DEEPAK FERTILISERS AND PETROCHEMICALS CORPORATION LIMITED

| Rev.10 | ACETONE Ph Eur SPECIFICATION | | Reference Ph Eur – 11.0 |
|---|---|---|---|
| FG Specification No | Supersedes | Effective date | Page No. |
| QC/PH-FG/SPEC/02 | Rev.09 | 01/01/2023 | 1 of 5 |

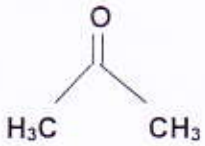
| Sr.No. | Test | Specifications | Method of Analysis No. |
|---|---|---|---|
| 1 | Appearance | Volatile, clear, colourless liquid. | QC/PH-FG/SPEC/02-01 |
| 2 | Solubility | Miscible with water and with ethanol (96%). | QC/PH-FG/SPEC/02-02 |
| 3 | Identification<br>a) Relative density at 20°C | 0.790 to 0.793 at 20°C | QC/PH-FG/SPEC/02-03 |
| | 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/02-04 |
| | c) Chemical test | A greenish-blue colour should be produced. | QC/PH-FG/SPEC/02-05 |
| 4 | Appearance of solution | The solution is clear and colourless. | 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.<br>On addition of 0.7 ml of 0.01M hydrochloric acid, solution should be red or orange. | QC/PH-FG/SPEC/02-07 |
| 6 | Relative density at 20°C | 0.790 to 0.793 at 20°C | QC/PH-FG/SPEC/02-03 |
| 7 | Reducing substances | The mixture should not be completely decolourised. | QC/PH-FG/SPEC/02-08 |
| 8 | Related substances (By GC)<br>a) Impurity A (Methanol)<br>b) Impurity B (IPA)<br>c) Impurity C (Benzene)<br>d) Any other impurity | <br>Not more than 0.05% v/v<br>Not more than 0.05% v/v<br>Not more than 2 ppm v/v<br>Not more than 0.05% v/v | QC/PH-FG/SPEC/02-09 |
| 9 | Matter insoluble in water | The solution should be clear. | QC/PH-FG/SPEC/02-10 |
| 10 | Residue on evaporation | Maximum 50 ppm | QC/PH-FG/SPEC/02-11 |
| 11 | Water | Maximum 3 g/L | QC/PH-FG/SPEC/02-12 |
| 12 | Residual solvents (By GC)<br>a) Benzene<br>b) Methanol<br>c) 2-Propanol | <br>Not more than 2 ppm v/v<br>Not more than 3000 ppm v/v<br>Not more than 5000 ppm v/v | QC/PH-FG/SPEC/02-13 |



| | PREPARED BY | CHECKED BY | AUTHORIZED BY |
|---|---|---|---|
| | Q.C | Q.C | Q.A |
| SIGNATURE | iphale | | Pspandit |
| DATE | 24/12/2022 | 27/12/2022 | 27/12/2022 |

## GENERAL INFORMATION

**Structure:**



**Molecular Formula:** $C_3H_6O$

**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/GE/01)

**Quantity to be sampled:**
Analysis Sample: About 560 ml
Control Sample: About 1120 ml
Stability Sample: About 6360 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, Solubility test 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-**
   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/02 | Rev. 0 | Format change –<br>1. General Information added.<br>2. History page added.<br>3. Referance updated | As per requirement of Schedule M.<br><br>Ph. Eur-7.0 |
| | Rev. 1 | Reference updated | As per SOP of Document and Data control |
| | Rev. 2 | 1. Reference updated<br>2. Detector temperature is reduced from 250°C to 225°C. Split ratio is increased from 1:50 to 1:5 And Column length and ID is increased form 50m to 60m and 0.3 to 0.32 respectively. | Ph. Eur -8.0<br>Refer Change Control No. RCPL/CC/QC/001-15 |
| | Rev. 3 | Reference updated | Ph. Eur -9.0<br>Refer Change Control No. RCPL/CC/QC/009-16 |
| | Rev. 4 | 1. Reference updated<br>2. Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing.<br>3. Shelf life is added. | Ph. Eur -9.5 Suppliment.<br>Refer Change Control No. RCPL/CC/QC/008-18 |
| | Rev. 5 | 1. Mentioned tests to be perform for Supporting equipments.<br>2. Quantity of Stability sample is added. | (Refer Change Control No. RCPL/CC/PDN/003-18) |
| | Rev. 6 | Test wise method of analysis (MOA) is prepared.<br>Method of Analysis No. is added. | (Refer Change Control No. RCPL/CC/QC/003-19) |
| | Rev. 7 | 1. Reference updated.<br>2. In MOA No. QC/PH-FG/SPEC/02-01<br>a) Procedure is updated<br>b) "Interpretation" is added.<br>3. In MOA No. QC/PH-FG/SPEC/02-02<br>c) Procedure is updated<br>d) "Interpretation" is added.<br>4. In MOA No. QC/PH-FG/SPEC/02-03<br>a) The term "sample" replaced by "substance to be examine"<br>b) "Limit" is added.<br>5. In MOA No. QC/PH-FG/SPEC/02-04<br>a) Solution preparation is updated.<br>b) The term "sample" replaced by "substance to be examine"<br>6. In MOA No. QC/PH-FG/SPEC/02-05 | Ph.Eur 10.0<br>(Refer Change Control No. RCPL/CC/QC/008-19) |

| Document number | Supersedes | Changes made | Reason for change |
|---|---|---|---|
| QC/PH-FG/SPEC/02 | Rev. 7 | a) Solution preparation is updated.<br>b) The term "sample" replaced by "substance to be examine"<br>7. In MOA No. QC/PH-FG/SPEC/02-06<br>a) "Interpretation" is added.<br>b) The term "sample" replaced by "substance to be examine".<br>8. In MOA No. QC/PH-FG/SPEC/02-07<br>a) Solution preparation is updated<br>b) The term "sample" replaced by "substance to be examine".<br>9. In MOA No. QC/PH-FG/SPEC/02-08<br>a) Solution preparation is updated.<br>b) In procedure "sample" term replaced by "substance to be examine".<br>10. In MOA No. QC/PH-FG/SPEC/02-09<br>a) chromatographic condition is updated for Column flow,Auxiliary gas purge flow , Makeup flow, Hydrogen flow, Air flow and Equilibration time.<br>b) In procedure "sample" term replaced by "Test solution"<br>11. In MOA No. QC/PH-FG/SPEC/02-11<br>a) The term "sample" and "Interpretation" replaced by "substance to be examine" and "Limit" respectively<br>12. In MOA No. QC/PH-FG/SPEC/02-12<br>a) The term "sample" is replaced by "substance"<br>b) "Limit" is added.<br>13. Following points are added in general information.<br>a) Quantity to be sampled is modified by adding term "About"<br>b) Mentioned tests to be perform for stability testing.<br>c) Quantity for stability sample for single analysis is added.<br>d) Desirable pack updated for addition of HM-DHPE containers.<br>e) Filter cleaning is added | |
| | Rev. 08 | 1. In MOA No. QC/PH-FG/SPEC/02-02 "The vapor is flammable" is removed.<br>2. In MOA No. QC/PH-FG/SPEC/02-09 chromatographic condition is updated | (Refer Change Control No. RCPL/CC/QC/004-21) |

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|---|---|---|---|
| QC/PH-FG/SPEC/02 | Rev. 08 | for addition of Injection mode, Total Flow and Pressure. Procedure is updated for injection sequence.<br>3. Residual solvents (By GC) test is added also new MOA No.QC/PH-FG/SPEC/02-13 is added. Same test is added in stability testing.<br>4. Quantity to be sampled and stability quantity for single analysis is updated. | |
| | Rev. 09 | 1. Reference updated. | Ph. Eur 11.0<br>(Refer Change control No. RCPL/CC/QC/s-22) |