

Rev.13	DICHLOROMETHANE NF SPECIFICATION		Reference
			USP-NF-2021
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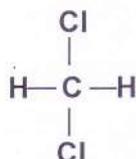
Sr.No.	Test	Specification	Method of Analysis No.
1	Description	Clear, colourless, mobile liquid having an odor resembling that of Chloroform.	QC/PH-FG/SPEC/15-01
2	Solubility	Miscible with alcohol, with ether, and with fixed and volatile oils.	QC/PH-FG/SPEC/15-02
3	Identification (By IR)	The IR absorption spectrum of the vapor shows strong doublet peaks at 7.8 μ m & 7.9 μ m and at 13.2 μ m & 13.4 μ m, & relatively few minor peaks.	QC/PH-FG/SPEC/15-03
4	Specific gravity at 25°C	Between 1.318 to 1.322 at 25°C	QC/PH-FG/SPEC/15-04
5	Water	Not more than 0.02%	QC/PH-FG/SPEC/15-05
6	Limit of hydrogen chloride	The pink color in the test cylinder is at least as intense as that in the comparison cylinder, and the color persists for not less than 15 minutes (Not more than 0.001%)	QC/PH-FG/SPEC/15-06
7	Limit of non volatile residue	Not more than 0.002%.	QC/PH-FG/SPEC/15-07
8	Free chlorine	The lower layer does not show a violet tint.	QC/PH-FG/SPEC/15-08
9	Assay(By GC)	Not less than 99.0% of methylene chloride.	QC/PH-FG/SPEC/15-09
10	Residual solvents (By GC) a) Methanol b) Ethanol c) 2-Methyl-2-butene d) Chloroform e) Carbon tetra chloride	Not more than 3000 ppm v/v Not more than 5000 ppm v/v Not more than 300 ppm v/v Not more than 60 ppm v/v Not more than 4 ppm v/v	QC/PH-FG/SPEC/15-10

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	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C	Q.C	Q.A
SIGNATURE	<i>R Sakate</i>	<i>[Signature]</i>	<i>Pspandit</i>
DATE	06/07/2021	07/07/2021	07/07/2021

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GENERAL INFORMATION

Structure:

Molecular Formula: CH₂Cl₂
Molecular Weight: 84.93

Desirable Pack:

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

Storage Condition:

Preserve in tight containers.

Handling precaution:

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

Sampling SOP:

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

Quantity to be sampled:

Analysis Sample: About 410 ml
Control Sample: About 320 ml
Stability Sample: About 4080 ml

Shelf Life:

Three years from the date of manufacturing.

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

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

2. For Tanker Rinsing-

- Perform Description, Solubility, Identification (By IR), Specific gravity at 25°C, Limit of non volatile residue, Assay by GC and Water tests.

3. Blending and Packing-

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

4. For Stability testing-

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- Perform Description, Solubility, Identification (By IR), Specific gravity at 25°C, Water, Limit of non volatile residue, Assay by GC and Residual solvent tests as per FG specification. (Stability quantity- About 340 ml for single analysis)

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Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/15	Rev. no. 0	Format change – 1. General Information added. 2. History page added.	As per requirement of Schedule M.
	Rev. no. 1	Reference updated.	USP-32 NF-27
	Rev. no. 2	1. Reference updated. 2. RUNA Logo inserted along with name of company.	USP-37 NF-32 As per SOP of Document and Data control (Refer Change control No. RCPL/CC/QC/004-15)
	Rev. no. 3	1. Reference updated 2. 0.25mm x 60m fused silica coated with a 1.4µm film of phase G43 used Column temp. Program is change. Split Ratio increased from 1:40 to 1:50 For residual solvents Test	USP-38 NF-33 (Refer change control No. RCPL/CC/QC/009-2015) (Refer Method validation protocol No. RCPL/QC/Method validation-Dichloromethane-BP & Ph. Eur/2015)
	Rev. no. 4	1. Reference updated	USP-39 NF-34 (Refer Change Control No. RCPL/CC/QC/002-16)
	Rev. no. 5	1. Reference updated	USP-39 NF-34 (Refer Change Control No. RCPL/CC/QC/002-16)
	Rev. no. 6	For Residual solvents test- Split Ratio is reduced from 50 to 30	(Refer Change Control No. RCPL/CC/QC/001-18) Refer method validation report of Dichloromethane NF
	Rev. no. 7	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. no. 8	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. 9	1. For Assay (By GC) test instead of TCD Detector and packed column FID Detector and capillary column is used.	Refer Change Control No. RCPL/CC/QC/001-19 and Refer method validation report of Dichloromethane NF (RCPL/QC/VAL_Methylene Chloride - NF/2019)

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	Rev. no. 10	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. 11	1. Following points are added in general information a) Filter cleaning is added. b) Mentioned tests to be perform for Stability testing. c) Quantity of stability sample for single analysis is added. d) 1,1 Dichloroethene and 1,2 Dichloroethene removed from Residual solvents test.	(Refer Change Control No. RCPL/CC/QC/004-20)
	Rev. no. 12	1. Reference updated. 2. In MOA No. QC/PH-FG/SPEC/15-07 - Procedure is updated for addition of time.	USP-NF-2021 (Refer change control No. RCPL/CC/QC/002-21)

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