

Rev.10	ACETONE 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	Specifications	Method of Analysis No.
1	Description	Transparent, clear, colorless, mobile, volatile liquid having characteristic odour. A solution (1 in 2) is neutral to litmus.	QC/PH-FG/SPEC/01-01 QC/PH-FG/SPEC/02-01 QC/PH-FG/SPEC/03-01 QC/PH-FG/SPEC/04-01
2	Solubility	Miscible with water, with ethanol (96%), with alcohol, with ether, with chloroform & with most volatile oils. The vapour is flammable.	QC/PH-FG/SPEC/01-01 QC/PH-FG/SPEC/02-01 QC/PH-FG/SPEC/03-01
3	Identification		QC/PH-FG/SPEC/01-03 QC/PH-FG/SPEC/02-03
	a) Relative density at 20°C	0.790 to 0.793 at 20°C	
	b) Chemical test	An intense red colour is produced which becomes violet with the addition of 3.5ml of acetic acid R.	QC/PH-FG/SPEC/01-04 QC/PH-FG/SPEC/02-04
	c) Chemical test	A greenish-blue colour should be produced.	QC/PH-FG/SPEC/01-05 QC/PH-FG/SPEC/02-05
	d) By IR	The spectrum obtained with the substance to be examined corresponds in position & relative intensity to those in the spectrum obtained with that of Acetone USP CRS or its working standard (Purity Index should not be less than 0.99)	QC/PH-FG/SPEC/03-03
e) By GC	The retention time of the test solution corresponds to that of Acetone USP CRS or its working standard (WS), as obtained in the Assay.	QC/PH-FG/SPEC/03-04	
4	Appearance of solution	The solution is clear and colourless.	QC/PH-FG/SPEC/01-06 QC/PH-FG/SPEC/02-06
5	Acidity or alkalinity	On addition of 0.5 ml of 0.01M sodium hydroxide, solution should be pink. On addition of 0.7 ml of 0.01M hydrochloric acid, solution should be red or orange.	QC/PH-FG/SPEC/01-07 QC/PH-FG/SPEC/02-07
6	Specific Gravity at 25°C	Not more than 0.789 at 25°C	QC/PH-FG/SPEC/03-05

	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C	Q.C	Q.A
SIGNATURE	<i>phabe</i>	<i>Phu</i>	<i>Pspanalit</i>
DATE	06/01/2022	07/01/2022	07/01/2022

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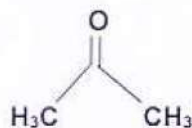
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7	Weight per ml at 25°C	About 0.79 g at 25°C	QC/PH-FG/SPEC/04-03
8	Reducing substances	The mixture should not be completely decolorized.	QC/PH-FG/SPEC/01-08 QC/PH-FG/SPEC/02-08
9	Readily Oxidizable substances	The permanganate color of the mixture does not completely disappear within 15 minutes.	QC/PH-FG/SPEC/03-08
10	Matter insoluble in water	The solution should be clear.	QC/PH-FG/SPEC/01-10 QC/PH-FG/SPEC/02-10
11	Boiling point	About 56°C	QC/PH-FG/SPEC/04-02
12	Residue on evaporation	Maximum 50 ppm	QC/PH-FG/SPEC/01-11 QC/PH-FG/SPEC/02-11
13	Nonvolatile residue	The weight of the residue does not exceed 2 mg (0.004%)	QC/PH-FG/SPEC/03-07
14	Water	Maximum 3 g/L	QC/PH-FG/SPEC/01-12 QC/PH-FG/SPEC/02-12
15	Water (By GC)	Not more than 0.5%	QC/PH-FG/SPEC/03-06
16	Assay (By GC)	Not less than 99.0% on the anhydrous basis.	QC/PH-FG/SPEC/03-04
17	Related substances (By GC) a) Impurity A (Methanol) b) Impurity B (IPA) c) Impurity C (Benzene) d) Any other impurity	Not more than 0.05% v/v Not more than 0.05% v/v Not more than 2 ppm v/v Not more than 0.05% v/v	QC/PH-FG/SPEC/01-09 QC/PH-FG/SPEC/02-09
18	Residual solvents (By GC) Benzene Methanol IPA	Not more than 2 ppm (v/v) Not more than 3000 ppm (v/v) Not more than 5000 ppm (v/v)	QC/PH-FG/SPEC/01-13 QC/PH-FG/SPEC/02-13 QC/PH-FG/SPEC/03-09

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GENERAL INFORMATION

Structure:



Molecular Formula: C₃H₆O

Molecular weight: 58.08

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:

Protected from light, Preserve in tight containers, remote from fire.

Handling precaution:

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

Sampling SOP:

As per the current approved sampling procedure (SOP/QC/GE/6).

Quantity to be sampled:

Analysis Sample: About 1200 ml

Control Sample: About 2400 ml

Stability Sample: About 8400 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 Acetone, then perform Appearance, Solubility, Identification by Relative density at 20°C & By IR and Water tests as per FG specification.
- If previous product is different then, perform Appearance, Solubility 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/ACETONE_RM/01.

2. For Tanker Rinsing-

- Perform Appearance, Solubility, Identification, Non volatile Residue, water, water (By GC), Assay and Related substances (By GC) 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.

5. For Stability testing-

Perform Appearance, Solubility, Identification, Non volatile Residue, water, water (By GC), Assay, Related substances (By GC) and residual solvents tests as per FG specification. (Stability sample quantity- About 700 ml for single analysis).

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Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/33	--	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	BP-2019. Refer Change Control No. RCPL/CC/QC/010-18
	Rev. 4	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. 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)
	Rev. 7	1. In MOA No. QC/PH-FG/SPEC/03-03 a) Procedure is updated for addition of spectrum range, Working std. added with CRS.	(Refer Change Control No. RCPL/CC/QC/004-20)

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		b) Purity index is added. c) The term sample replaced by substance to be examine. 2. In MOA No. QC/PH-FG/SPEC/03-04 a) Chromatographic condition is updated for addition of Auxiliary gas, Purge flow and Column flow, Makeup flow, Hydrogen, Air flow and Equilibration time. b) The term sample replaced by substance to be examine c) Solution preparation is updated for addition of test solution. d) Working standard added with CRS.			
	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/01-13 and QC/PH-FG/SPEC/02-13 are added.		BP-2022 Refer change control No. RCPL/CC/QC/004-21	

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