

Rev.13	ACETONE BP SPECIFICATION		Reference
			BP-2023
FG Specification No. QC/PH-FG/SPEC/01	Supersedes Rev.12	Effective date 01/01/2023	Page No. 1 of 5

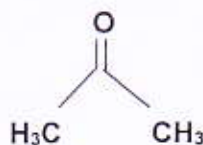
Sr.No.	Test	Specifications	Method of Analysis No.
1	Appearance	Volatile, clear, colourless liquid.	QC/PH-FG/SPEC/01-01
2	Solubility	Miscible with water and with ethanol (96%).	QC/PH-FG/SPEC/01-02
3	Identification		
	a) Relative density at 20°C	0.790 to 0.793 at 20°C	QC/PH-FG/SPEC/01-03
	b) Chemical test	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
	c) Chemical test	A greenish-blue colour should be produced.	QC/PH-FG/SPEC/01-05
4	Appearance of solution	The solution is clear and colourless.	QC/PH-FG/SPEC/01-06
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
6	Relative density at 20°C	0.790 to 0.793 at 20°C	QC/PH-FG/SPEC/01-03
7	Reducing substances	The mixture should not be completely decolourised.	QC/PH-FG/SPEC/01-08
8	Related substances (By GC)		QC/PH-FG/SPEC/01-09
	a) Impurity A (Methanol)	Not more than 0.05% v/v	
	b) Impurity B (IPA)	Not more than 0.05% v/v	
	c) Impurity C (Benzene)	Not more than 2 ppm v/v	
	d) Any other impurity	Not more than 0.05% v/v	
9	Matter insoluble in water	The solution should be clear.	QC/PH-FG/SPEC/01-10
10	Residue on evaporation	Maximum 50 ppm	QC/PH-FG/SPEC/01-11
11	Water	Maximum 3 g/L	QC/PH-FG/SPEC/01-12
12	Residual solvents (By GC)		QC/PH-FG/SPEC/01-13
	a) Benzene	Not more than 2 ppm v/v	
	b) Methanol	Not more than 3000 ppm v/v	
	c) 2-Propanol	Not more than 5000 ppm v/v	

	PREPARED BY	CHECKED BY	AUTHORIZED BY
	Q.C	Q.C	Q.A
SIGNATURE	<i>Uphale</i>	<i>Q.C</i>	<i>Pspandit</i>
DATE	28/12/2022	28/12/2022	29/12/2022

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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.

Handling precaution:

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

Sampling SOP:

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

Quantity to be sampled:

Analysis Sample: About 560 ml

Control Sample: About 1120 ml

Stability Sample: About 3360 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 and Water tests as per FG specification.
- If previous product is different then, perform Appearance and 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/ACETONE_RM/01

2. For Tanker Rinsing-

- Perform Appearance, Solubility, Identification, 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 to be perform only for Packing.

4. For stability testing-

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- Perform Appearance, Solubility, Identification, Related substances (By GC), Residue on evaporation, Water and Residual solvents (By GC) tests as per FG specification. (Stability sample quantity- About 530 ml for single analysis).

Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/01	Rev. 0	Format change – 1. General Information added. 2. History page added. 3. Reference updated	As per requirement of Schedule M. BP-2013
	Rev. 1	Reference updated	BP-2014
	Rev. 2	1. Reference updated 2. Detector temperature is reduced from 250°C to 225°C. Split ratio is adjusted from 1:50 to 1:5 And Column length and ID is increased form 50m to 60m and 0.30 to 0.32 respectively. 3. RUNA Logo inserted along with the name of company.	BP-2015 Refer Change Control No. RCPL/CC/QC/001-15 As per SOP of Document and Data control
	Rev. 3	1. Reference Updated 2. Mentioned brief procedure for Appearance of solution and Matter insoluble in water tests	BP-2016 (Refer Change Control No. RCPL/CC/QC/015-15)
	Rev. 4	Reference Updated.	BP-2017 (Refer Change Control No. RCPL/CC/QC/010-16)
	Rev. 5	Reference Updated.	BP-2018 (Refer Change Control No. RCPL/CC/QC/006-17)
	Rev. 6	1. Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing. 2. Shelf Life is added.	Refer Change Control No. RCPL/CC/QC/003-18)
	Rev. 7	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. 8	Test wise method of analysis (MOA) is prepared. Method of Analysis No. is added.	(Refer Change Control No. RCPL/CC/QC/003-19)

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Document number	Supersedes	Changes made	Reason for change
	Rev. 9	<ol style="list-style-type: none"> 1. Reference updated. 2. In MOA No. QC/PH-FG/SPEC/01-01 <ol style="list-style-type: none"> a) Procedure is updated b) "Interpretation" is added. 3. In MOA No. QC/PH-FG/SPEC/01-02 <ol style="list-style-type: none"> a) Procedure is updated b) "Interpretation" is added. 4. In MOA No. QC/PH-FG/SPEC/01-03 <ol style="list-style-type: none"> a) The term "sample" replaced by "substance to be examine" b) "Limit" is added. 5. In MOA No. QC/PH-FG/SPEC/01-04 <ol style="list-style-type: none"> a) Solution preparation is updated. b) The term "sample" replaced by "substance to be examine" 6. In MOA No. QC/PH-FG/SPEC/01-05 <ol style="list-style-type: none"> a) Solution preparation is updated b) The term "sample" replaced by "substance to be examine" 7. In MOA No. QC/PH-FG/SPEC/01-06 <ol style="list-style-type: none"> a) "Interpretation" is added. 8. In MOA No. QC/PH-FG/SPEC/01-07 <ol style="list-style-type: none"> a) Solution preparation is updated b) The term "sample" replaced by "substance to be examine". 9. In MOA No. QC/PH-FG/SPEC/01-08 <ol style="list-style-type: none"> a) Solution preparation is updated. b) In procedure "sample" term replaced by "substance to be examine". 10. In MOA No. QC/PH-FG/SPEC/01-09 <ol style="list-style-type: none"> a) chromatographic condition is updated for Column, Makeup, Hydrogen, Air flow and Equilibration time. b) In procedure "sample" term replaced by "Test solution" 11. In MOA No. QC/PH-FG/SPEC/01-11 <ol style="list-style-type: none"> a) The term "sample" and "Interpretation" replaced by "substance to be examine" and "Limit" respectively 12. In MOA No. QC/PH-FG/SPEC/01-12 <ol style="list-style-type: none"> a) The term "sample" is replaced by "substance" b) "Limit" is added. 13. Following points are added in general information. 	BP-2020 (Refer Change Control No. RCPL/CC/QC/007-19)

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		<ul style="list-style-type: none"> 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. 	
	Rev.10	1. Reference updated.	BP-2021 (Refer Change Control No. RCPL/CC/QC/001-21)
	Rev. 11	<ul style="list-style-type: none"> 1. Reference updated. 2. In MOA No. QC/PH-FG/SPEC/01-02 "The vapor is flammable" is removed. 3. In MOA No. QC/PH-FG/SPEC/01-09 chromatographic condition is updated for addition of Injection mode, Total Flow and Pressure. Procedure is updated for injection sequence. 4. Residual solvents (By GC) test is added also new MOA No. QC/PH-FG/SPEC/01-12 is added. Same test is added in stability testing. 5. Quantity to be sampled and stability quantity for single analysis is updated. 	BP-2022 (Refer Change Control No. RCPL/CC/QC/004-21)
	Rev. 12	1. Reference Updated.	BP-2023 (Refer Change Control No. RCPL/CC/QC/009-22)

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