

Rev.10	<b>METHANOL BP / Ph Eur / NF / IP SPECIFICATION</b>		<b>Reference</b>
			<b>BP-2022, Ph Eur- 10.0</b>
			<b>USP-NF-2021, IP-2018</b>
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Sr. No.	Test	Specification	Method of Analysis No.
1	Appearance	A Clear, colourless, volatile, hygroscopic liquid with characteristic odour. Is flammable.	QC/PH-FG/SPEC/09-01 QC/PH-FG/SPEC/10-01 QC/PH-FG/SPEC/11-01 QC/PH-FG/SPEC/12-01
2	Solubility	Miscible with water, with methylene chloride, with alcohol, with ether, with benzene, and with most other organic solvents.	QC/PH-FG/SPEC/09-02 QC/PH-FG/SPEC/10-02 QC/PH-FG/SPEC/11-02
3	Boiling point(As per BP/Ph Eur)	About 64°C.	QC/PH-FG/SPEC/09-03 QC/PH-FG/SPEC/10-03
4	Boiling point(As per IP)	About 65°C	QC/PH-FG/SPEC/12-02
5	A. Refractive index at 20±0.5°C (As per BP/Ph.Eur)	1.328 to 1.330 at 20±0.5°C	QC/PH-FG/SPEC/09-04 QC/PH-FG/SPEC/10-04
	B. By IR (As per BP/Ph Eur)	Comparison with Ph. Eur. Reference spectrum of methanol.	QC/PH-FG/SPEC/09-05 QC/PH-FG/SPEC/10-05
	C. By IR (As per NF)	The spectrum obtained with the substance to be examined corresponds in position & relative intensity to those in the spectrum obtained with that of Methanol USP CRS of its working standard. (Purity index should not be less than 0.99)	QC/PH-FG/SPEC/11-03
	D. By GC (As per NF)	The retention time of the major peak of the sample solution corresponds to that of the Standard solution, as obtained in the assay.	QC/PH-FG/SPEC/11-04
6	Appearance of solution	The substance to be examined is clear and colourless.	QC/PH-FG/SPEC/09-06 QC/PH-FG/SPEC/10-06
7	Acidity or alkalinity	Not more than 0.9 ml of 0.01M sodium hydroxide is required to change the colour of the indicator to pink.	QC/PH-FG/SPEC/09-07 QC/PH-FG/SPEC/10-07
8	Acidity (As per NF)	Not more than 0.45ml of 0.02N NaOH is required to produce pink.	QC/PH-FG/SPEC/11-05
9	Alkalinity (As ammonia) (As Per NF)	Not more than 0.20ml of 0.02N H <sub>2</sub> SO <sub>4</sub> is required to produced pink color (3ppm)	QC/PH-FG/SPEC/11-06
10	Relative density at 20°C	0.791 to 0.793 at 20°C	QC/PH-FG/SPEC/09-08 QC/PH-FG/SPEC/10-08
11	Weight per ml at 25°C	About 0.791 g at 25°C	QC/PH-FG/SPEC/12-03

	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C	Q.C	Q.A
SIGNATURE	<u>upabe</u>	<u>Q.C</u>	<u>Pspandit</u>
DATE	06/01/2022	07/01/2022	08/01/2022



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12	Reducing substances	The pink colour should not completely discharged within 5 min.	QC/PH-FG/SPEC/09-11 QC/PH-FG/SPEC/10-11
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13	Readily carbonizable substances	No decolorization develops.	QC/PH-FG/SPEC/11-08
14	Readily oxidizable substances	The pink color does not completely disappear within 5 min.	QC/PH-FG/SPEC/11-09
15	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
16	Residue on evaporation	Maximum 10 ppm.	QC/PH-FG/SPEC/09-12 QC/PH-FG/SPEC/10-12
17	Non volatile residue	The weight of the residue does not exceed 2mg (NMT 0.001% w/w).	QC/PH-FG/SPEC/11-11
18	Absorbance At 230 nm At 250 nm At 270 nm At 290 nm	Maximum 0.15 Maximum 0.05 Maximum 0.02 Maximum 0.01	QC/PH-FG/SPEC/09-09 QC/PH-FG/SPEC/10-09
19	Water	Maximum 0.10%	QC/PH-FG/SPEC/09-13 QC/PH-FG/SPEC/10-13
20	Assay by GC	Not less than 99.5%	QC/PH-FG/SPEC/11-04
21	Impurity A (By GC)	Maximum 2 ppm v/v	QC/PH-FG/SPEC/09-10 QC/PH-FG/SPEC/10-10
22	Related substances (By GC) A. Any impurity (For each impurity) B. Total impurities	Not more than 0.1% Not more than 0.3%	QC/PH-FG/SPEC/09-10 QC/PH-FG/SPEC/10-10
23	Residual solvents (By GC) Benzene Ethanol Acetone	Not more than 2 ppm v/v Not more than 5000 ppm v/v Not more than 5000 ppm v/v	QC/PH-FG/SPEC/09-14 QC/PH-FG/SPEC/10-14 QC/PH-FG/SPEC/11-12

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### GENERAL INFORMATION

**Structure:**
 $\text{H}_3\text{C} - \text{OH}$ 
**Molecular Formula:** CH<sub>4</sub>O

**Molecular weight:** 32.04

**Desirable Pack:**

To be supplied in MS drums/SS containers/HDPE containers/HM-HDPE containers and Glass bottles. 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/QC/GE/01)

**Quantity to be sampled:**

Analysis Sample: About 1300 ml

Control Sample: About 200 ml

Stability Sample: About 1640 ml

**Shelf Life:**

Three years from the date of manufacturing.

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

- If previous product is any grade of Methanol, then perform Appearance, Solubility, Identification by Refractive index at 20±0.5°C & By IR (As per NF), Absorbance and Water tests as per FG specification.
- If previous product is different then perform Appearance, Solubility tests as per FG specification and calculate previous product 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 Appearance, Solubility, Identification, Absorbance, Impurity A (By GC), Related substances (By GC) and Water tests as per FG specification.

**3. For Blending and Packing-**

- Perform all tests as per FG specification.
  - Residual solvents test to be perform only for packing.
4. For method of analysis refer current revision of FG specification of respective grade.

**5. For Stability testing-**

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**Note continued...**

- Perform Description, Solubility, Identification, Absorbance, Non volatile residue, Assay by GC, Related substance (By GC), Residual solvents (By GC) and Water tests as per FG specification. (Stability Sample quantity- About 970 ml for single analysis).

Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/37	--	Original issue	--
	Rev.0	MOA updated only revising its Specification, General information and history.	BP-2018 (Refer Change Control No. RCPL/CC/QC/006-17) (Refer Deviation No. RCPL/DEV/QC/007-17)
	Rev.1	Reference updated.	IP-2018 (Refer Change Control No. RCPL/CC/QC/002-18)
	Rev.2	1. Reference updated. 2. Mentioned tests to be perform for Bullet 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.3	Reference updated.	Ph. Eur -9.5 Supplement. Refer Change Control No. RCPL/CC/QC/008-18
	Rev.4	1. Reference updated  2. Mentioned tests to be perform for Supporting equipments 3. Quantity of Stability sample is added.	BP-2019. Refer Change Control No. RCPL/CC/QC/010-18 Refer Change Control No. RCPL/CC/PDN/003-18
	Rev.5	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.6	1. Reference updated 2. Following points are added in general information. a) Quantity to be sampled is modified by adding term "About" b) Mentioned tests to be perform for stability testing. c) Quantity for stability sample for single analysis is added. d) Desirable pack updated for addition of HM-DHPE containers. e) Filter cleaning is added.	BP-2020, Ph.Eur.10.0 (Refer Change Control No. RCPL/CC/QC/007-19, RCPL/CC/QC/008-19 and RCPL/CC/QC/001-20)

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	Rev.07	1. In MOA No. QC/PH-FG/SPEC/11-03 a) Procedure is updated for addition of spectrum range. b) "Interpretation" is added. c) Purity index is added.	Refer Change Control No. RCPL/CC/QC/004-20
	Rev.08	1. Reference updated.	BP-2021 & USP-NF-2021 (Refer Change Control No. RCPL/CC/QC/001-21 & RCPL/CC/QC/002-21)
	Rev.09	1. Reference updated. 2. "Residual solvents (By GC)" test added in BP and Ph.Eur specifications hence MOA No. QC/PH-FG/SPEC/09-14 and QC/PH-FG/SPEC/10-14 are added.	BP-2022 (Refer Change Control No. RCPL/CC/QC/004-21)

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