleaning-**

- If previous product is any grade of Methanol, then perform Description, Solubility, Identification (By IR), and Water tests.
- If previous product is different, then perform Description, Solubility tests as per FG specification and calculate its carry over by using "Purity (By GC)" method from Raw material specification. (Limit - NMT 0.2%)  
QC/SPEC/METHANOL\_RM/01

**2. For Tanker Rinsing-**

- Perform Description, Solubility, Identification, Non volatile residue, Assay by GC and Water tests as per FG specification.

**3. Blending and Packing-**

- Perform all tests as per FG specification.
- Residual solvents test to be perform only for packing.

**4. For Stability testing-**

- Perform Description, Solubility, Identification (By IR and By GC), Water, Limit of non volatile residue, Assay, -Related solvents tests. (Stability quantity- 650 ml for single analysis).

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Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/11	Rev. no. 0	Format change – 1. General Information added. 2. History page added. 3. Reference updated	As per requirement of Schedule M.  USP-32 NF-27
	Rev. no. 1	Reference updated	USP-37 NF-32
	Rev. no. 2	Detector temp. is reduced from 280°C to 230°C RUNA Logo inserted along with the name of company	Refer Change Control No. RCPL/CC/QC/003-15 As per SOP of Document and Data control
	Rev. no. 3	Reference updated.	USP-38 NF-33
	Rev. no. 4	Reference updated.	USP-39 NF-34 (Refer Change Control No. RCPL/CC/QC/002-16)
	Rev. no. 5	Reference updated.	USP-40 NF-35 (Refer Change Control No. RCPL/CC/QC/002-17)
	Rev. no. 6	1. Reference updated. 2. Mentioned tests to be perform for Buret Rinsing, Filter Rinsing and Tanker Rinsing. 3. Shelf Life is added.	USP-41 NF-36 (Refer Change Control No. RCPL/CC/QC/003-18)
	Rev. no. 7	1. Mentioned tests to be perform for Supporting equipments 2. Quantity of Stability sample is Added.	Refer Change Control No. RCPL/CC/PDN/003-18
	Rev. no. 8	1. Reference updated. 2. Test wise method of analysis (MOA) is prepared. Method of Analysis No. is added.	USP-42, NF-37 (Refer Change Control No. RCPL/CC/QC/003-19)
	Rev. no. 9	1. In MOA No. QC/PH-FG/SPEC/11-01 a) Procedure is updated. b) "Interpretation" is added. 2. In MOA No. QC/PH-FG/SPEC/11-02 a) Procedure is updated. b) "Interpretation" is added. 3. In MOA No. QC/PH-FG/SPEC/11-03 a) Procedure is updated for addition of specrum range. b) "Interpretation" is added. c) Purity index is added. 4. In MOA No. QC/PH-FG/SPEC/11-04	Refer Change Control No. RCPL/CC/QC/004-20

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	<p>a) Chromatographic condition is updated for addition of Auxiliary gas, Linear velocity, Purge flow, Split ratio, Column flow, Makeup flow, Hydrogen, Air flow Equilibration time</p> <p>b) The term sample is replaced by test solution in procedure.</p> <p>5. In MOA No. QC/PH-FG/SPEC/11-05</p> <p>a) reagent require is added.</p> <p>b)The term sample is replaced by substance to be examine.</p> <p>6. In MOA No. QC/PH-FG/SPEC/11-06</p> <p>a) reagent require is added.</p> <p>b) Solution preparation is added.</p> <p>7. In MOA No. QC/PH-FG/SPEC/11-07</p> <p>a) The term sample is replaced by substance.</p> <p>b) The word interpretation replaced by word limit.</p> <p>8. In MOA No. QC/PH-FG/SPEC/11-08</p> <p>a) Reagent require is added.</p> <p>b) The term sample replace by substance to be examine.</p> <p>9. In MOA No. QC/PH-FG/SPEC/11-09</p> <p>a) The term sample is replaced by substance to be examine.</p> <p>b) reagent require is added.</p> <p>c) Solution preparation is added.</p> <p>10. In MOA No. QC/PH-FG/SPEC/11-10</p> <p>a) solution preparation is updated.</p> <p>b) The term sample replaced by test solution.</p> <p>c) Reagent require is added.</p> <p>11. In MOA No. QC/PH-FG/SPEC/11-11</p> <p>a) The term sample is replaced by substance to be examine.</p> <p>12. In MOA No. QC/PH-FG/SPEC/11-12</p> <p>a) Chromatographic condition is updated for addition of Auxiliary gas, Linear velocity, Purge flow, Split ratio, Column flow, Hydrogen flow, Air flow and Equilibration time.</p> <p>b) The term sample is replaced by test solution in procedure.</p> <p>13. Following points are added in general information.</p> <p>a) Quantity to be sampled is modified by adding term "About"</p>	
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		b) Mentioned tests to be perform for stability testing. c) Quantity for stability sample for single analysis is added. 13. Filter cleaning is added.	
	Rev.10	1. Reference updated. 2. In MOA No. QC/PH-FG/SPEC/11-11- Procedure is updated for addition of time	USP-NF-2021 (Refer Change Control No. RCPL/CC/QC/002-21)

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