BIOSPECTRA
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URACIL STABILITY ANALYTICAL PROCEDURE

LOT NUMBER: _____

TIME POINT: _____

PACKAGING: _____

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1. SPECIFICATIONS:

1.1. Refer to the applicable Uracil stability data card (BSI-LST-0154 or BSI-LST-0219) for specifications.

2. SAFETY:

2.1. Standard laboratory safety regulations apply. Read and understand the material Safety DataSheet before handling this product and all reagents specified in this procedure.

3. EQUIPMENT:

3.1. Analytical balance, or equivalent
3.2. Calibrated Oven
3.3. Endosafe Nexgen PTS Reader
3.4. MP50 Melting Range
3.5. Muffle Furnace
3.6. Perkin Elmer Flexar HPLC
3.7. Perkin Elmer NexION 350X
3.8. Perkin Elmer Spectrum Two UATR
3.9. XL200 PH/MV/conductivity meter

4. REAGENTS:

4.1. **Uracil IR Reference Standard**: Dry an LOD vial in an oven at 105°C for 30 minutes. Cool the vial in a desiccator for 15 minutes and weigh the vial on the analytical balance. Tare the vial and weigh approximately 5.0 grams of Uracil from an outside source into the vial. Dry the standard in an oven at 105°C for 3 hours. Allow the standard to cool, cap, and store in a desiccator. Perform a UATR analysis on the Reference Standard and compare it to a previously approved reference standard scan. The correlation must be 0.95 or greater between the two scans to be approved for use.

5. REFERENCES:

5.1. BSI-ATM-0016, Uracil Testing Methods
5.2. BSI-ATM-0105, Uracil Assay via Liquid Chromatography with UV Detection
5.3. BSI-FRM-0634, HPLC Analysis Data Sheet
5.4. BSI-LST-0154, Uracil Stability Data Card
5.5. BSI-LST-0219, Uracil 4201 Stability Data Card
5.6. BSI-RPT-0532, Analytical Method Validation Report: Uracil Assay vis HPLC
5.7. BSI-SOP-0098, Balance SOP
5.8. BSI-SOP-0126, Laboratory Notebooks
5.9. BSI-SOP-0254, Spectrum Two UATR SOP
5.10. BSI-SOP-0448, Perkin Elmer Flexar HPLC and TotalChrom Software

6. ANALYTICAL PROCEDURE:

6.1. APPEARANCE AND COLOR

Place a suitable amount of sample in a clean and dry glass beaker. In an area with sufficient lighting, view the sample from all sides. The sample should be white to slightly yellow and characteristic of a powder.

Sample Weight [_____g]

Appearance Result [_____]

Balance S/N/Due Date [_____/_____]

Analyzed By: [_____/_____] Reviewed By: [_____/_____]

6.2. ASSAY (HPLC – DRIED BASIS)

Refer to Analytical Procedure or Notebook Pages.

Reference [_____]

Assay Result	
Result	Performed By

Transcribed By: [_____/_____] Reviewed By: [_____/_____]

6.3. IDENTIFICATION (IR)

Follow Spectrum Two UATR SOP for sample preparation and analysis. Analyze the sample after it has been dried for 3 hours at 105°C. The LOD sample may be utilized for this test.

☐ LOD sample was utilized. Refer to section 6.4.

☐ Sample dried at [_____°C] for [_____hours].

Sample and standard crushed prior to analyzing? ☐ Yes ☐ No

Oven S/N/Due Date (If applicable) [_____/_____]

Calibrated Timer S/N/Due Date (If applicable) [_____/_____]

Uracil IR Reference Standard [_____/_____]

Spectrum Two UATR S/N/Due Date [_____/_____]

Correlation [_____] Identification Result [_____]

Analyzed By: [_____/_____] Reviewed By: [_____/_____]

6.4. LOSS ON DRYING

Dry a Loss on Drying (LOD) vial in the oven at 105 ± 2°C for 30 minutes. Cool for 15 minutes in a desiccator, weigh the LOD vial, and record results. If the substance to be tested is in the form of large crystals, reduce the particle size to about 2mm by quickly crushing. Transfer approximately 1-2g of the sample to the LOD vial, and accurately weigh the vial and contents. By gentle, sideways shaking, distribute the sample as evenly as possible in the LOD vial. Place the LOD vial containing the sample into the oven and dry at 105°C ± 2°C for 3 hours. Remove the LOD vial from the oven and allow to cool in the desiccator for 15 minutes. Reweigh the LOD vial and sample and retain the dried sample to perform the IR and Assay (if applicable). Calculate the %LOD as follows:

$$\%LOD = \frac{[initial\ sample\ weight\ (g) - final\ sample\ weight\ (g)]}{initial\ sample\ weight\ (g)} x100$$

Initial Vial Weight	Initial Sample Weight	Final Vial Weight	Final Sample Weight	Result
g	g	g	g	%

Vial dried for [_____minutes] and cooled for [_____minutes] before weighing.

Sample drying time [_____hours]

Sample cooled for [_____minutes] before weighing.

Balance S/N/Due Date [_____/_____]

Oven temperature [_____°C] Oven S/N/Due Date [_____/_____]

Calibrated Timer S/N/Due Date [_____/_____]

Analyzed By: [_____/_____] Reviewed By: [_____/_____]

6.5. REACTION

Stability:

The 1% solution prepared for solubility must be neutral to faintly basic, basic or acidic when tested with broad range pH paper or calibrated pH meter. For the result, document the result as Passes Test. Then specify if the result was neutral, basic, faintly basic, or acidic. Example: Passes Test – Basic.

☐ Sample from Solubility 1% Solution was utilized. Refer to section 6.6.

Sample Weight [_____g] dissolved in [_____mL] boiling water (if applicable).

Balance S/N/Due Date [_____/_____]

pH Paper [_____/_____] pH_____]

Reaction Result [_____]

Analyzed By: [_____/_____] Reviewed By: [_____/_____]

6.6. SOLUBILITY

Weigh 1 gram of sample and dissolve in 99 mL of boiling water. In an area with sufficient lighting, view the sample from all sides. The solution must be clear or faintly hazy with no more than a light-yellow color in order to pass test.

Sample Weight [_____g] dissolved in [_____mL] of boiling water.

Balance S/N/Due Date [_____/_____]

Solubility Result [_____]

Analyzed By [_____/_____] Reviewed By [_____/_____]

BALANCE PRINTOUTS

ATTACHMENTS

ANALYSIS	ATTACHMENTS
Assay	Initial/Date: _____
UATR	Initial/Date: _____

APPLICABLE AUDIT TRAILS REVIEWED: (INITIAL/DATE) _____

REVIEWED BY:_____ DATE:_____