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Rev.10	METHANOL Ph Eur SPECIFICATION		Reference Ph Eur - 11.0
FG Specification No QC/PH-FG/SPEC/10	Supersedes Rev.09	Effective date 01/01/2023	Page No 1 of 5

Sr.No.	Test	Specification	Method of Analysis No.
1	Appearance	Clear, colourless volatile, hygroscopic liquid.	QC/PH-FG/SPEC/10-01
2	Solubility	Miscible with water and with methylene chloride.	QC/PH-FG/SPEC/10-02
3.	Boiling point	About 64°C.	QC/PH-FG/SPEC/10-03
4	Identification		QC/PH-FG/SPEC/10-04
	a) Refractive index at 20±0.5°C	1.328 to 1.330 at 20±0.5°C	
	b) By IR	Comparison with Ph. Eur. Reference spectrum of methanol.	QC/PH-FG/SPEC/10-05
5	Appearance of solution	The substance to be examined is clear and colourless.	QC/PH-FG/SPEC/10-06
6	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/10-07
7	Relative density at 20°C	0.791 to 0.793 at 20°C	QC/PH-FG/SPEC/10-08
8	Absorbance At 230 nm At 250 nm At 270 nm At 290 nm Between 230 nm to 290 nm	Maximum 0.15 Maximum 0.05 Maximum 0.02 Maximum 0.01 The absorption curve should be smooth.	QC/PH-FG/SPEC/10-09
9	Impurity A (By GC)	Maximum 2 ppm v/v	QC/PH-FG/SPEC/10-10
10	Related substances (By GC) a) Any impurity b) Total	Not more than 0.1% Not more than 0.3%	QC/PH-FG/SPEC/10-10
11	Reducing substances	The pink colour should not completely discharged within 5 min.	QC/PH-FG/SPEC/10-11
12	Residue on evaporation	Maximum 10 ppm	QC/PH-FG/SPEC/10-12
13	Water	Maximum 0.10%	QC/PH-FG/SPEC/10-13
14	Residual solvents (By GC) a) Benzene b) Ethanol c) Acetone	Not more than 2ppm v/v Not more than 5000ppm v/v Not more than 5000ppm v/v	QC/PH-FG/SPEC/10-14

	PREPARED BY Q.C	CHECKED BY Q.C	AUTHORIZED BY Q.A
SIGNATURE	<i>Uphale</i>	<i>Coppe</i>	<i>Pspandit</i>
DATE	24/12/2022	27/12/2022	27/12/2022

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GENERAL INFORMATION

Structure:

Molecular Formula: CH₄O

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:

In an airtight container.

Handling precaution:

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

Sampling SOP:

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

Quantity to be sampled:

Analysis Sample: About 790 ml

Control Sample: About 1580 ml

Stability Sample: About 7920 ml

Shelf Life:

Three years from the date of manufacturing.

Note:
1. For Bullet, Filter and Supporting equipment 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, 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, Relative Density at 20°C, Absorbance, Impurity A (By GC), Related substances (By GC), Residue on evaporation and Water tests as per FG specification.

3. Blending and Packing-

- Perform all tests as per FG specification.
- Residual solvents (By GC) test perform only for packing.

4. For Stability testing-

- Perform Appearance, Solubility, Identification, Absorbance, Impurity A (By GC), Related substances (By GC), Residue on evaporation, Residual solvents (By GC) and Water tests as per FG specification. (Stability sample quantity- About 660 ml for single analysis).

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Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/10	Rev.0	Format change – 1. General Information added. 2. History page added. 3. Reference updated	As per requirement of Schedule M. Ph.Eur-7.0
	Rev.1	RUNA Logo inserted along with the name of company.	As per SOP of Document and Data control
	Rev.2	1. Reference updated 2. Detector temperature is reduced from 280°C to 230°C. Split ratio is adjusted from 1:20 to 1:10	Ph.Eur-8.0 Refer Change Control No. RCPL/CC/QC/003-15
	Rev.3	Reference updated	Ph.Eur-9.0 Refer Change Control No. RCPL/CC/QC/009-16
	Rev.4	1. Reference updated 2. Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing. 3. Shelf life is added.	Ph. Eur-9.5 Suppliment. Refer Change Control No. RCPL/CC/QC/008-18
	Rev.5	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.6	1. GAM No. Added for Boiling Point test. 2. Test wise method of analysis (MOA) is prepared. Method of Analysis No. is added.	(Refer Change Control No. RCPL/CC/QC/002-19) (Refer Change Control No. RCPL/CC/QC/003-19)
	Rev.7	1. Reference updated 2. In MOA No.QC/PH-FG/SPEC/10-01 a) Procedure is updated b) Intepretation is added. 3. In MOA No.QC/PH-FG/SPEC/10-02 a) Procedure is updated b) Intepretation is added. 4. In MOA No.QC/PH-FG/SPEC/10-03 a) "Interpretation" term replaced by "Limit". 5. In MOA No.QC/PH-FG/SPEC/10-04	Ph.Eur. 10.0 (Refer Change Control No. RCPL/CC/QC/008-19)

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		a) limit is added. 6. In MOA No.QC/PH-FG/SPEC/10-05 a) Procedure is updated and spectrum range added. b) Working standard added with CRS and Purity index added. 7. In MOA No.QC/PH-FG/SPEC/10-06 a) interpretation is added. 8. In MOA No.QC/PH-FG/SPEC/10-07 a) solution preparation is updated b) "sample" term replaced by "substance to be examine" 9. In MOA No.QC/PH-FG/SPEC/10-08 a) limit is added. b) "sample" term replaced by "substance" 10. In MOA No.QC/PH-FG/SPEC/10-09 a) Incorporation of spectrum nature details between 230nm to 290nm is added b) "Interpretation" term replaced by "Limit". 11. In MOA No.QC/PH-FG/SPEC/10-10 a) chromatographic condition is updated for purge flow, makeup flow, hydrogen flow, air flow, Auxiliary gas and equilibration time. b) In procedure sample term replaced by test solution (a) 12. In MOA No.QC/PH-FG/SPEC/10-11 a) In Procedure "sample" term replaced by "substance to be examine". b) Solution preparation is added . 13. In MOA No.QC/PH-FG/SPEC/10-12 a) Limit is added. b) "sample" term replaced by "substance". 14. In MOA No.QC/PH-FG/SPEC/10-13 a) Limit is added. b) "sample" term replaced by "substance". 15. Following points are added in	

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Document number	Supersedes	Changes made	Reason for change
		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-HDPE containers e) Filter cleaning is added.	
	Rev.08	1. In MOA No. QC/PH-FG/SPEC/10-03 "It is flammable" is removed. 2. In MOA No. QC/PH-FG/SPEC/10-10 chromatographic condition is updated for addition of Injection mode, Total Flow and Pressure. Procedure is updated for injection sequence. 3. Residual solvents (By GC) test is added also new MOA No. QC/PH-FG/SPEC/10-14 is added. Same test is added in stability testing. 4. Quantity to be sampled and stability quantity for single analysis is updated.	Refer Change Control No. RCPL/CC/QC/004-21
	Rev. 09	Reference updated.	Ph. Eur 11.0 (Refer Change control No. RCPL/CC/QC/008-22)

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