**APPENDIX I ZYX /CQA/SOP-039/FR-01**

 **LOG BOOK OF TOC ANALYSER**

**Instrument ID : -------------------------------**

**Location : -------------------------------**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sr. No | Date | Name of Sample | Batch No / A.R. No | Done by | Checked by |  Remarks |
|  |  |  |  |  |  |  |
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**ZYX/CQA/SOP-039/FR-02 APPENDIX II**

 **CALIBRATION BY POTASSIUM HYDROGEN PHTHALATE**

 (Note: Calibration shall be done on the day of sample analysis)

1.0 Instrument ID . : -------------------------

2.0 Location : --------------------------

3.0 Date of Calibration : ---------------------------

4.0Preparation of Standard solution

 Wt of KHP (Batch/ Lot No------------------Make-------------). -------------------gm

 dissolved in -------------ml water (1000 ppm)

 Dilute -----------ml of solution(1000ppm) to --------------ml of purified water.(10ppm)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water (250ppb)

 Dilute -----------ml of solution (10ppm) to-------------- ml of purified water (500ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(750ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(1000ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(2000ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(5000ppb)

 Observations :

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sr.No | Concentration |  Area Count | Average AreaCount |  SD | RSD |
|  |  | I | II | III | IV | V |  |  |  |
| 1. | 10ppm |  |  |  |  |  |  |  |  |
| 2. | 0ppb |  |  |  |  |  |  |  |  |
| 3. | 250ppb |  |  |  |  |  |  |  |  |
| 4. | 500ppb |  |  |  |  |  |  |  |  |
| 5. | 750ppb |  |  |  |  |  |  |  |  |
| 6. | 1000ppb |  |  |  |  |  |  |  |  |
| 7. | 2000ppb |  |  |  |  |  |  |  |  |
| 8. | 5000ppb |  |  |  |  |  |  |  |  |
| Slope |  |  |
| Intercept |  |  |
| Correlation coefficient |  |  |

Acceptance criteria : Linearity : Correlation coefficient should not be less than 0.98

 Standard Deviation: NMT 1.0

 RSD (C.V.) : NMT 5.0%

Remarks : Complies / Does not Comply

Done by : Checked By : Authorised By :

Date : Date : Date :

**APPENDIX III ZYX/CQA/SOP-039/FR-03**

 **CALIBRATION BY SUCROSE (Alternate Method)**

(Note : Calibration shall be done on the day of sample analysis)

1.0 Instrument ID.. : -------------------------

2.0 Location : -------------------------

3.0 Date of Calibration :-------------------------

4.0Preparation of Standard solution

 Wt of Sucrose (Batch/ Lot No------------------Make-------------)------------------.gm

 dissolved in -------------ml water (50 ppm)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (250ppb)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (500ppb)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (1000ppb)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sr.No | Concentration |  Area Count | Average AreaCount |  SD | RSD |
|  |  | I | II |  III | IV | V |  |  |  |
| 1. | 0ppb |  |  |  |  |  |  |  |  |
| 2. | 250ppb |  |  |  |  |  |  |  |  |
| 3. | 500ppb |  |  |  |  |  |  |  |  |
| 4. | 1000ppb |  |  |  |  |  |  |  |  |
| Slope |  |  |
| Intercept |  |  |
| Correlation coefficient |  |  |

Acceptance criteria : Linearity : Correlation coefficient should not be less than 0.98

 Standard Deviation : NMT 1.0

 RSD : NMT 5.0%

Remarks : Complies / Does not Comply

Done by : Checked By : Authorised By :

Date : Date :: Date :

 **APPENDIX IV ZYX/CQA/SOP-039/FR-04**

 SYSTEM SUITABILITY BY 1,4 BENZOQUINONE (WEEKLY)

1.0 Instrument ID :------------------- :

2.0 Location :---------------------

3.0 Date of System Suitability :----------------------

4.0 Preparation of Standard solution

4.1 Wt of 1,4 Benzoquinone (Batch/ Lot No------------------Make-------------)------------------.gm

 dissolved in -------------ml water (50 ppm)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (500ppb)

* 1. Observations:

Mean Area of Sucrose----------------

 Mean area of 1.4 Benzoquinone----------------.

 Mean area of pure water------------------

4.3 Calculation of Response efficiency (% recovery)

 % R = (Rss - Rw)

 ---------------- X 100

 (Rs-Rw)

 Where Rss = Mean area counts of 1,4 Benzoquinone solution

 Rs = Mean area counts of sucrose

 Rw = Mean area counts of pure water

Acceptance criteria : The system is said to be passing the test if the % recovery in between 85% to 115%.

Remarks : Complies / Does not comply

Done by ; Checked by ; Authorized by :

Date: Date : Date

  **APPENDIX V ZYX/CQA/SOP-039/FR-05**

 **INSCAL--------------------**

 **CALIBRATION BY POTASSIUM HYDROGEN PHTHALATE, OR SUCROSE, 1.4 BENZOQUINONE**

 **(HALF YEARLY RECORD)**

1.0 Instrument ID :------------------------------

2.0 Location :------------------------------

3.0 Date of Calibration :------------------------------

4.0 Next Due date ofCalibration :------------------------------

**5.0 By KHP**

5.1 Preparation of Standard solution

5.2 Wt of KHP (Batch/ Lot No------------------Make-------------)------------------.gm , dissolved in -------------ml water (1000ppm)

 Dilute -----------ml of solution(1000ppm) to --------------ml of purified water.(10ppm)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water (250ppb)

 Dilute -----------ml of solution (10ppm) to-------------- ml of purified water (500ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(750ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(1000ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(2000ppb)

 Dilute -----------ml of solution (10ppm) to --------------ml of purified water(5000ppb)

Observations :

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sr.No | Concentration |  Area Count | Average AreaCount | SD | RSD | Acceptance criteria |
|  |  | I | II | III | IV | V |  |  |  | Correlation coefficient should not be less than 0.98SD : NMT 1.0RSD : NMT 5.0%  |
| 1. | 10ppm |  |  |  |  |  |  |  |  |
| 2. | 0ppb |  |  |  |  |  |  |  |  |
| 3. | 250ppb |  |  |  |  |  |  |  |  |
| 4. | 500ppb |  |  |  |  |  |  |  |  |
| 5. | 750ppb |  |  |  |  |  |  |  |  |
| 6. | 1000ppb |  |  |  |  |  |  |  |  |
| 7. | 2000ppb |  |  |  |  |  |  |  |  |
| 8. | 5000ppb |  |  |  |  |  |  |  |  |
| Slope |  |  |
| Intercept |  |  |
| Correlation coefficient |  |  |

**6.0 By Sucrose**

6.1 Preparation of Standard solution

 Wt of Sucrose (Batch/ Lot No------------------Make-------------)------------------.gm

 dissolved in -------------ml water (50 ppm)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (250ppb)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (500ppb)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (1000ppb)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sr.No | Concentration |  Area Count | Average AreaCount |  SD | RSD |
|  |  | I | II |  III | IV | V |  |  |  |
| 1 | 0ppb |  |  |  |  |  |  |  |  |
| 2. | 250ppb |  |  |  |  |  |  |  |  |
| 3. | 500ppb |  |  |  |  |  |  |  |  |
| 4. | 1000ppb |  |  |  |  |  |  |  |  |
| Slope |  |  |
| Intercept |  |  |
| Correlation coefficient |  |  |

 Acceptance criteria : Linearity : Correlation coefficient should not be less than 0.98

 Standard Deviation : NMT 1.0

 RSD : NMT 5.0%

**7.0 By 1,4 Benzoquinone**

Preparation of Standard solution

7.1Wt of 1’4 Benzoquinone (Batch/ Lot No------------------Make-------------)------------------.gm

 dissolved in -------------ml water (50 ppm)

 Dilute-------- ml of solution (50ppm) to---------------ml Purified water (500ppb)

7.2 Observations:

Mean Area of Sucrose----------------

 Mean area of 1.4 Benzoquinone----------------.

 Mean area of pure water------------------

7.3 Calculation of Response efficiency (% recovery)

% R = (Rss - Rw)

 ---------------- X 100

 (Rs-Rw)

 Where Rss = Mean area counts of 1,4 Benzoquinone solution

 Rs = Mean area counts of sucrose

 Rw = Mean area counts of pure water

Acceptance criteria : The system is said to be passing the test if the % recovery in between 85% to 115%.

Remarks : Complies / Does not comply

Done by ; Checked by ; Authorized by :

Date: Date : Date :

**APPENDIX VI ZYX/CQA/SOP-039/FR-06**

 **TOC SUMMARY SHEET INSCAL----------------------**

**Instrument ID : -------------------------------**

**Location : -------------------------------**

|  |  |  |  |
| --- | --- | --- | --- |
|  **TEST** |  **OBSERVATION** | **ACCEPTANCE CRITERIA** |  **STATUS** |
| By Potassium hydrogen phthalate orBy Sucrose |  | Linearity : Correlation coefficient should not be less than 0.98 Standard Deviation : NMT 1.0 RSD : NMT 5.0%  | Complies/ Does not Comply |
| By 1,4 Benzoquinone |  | The system is said to be passing the test if the % recovery in between 85% to 115% | Complies/ Does not Comply |

**Remarks:** **All the parameters for the calibration as per predefined acceptance criteria are under limit hence the instrument is suitable**

 **for routine analysis**

Remarks : Complies / Does not comply

Done by ; Checked by ; Authorized by :

Date: Date : Date :