

Rev. 12	DICHLOROMETHANE BP / Ph Eur / NF / IP SPECIFICATION		Reference
			BP-2022, Ph.Eur-10.0
			USP-NF-2021, IP-2018
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Sr.No.	Test	Specification	Method of Analysis No.
1	Description	Clear, colourless, volatile, mobile, sweet smelling liquid having an odor resembling that of Chloroform.	QC/PH-FG/SPEC/13-01 QC/PH-FG/SPEC/14-01 QC/PH-FG/SPEC/15-01 QC/PH-FG/SPEC/16-01
2	Solubility	Sparingly soluble in water, miscible with ethanol (96%), with alcohol, with ether, and with fixed and volatile oils	QC/PH-FG/SPEC/13-02 QC/PH-FG/SPEC/14-02 QC/PH-FG/SPEC/15-02
3	Identification a) Refractive index at 20°C ± 0.5°C	1.423 to 1.425 at 20°C ± 0.5°C	QC/PH-FG/SPEC/13-03 QC/PH-FG/SPEC/14-03
	b) By IR	The spectrum obtained with the substance corresponds in position & relative intensity to those in the spectrum obtained with that of Methylene chloride CRS or its Working standard. (Purity index should not be less than 0.99). The IR absorption spectrum of the vapor shows strong doublet peaks at 7.8µm & 7.9 µm and at 13.2 µm & 13.4 µm, & relatively few minor peaks.	QC/PH-FG/SPEC/13-04 QC/PH-FG/SPEC/14-04 QC/PH-FG/SPEC/15-03
	c) Relative density at 20°C	1.320 to 1.332 at 20°C	QC/PH-FG/SPEC/13-07 QC/PH-FG/SPEC/14-07
	d) Chemical test	A violet colour is produced.	QC/PH-FG/SPEC/13-12 QC/PH-FG/SPEC/14-12
	e) Chemical Test	Passes the test	QC/PH-FG/SPEC/13-13 QC/PH-FG/SPEC/14-13
4	Appearance of solution	The substance to be examined is clear and colourless	QC/PH-FG/SPEC/13-05 QC/PH-FG/SPEC/14-05
5	Acidity	Not more than 0.15 ml of 0.1M sodium hydroxide should require to change the colour of the indicator to blue.	QC/PH-FG/SPEC/13-06 QC/PH-FG/SPEC/14-06
6	Relative density at 20°C	1.320 to 1.332 at 20°C	QC/PH-FG/SPEC/13-07 QC/PH-FG/SPEC/14-07

	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C	Q.C	Q.A
SIGNATURE	<i>wphafe</i>	<i>Q.C</i>	<i>Spandit</i>
DATE	06/01/2022	07/01/2022	08/01/2022

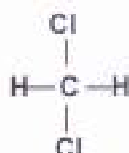


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Sr.No.	Test	Specification	Method of Analysis No.	
7	Specific gravity at 25°C	1.318 to 1.322 at 25°C	QC/PH-FG/SPEC/15-04	
8	Weight per ml at 25°C	About 1.32 g at 25°C	QC/PH-FG/SPEC/16-03	
9	Boiling point	About 40°C	QC/PH-FG/SPEC/16-02	
10	Limit of hydrogen 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	
11	Ethanol, 2-methylbut-2-ene and volatile impurities (By GC) Ethanol 2-methylbut-2-ene Impurity A (Carbon tetrachloride) Impurity B (Chloroform) Total of impurities other than ethanol and 2-methylbut-2-ene	Maximum 2.0% v/v Maximum 300 ppm v/v Maximum 10 ppm v/v Maximum 50 ppm v/v Maximum 0.1% v/v	QC/PH-FG/SPEC/13-08 QC/PH-FG/SPEC/14-08	
12	Assay (By GC)	Not less than 99.0% of methylene chloride.	QC/PH-FG/SPEC/15-09	
13	Free Chlorine	No blue colour should develop. The lower layer does not show a violet tint.	QC/PH-FG/SPEC/13-09 QC/PH-FG/SPEC/14-09 QC/PH-FG/SPEC/15-08	
14	Residue on evaporation/ Limit of non volatile residue	Maximum 20 ppm (Not more than 0.002%)	QC/PH-FG/SPEC/13-10 QC/PH-FG/SPEC/14-10 QC/PH-FG/SPEC/15-07	
15	Water	Maximum 0.02% m/m	QC/PH-FG/SPEC/13-11 QC/PH-FG/SPEC/14-11 QC/PH-FG/SPEC/15-05	
16	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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GENERAL INFORMATION

Structure:



Molecular Formula: CH₂Cl₂

Molecular Weight: 84.9

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 air tight container, Protected from light.

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 832 ml

Control Sample: About 1664 ml

Stability Sample: About 7560 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 Dichloromethane, then perform Description, Solubility, Identification by Refractive index at 20°C ± 0.5°C & By IR (As per USP) and Water tests as per FG specification.
- If previous product is different then, perform Description, 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/MDC_RM/01

2. For Tanker Rinsing-

- Perform Description, Solubility, Identification by Refractive index at 20°C ± 0.5°C & By IR (As per USP), Ethanol, 2-methylbut-2-ene and volatile impurities (By GC) Assay 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 test to be perform only for packing.

- 4. For method of analysis refer current revision of FG specification of respective grade.

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Note continued...

5. For Stability testing-

- Perform Description, Solubility, Identification, Ethanol, 2-methylbut-2-ene and volatile impurities (By GC) Assay By GC, Residue on evaporation, Water and Residual solvents tests as per specification. (Stability Sample quantity- About 830ml for single analysis).

Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/35	--	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	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.2	Reference updated.	IP-2018 (Refer Change Control No. RCPL/CC/QC/002-18)
	Rev.3	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.4	Reference updated	Ph. Eur -9.5 Supplement. Refer Change Control No. RCPL/CC/QC/008-18
	Rev.5	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.6	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
	Rev.7	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

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Document number	Supersedes	Changes made	Reason for change
	Rev.8	1. Reference updated. 1. 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-HDPE 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)
	Rev. 09	1,1-Dichloroethen and 1,2 Dichloroethen impurities removed from residual solvents test.	(Refer Change Control No. RCPL/CC/QC/004-20)
	Rev.10	1. Reference updated.	BP-2021 & USP-NF-2021 (Refer change control No. RCPL/CC/QC/001-21 & RCPL/CC/QC/002-21)
	Rev.11	1. Reference updated. 2. In Identification test "Relative density at 20°C" and two "Chemical test" and "Residual solvents (By GC)" tests added in BP and Ph.Eur specification, hence MOA No. QC/PH/FG/SPEC/13-12, QC/PH/FG/SPEC/13-13, QC/PH/FG/SPEC/14-12, QC/PH/FG/SPEC/13-13 QC/PH/FG/SPEC/13-14 and QC/PH/FG/SPEC/14-14 tests are added. 3. Quantity to be sampled and stability quantity for single analysis is updated.	BP-2022(Refer change control No. RCPL/CC/QC/004-21)