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L-GLUTAMINE TESTING METHODS

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1. PURPOSE:

1.1. To provide Laboratory Personnel with procedures for testing L-Glutamine.

2. SCOPE:

2.1. Applies to the testing of L-Glutamine in the Laboratory at all BioSpectra Facilities. Methods include testing for all types of L-Glutamine sold by BioSpectra; only the specific tests required for the desired type must be tested.

3. RESPONSIBILITIES:

3.1. The Laboratory Manager or qualified designee is responsible for control, training, maintenance and implementation of this procedure.
3.2. The Laboratory Technicians are responsible for compliance with the terms of this procedure. This includes notifying the Quality Assurance / Laboratory Manager or designee if any analyses fail to meet their respective specifications.
3.3. Standard laboratory safety regulations apply. Before working with any chemical, read and understand the Safety Data Sheet (SDS).

4. EQUIPMENT:

4.1. Analytical Balance
4.2. Anhydrous Potentiometric Electrode
4.3. Anton Paar MCP 5300 Polarimeter
4.4. Calibrated Oven
4.5. Calibrated Pipettes
4.6. Calibrated Timer
4.7. EndoSafe NexGen PTS Endotoxin Reader
4.8. Metrohm 907 Titrando Auto-Titrator
4.9. Muffle Furnace
4.10. Perkin Elmer NexION 350X ICP-MS
4.11. Perkin Elmer Spectrum Two UATR
4.12. Vacuum Distillation Apparatus
4.13. XL200 pH/mV/Conductivity Meter, or equivalent
4.14. OPI-180 OD Handheld Colorimeter SOP

5. REAGENTS:

5.1. **0.01 – 1.0EU/mL Endotoxin Cartridges:** Purchased Commercially.
5.2. **0.02N Hydrochloric Acid:** Purchased Commercially or Slowly add 20mL of 0.1N Hydrochloric Acid to 80mL of Purified Water to make a total volume of 100mL.
5.3. **0.02N Sulfuric Acid:** Slowly add 20mL of 0.1N Sulfuric Acid to 80mL of Purified Water to make a total volume of 100mL.
5.4. **0.1N Hydrochloric Acid:** Purchased Commercially.
5.5. **0.1N Perchloric Acid:** Purchased Commercially.
5.6. **0.1N Silver Nitrate:** Purchased Commercially.
5.7. **0.1N Sulfuric Acid:** Purchased Commercially.
5.8. **0.5% Boric Acid:** Dissolve 1 gram of Boric Acid in 200mL of Purified Water and mix well.
5.9. **2N Acetic Acid:** Slowly add 12mL of Glacial Acetic Acid to 25mL of Purified Water in a 100mL volumetric flask. If solution feels warm, stopper and allow to cool to room temperature. Bring to final volume with Purified Water.
5.10. **3N Hydrochloric Acid:** Pipette 25.75mL of concentrated Hydrochloric Acid and transfer to a 100mL volumetric flask that contains a small amount of Purified Water. Dilute to volume with Purified Water.
5.11. **98% Formic Acid:** Purchased Commercially.

5.12. **Ammonium Chloride:** Purchased Commercially.
5.13. **Barium Chloride Dihydrate:** Purchased Commercially.
5.14. **Barium Chloride TS:** Dissolve 12g of Barium Chloride Dihydrate in Purified Water. Filter and dilute to make a total volume of 100mL with Purified Water.
5.15. **Boric Acid:** Purchased Commercially.
5.16. **Butyl Alcohol:** Purchased Commercially.
5.17. **Glacial Acetic Acid:** Purchased Commercially.
5.18. **Hydrochloric Acid, concentrated:** Purchased Commercially.
5.19. **L-Glutamine Certified Reference Standard (CRS):** Purchased Commercially.
5.20. **LAL Reagent Water:** Purchased Commercially.
5.21. **Litmus Paper:** Purchased Commercially.
5.22. **Magnesium Oxide:** Purchased Commercially.
5.23. **Ninhydrin:** Purchased Commercially.
5.24. **Nitric Acid, concentrated:** Purchased Commercially.
5.25. **Phenol:** Purchased Commercially.
5.26. **Phenol-Sodium Pentacyanonitrosylferrate (III) TS**: Dissolve 5 grams of Phenol and 25 mg of Sodium Pentacyanonitrosylferrate (III) Dihydrate in sufficient water to make 500mL. Preserve in a dark, cold place.
5.27. **Potassium Hydrogen Phthalate (KHP):** Prepare an appropriate sample container at 120°C for 30 minutes. Allow to cool in a desiccator. Crush and dry a suitable amount of Potassium Hydrogen Phthalate. Dry at 120°C for 2 hours. Cool and store in a desiccator in a closed container. Stable for 3 months.
5.28. **Purified Water:** In-House or Purchased Commercially.
5.29. **Sodium Hydroxide Pellets:** Purchased Commercially.
5.30. **Sodium Hypochlorite TS**: Purchased Commercially.
5.31. **Sodium Hypochlorite-Sodium Hydroxide TS**: To a volume of Sodium Hypochlorite TS equivalent to 1.05 grams (NaClO: 74.44g/mol), add 15 grams of Sodium Hydroxide Pellets, dissolve in Purified Water, dilute to 1000mL, and mix well. Prepare immediately before use.
5.32. **Sodium Pentacyanonitrosylferrate (III) Dihydrate**: Purchased Commercially.
5.33. **Standard Ammonium Solution**: Dissolve 2.97 grams of Ammonium Chloride in Purified Water to make 1000mL. Dilute 10.0mL of this solution to 1000mL with Purified Water and mix well.
5.34. **Sulfuric Acid, concentrated:** Purchased Commercially.

6. REFERENCES:

6.1. BSI-MEM-0130, Endosafe NexGen PTS Endotoxin Reader: Qualified Products
6.2. BSI-RPT-1698, Analytical Method Validation Report: L-Glutamine Assay by Potentiometric Titration with 0.1N Perchloric Acid
6.3. BSI-SOP-0019, Result Reporting
6.4. BSI-SOP-0094, Muffle Furnace SOP and Calibration
6.5. BSI-SOP-0098, Balance SOP
6.6. BSI-SOP-0126, Laboratory Notebooks
6.7. BSI-SOP-0134, Pipette SOP
6.8. BSI-SOP-0140, Standardization of Titrants
6.9. BSI-SOP-0143, Metrohm Titrando 907 Auto-Titrator SOP
6.10. BSI-SOP-0244, VWR Gravity Convection Oven Operation and Calibration (Model Number 414005-106)
6.11. BSI-SOP-0254, Spectrum Two UATR SOP
6.12. BSI-SOP-0255, XL200 pH/mV/Conductivity Meter SOP
6.13. BSI-SOP-0303, NexION 350X ICP-MS SOP
6.14. BSI-SOP-0345, Endosafe Nexgen-PTS Endotoxin Reader SOP

6.15. BSI-SOP-0420, Analytical Method for the Determination of ICH Q3D Elemental Impurities (Class 1, 2A, 2B, 3 & 4) by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) in Cytidine, Uridine, L-Arginine HCl, and L-Glutamine
6.16. BSI-SOP-0490, MCP 5300 Polarimeter SOP
6.17. BSI-SOP-0668, OPI-180 OD Handheld Colorimeter SOP
6.18. *Current USP, JP*

7. ANALYTICAL PROCEDURES:

Note: **Laboratory Summary Sheet will include the most stringent specifications.**

- Testing required for LGLM-4250: USP Testing
- Testing required for LGLM-4251: USP/JP Testing is required.

7.1. AMMONIUM (JP):

7.1.1. Setup a clean vacuum distillation apparatus as pictured (minor modifications are permissible due to glassware availability) – Note: A temperature probe should be in the water bath next to the distillation flask, not inside the apparatus.

7.1.1.1. All rubber parts should be boiled 10-30 minutes with Sodium Hydroxide TS and then 30-60 minutes in clean water, then rinsed with water before use.

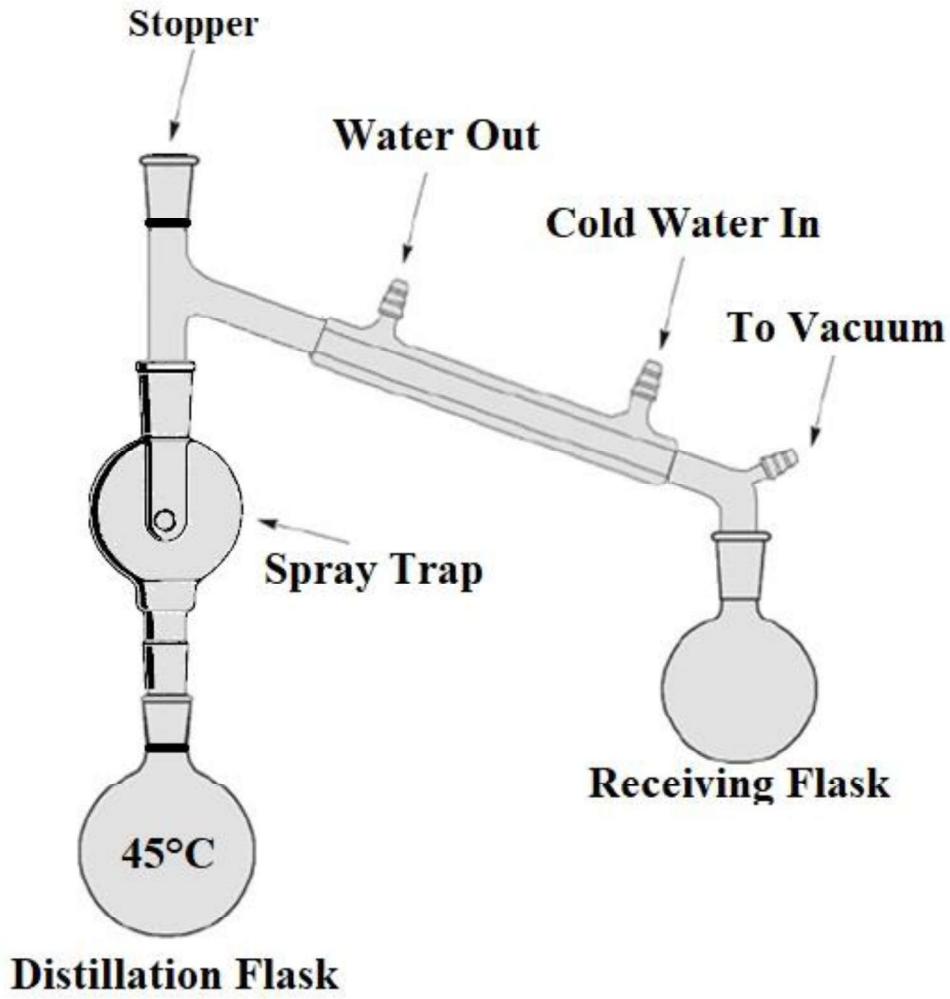

Figure 1: Vacuum Distillation Apparatus

7.1.2. Sample Test Solution:
- 7.1.2.1. Remove the distillation flask from the distillation set up.
- 7.1.2.2. Weigh and transfer 0.10g of sample into the distillation flask.
- 7.1.2.3. Add 70mL of Purified Water and 1 gram of Magnesium Oxide to the distillation flask.
- 7.1.2.4. Connect the distillation flask to the vacuum condenser as pictured.
- 7.1.2.5. Add 20mL of 0.5% Boric Acid to the receiving flask.
- 7.1.2.6. Distill at 45°C +/-10°C and adjust vacuum until a rate of ~1-2mL per minute of distillate is achieved.
- 7.1.2.7. Stop the distillation when ~30mL of distillate is obtained in the receiving flask.
  - 7.1.2.7.1. Note: Take care to relieve the pressure from the apparatus slowly to avoid unintentional liquid transfer to the vacuum system
- 7.1.2.8. Remove the receiving flask and rinse the lower condenser end with Purified Water to the receiving flask, transfer to a 100mL graduated cylinder dilute to 100mL with Purified Water and mix thoroughly.

7.1.3. Standard Control Solution:
- 7.1.3.1. Remove the distillation flask from the distillation set up.
- 7.1.3.2. Aliquot 10.0mL of Standard Ammonium Solution to the distillation flask.
- 7.1.3.3. Add 70mL of Purified Water and 1 gram of Magnesium Oxide to the distillation flask.
- 7.1.3.4. Connect the distillation flask to the vacuum condenser as pictured.
- 7.1.3.5. Add 20mL of 0.5% Boric Acid to the receiving flask.
- 7.1.3.6. Distill at 45°C+/-10°C and adjust vacuum until a rate of ~1-2mL per minute of distillate is achieved.
- 7.1.3.7. Stop the distillation when ~30mL of distillate is obtained in the receiving flask.
- 7.1.3.8. Remove the receiving flask and rinse the lower condenser end with Purified Water to the receiving flask, transfer to a 100mL graduated cylinder dilute to 100mL with Purified Water and mix thoroughly.

7.1.4. Analysis:
- 7.1.4.1. Aliquot 30mL of both *Standard Control Solution* and *Sample Test Solution* to 50mL Nessler tubes.
- 7.1.4.2. Add 6.0mL of Phenol-Sodium Pentacyanonitrosylferrate (III) TS to each solution, and mix.
- 7.1.4.3. Add 4mL of Sodium Hypochlorite-Sodium Hydroxide TS.
- 7.1.4.4. Dilute to 50mL with Purified Water and mix.
- 7.1.4.5. Allow to stand for 60 minutes.
- 7.1.4.6. Compare the color of the *Standard Control Solution* to the *Sample Test Solution* against a white background by viewing downward or transversely.
- 7.1.4.7. The color developed in the *Sample Test Solution* is not more intense than that of the *Standard Control Solution* to report as NMT 0.1%.

7.2. **APPEARANCE AND COLOR:**
- 7.2.1. Place ~10 grams of sample into a clean, dry, glass beaker.
- 7.2.2. In an area with sufficient lighting, viewed the sample from all sides.
- 7.2.3. The sample should be white in color and characteristic of crystals or a crystalline powder.
- 7.2.4. If the appearance and color result is unable to be definitively determined visually, the sample may be analyzed using the Colorimeter. Refer to BSI-SOP-0668, OPI-180 OD Handheld Colorimeter SOP.
- 7.2.5. Any non-conformance will be reported to the Laboratory Manager or designee, immediately.

7.3. **ASSAY (DRIED BASIS) (USP/JP):**

7.3.1. Perform a daily check or standardization of 0.1N Perchloric Acid as per Standardization of Titrants.

7.3.2. Blank Preparation:

7.3.2.1. Add 3mL of 98% Formic Acid and 50mL of Glacial Acetic Acid to a suitable beaker and mix well.

7.3.3. Sample Preparation:

7.3.3.1. Accurately weigh 350mg of dried sample (dried according to the Loss on Drying procedure) into a suitable beaker.

7.3.3.2. Completely dissolve sample in 3mL of 98% Formic Acid.

7.3.3.2.1. Note: Ensure sample is completely dissolved before addition of Glacial Acetic Acid.

7.3.3.3. Add 50mL of Glacial Acetic Acid.

7.3.3.4. Mix well.

7.3.4. Titrate to a potentiometric endpoint with 0.1N Perchloric Acid using the Metrohm Titrando 907 and Anhydrous Potentiometric Electrode.

7.3.5. Calculate %L-Glutamine using the following equation in the Metrohm® Tiamo™ software:

$$\%\text{L-Glutamine} = \frac{\Big(\big(Sample\ Endpoint\ (mL) - Blank\ Endpoint\ (mL)\big)\Big)\,(Normality\ of\ Titrant)(14.61)}{Sample\ Weight\ (g)}$$

7.4. **CHLORIDE AND SULFATE <*CHLORIDE*>:**

7.4.1. USP Standard Preparation (0.05% Maximum):

7.4.1.1. Pipette 0.50 mL of 0.02N HCl into a Nessler Color Comparison tube and dilute to approximately 40 mL with purified water.

7.4.2. JP Standard Preparation (0.02% Maximum):

7.4.2.1. Pipette 0.20 mL of 0.02N HCl into a Nessler Color Comparison tube and dilute to approximately 40 mL with purified water.

7.4.3. Sample Preparation:

7.4.3.1. Weigh 0.7 grams of sample and dissolve in approximately 40 mL of purified water.If necessary, neutralize the solution with nitric acid to litmus.

7.4.4. Procedure:

7.4.4.1. To each solution, add 1 mL of concentrated nitric acid and 1 mL of 0.1N silver nitrate.

7.4.4.2. Dilute to 50 mL with purified water. Cover with parafilm, and mix by inversion.

7.4.4.3. After 5 minutes, the turbidity of the sample preparation does not exceed that produced by the standard when viewed against a dark background.

7.5. **CHLORIDE AND SULFATE <*SULFATE*>:**

7.5.1. USP Standard Preparation (0.03% Maximum):

7.5.1.1. Pipette 0.25 mL of 0.02N Sulfuric Acid into a Nessler Color Comparison tube and dilute to approximately 40 mL with purified water.

7.5.2. JP Standard Preparation (0.02% Maximum):

7.5.2.1. Pipette 0.17 mL of 0.02N Sulfuric Acid into a Nessler Color Comparison tube and dilute to approximately 40 mL with purified water.

7.5.3. Sample Preparation:

7.5.3.1. Weigh 0.8 grams of sample and dissolve in approximately 40 mL of purified water. If necessary, neutralize the solution with hydrochloric acid to litmus.

7.5.4. Procedure:

7.5.4.1. To each solution, add 1 mL of 3N HCl and 3 mL of Barium Chloride TS.

7.5.4.2. Dilute to 50 mLwith purified water. Cover with parafilm and mix by inversion.
7.5.4.3. After 10 minutes, the turbidity of the preparation does not exceed that produced by the standard when viewed against a dark background.

7.6. **CLARITY AND COLOR OF SOLUTION (JP):**

7.6.1. Dissolve 0.5 grams of sample in 20mL of Purified Water.
7.6.2. Solution should be clear and colorless.

7.7. **ENDOTOXIN:**

7.7.1. Accurately weigh 0.300g of sample into a sterile tube.
7.7.2. Dissolve in 9mL of LAL reagent water. Mix thoroughly.
7.7.3. Adjust the pH to between 6-8 with 0.1N NaOH.
7.7.4. Dilute to 10mL with LAL reagent water for a final concentration of 0.0300 g/mL.
7.7.5. Analyze using 10-0.1 EU/mL Endotoxin Cartridge.
7.7.6. Refer to Endosafe nexgen-PTS Endotoxin Reader SOP for instrument analysis.

7.8. **IDENTIFICATION A, (IR) (USP/JP):**

7.8.1. Follow Spectrum Two UATR SOP for sample preparation and analysis.

7.9. **HEAVY METALS (JP) AND IRON (USP/JP):**

7.9.1. Refer to BSI-SOP-0420, Analytical Method for the Determination of ICH Q3D Elemental Impurities (Class 1, 2A, 2B, 3 & 4) by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) in Cytidine, Uridine, L-Arginine HCl, and L-Glutamine for sample preparation and analysis.

7.10. **LOSS ON DRYING (105°C) (USP/JP):**

7.10.1. Dry a LOD vial in an oven at 105 ± 2˚C for 30 minutes.
7.10.2. Cool for 15 minutes in adesiccator, weigh the LOD vial, and record the weight.
7.10.2.1. Note: If the substance to be tested is in the form of large crystals, reduce the particle size to about 2mm by quickly crushing before weighing.
7.10.3. Transfer $1-2$ grams of the sample to the LOD vial and accurately weigh the vial and contents. By gentle, sidewise shaking, distribute the sample as evenly as possible in the LOD vial to a depth of about 5mm.
7.10.4. Place the LOD vial containing the sample into the oven and dry at 105°C ± 2°C for 3 hours.
7.10.5. Remove the LOD vial from the oven and allow it to cool in the desiccator for 15 minutes.
7.10.6. Reweigh the LOD vial and sample and retain the dried sample for other analyses, if necessary.
7.10.7. Calculate the %LOD as follows:

$$\%LOD = \frac{Initial\ Sample\ Weight\ (g) - Final\ Sample\ Weight\ (g)}{Initial\ Sample\ Weight\ (g)} \times 100$$

7.11. **OPTICAL ROTATION, SPECIFIC ROTATION @ 20°C (USP/JP):**

7.11.1. Sample Solution (40mg/mL L-Glutamine):
7.11.1.1. Accurately weigh 4.0 grams of sample and transfer to a 100 mL volumetric flask.
7.11.1.2. Dissolve sample in purified water by heating to 40°C.
7.11.1.3. Fill to volume with purified water and mix well.
7.11.2. Refer to MCP 5300 Polarimeter, DCN: BSI-SOP-0490 for instrument analysis.
7.11.2.1. Optical Zero Reference: Purified Water.
7.11.2.2. The following information will be required to be entered into the software:
7.11.2.3. Volume (dryness)(mL), Mass (dryness)(g), Drying Loss (%)
7.11.2.3.1. Utilize the sample's Loss on Drying result for drying loss.

7.11.2.4. Analysis: Perform at 20°C.

7.11.3. Refer to MCP 300 Polarimeter, DCN: BSI-SOP-0257 for instrument analysis.

7.11.3.1. Select the following method in the software: Specific Rotation @ 20°C – BioSpectra (LOD)

7.11.3.2. Calculate the result using the following calculation:

7.11.3.2.1. Specific Rotation = (Raw Result) * (100 / (100-Drying Loss))

7.11.3.2.2. Utilize the sample's Loss on Drying result for drying loss.

7.12. **pH (1 in 50) (JP):**

7.12.1. Weigh out 1.0 grams of sample, transfer to a beaker, dissolve in 50mL of purified water, and mix well.

7.12.2. Follow the appropriate SOP for pH calibration and measurement.

7.13. **RESIDUE ON IGNITION (USP/JP):**

7.13.1. Turn on the muffle furnace and allow it to stabilize at 600°C. Follow the muffle furnace calibration procedure for operation of the furnace.

7.13.2. Inspect a quartz crucible for cracks, chips, and discoloration.

7.13.3. Utilize forceps to insert and remove the crucible from the furnace.

7.13.4. Ignite a quartz crucible at 600 ± 50°C for 30 minutes. Cool in a desiccator for 1.5 hours and weigh using an analytical balance.

7.13.5. Weigh 1.0 grams of sample in the previously ignited quartz crucible. Moisten the sample with 1.0mL of concentrated Sulfuric Acid.

7.13.6. Volatilize the sample until the sample is thoroughly charred and white fumes are no longer evolved. Heat the sample slowly, so that the sample does not boil over and sample is not lost.

7.13.6.1. The rate of heating should be such that from ½ to 1 hour is required to volatilize the sample.

7.13.6.2. Continue to heat the sample until all excess sulfuric acid has been volatilized.

7.13.7. Ignite in the muffle furnace at 600 ± 50°C for 15 minutes or until all carbon has been removed.

7.13.8. Cool in a desiccator for the same amount of time employed in the preparation of the crucible and weigh on an analytical balance.

7.13.9. Calculate the %ROI as follows:

$$\%ROI = \frac{Residue\ Weight\ (g)}{Sample\ Weight\ (g)} \times 100$$

7.13.10. If the amount of residue exceeds the limit specified, repeat the moistening with sulfuric acid using up to 1mL, heat to char, then ignite at 600 ± 50°C for 30 minutes until two consecutive weighings of the residue do not differ by more than 0.0005g or until the specification is met.

7.14. **RELATED COMPOUNDS/SUBSTANCES (THIN-LAYER CHROMATOGRAPHY:**

7.14.1. Solution Preparation:

7.14.1.1. Note: All solutions can be scaled as needed.

7.14.1.2. Developing Solvent System (3:1:1 Butyl Alcohol: Glacial Acetic Acid: Purified Water): Mix 60mL of Butyl Alcohol, 20mL of Glacial Acetic Acid, and 20mL of Purified Water.

7.14.1.3. Spray Reagent (2mg/mL Ninhydrin in 95:5 Butyl Alcohol: 2N Acetic Acid): Dissolve 100mg of Ninhydrin in 47.5mL of Butyl Alcohol and 2.5mL of 2N Acetic Acid. Mix well.

7.14.1.4. Sample Solution (10mg/mL L-Glutamine Sample): Accurately weigh and transfer 100mg of L-Glutamine sample to a 10mL volumetric flask, dissolve, and fill to volume with Purified Water. Mix well.

7.14.1.5. USP Standard Stock Solution (0.1 mg/mL L-Glutamine CRS): Accurately weigh and transfer 10mg of L-Glutamine CRS to a 100mL volumetric flask, dissolve, and fill to volume with purified water. Mix well.

7.14.1.6. JP Standard Stock Solution (10 mg/mL L-Glutamine CRS): Accurately weigh and transfer 100mg of L-Glutamine CRS to a 10mL volumetric flask, dissolve, and fill to volume with purified water. Mix well.

7.14.1.7. USP Standard Test Solution (0.05 mg/mL L-Glutamine CRS): Accurately pipette 5.0mL of *USP Standard Stock Solution* into a 10mL volumetric flask, fill to volume with Purified Water, and mix well.

7.14.1.8. JP Standard Test Solution (0.02mg/mL L-Glutamine CRS): Accurately pipette 1.0 mL of *JP Standard Stock Solution* into a 10mL volumetric flask, dilute to volume with purified water and mix well. Accurately pipette 1.0mL of the resulting solution into a 50mL volumetric flask, dilute to volume with purified water and mix well.

Table 1: Chromatographic System:

Parameter	Setting
Mode	Thin-Layer Chromatography (TLC)
Adsorbent	0.25mm Layer of Chromatographic Silica Gel Mixture
Application Volume	5µL
Developing Solvent System	3:1:1 Butyl Alcohol: Glacial Acetic Acid: Purified Water
Spray Reagent	2mg/mL Ninhydrin in 95:5 Butyl Alcohol: 2N Acetic Acid

7.14.2. Analysis:

7.14.2.1. Spot 5µL of *Sample Solution* and *Standard Test Solution* onto the TLC plate.

7.14.2.2. Place the plate in the chamber, ensuring the spots or bands are above the surface of the mobile phase.

7.14.2.3. Allow the mobile phase to ascend the plate until the solvent front has traveled three-quarters of the length of the plate.

7.14.2.4. Remove the plate, mark the solvent front with a pencil.

7.14.2.5. Dry the plate at 80°C for 30 minutes.

7.14.2.6. Spray with *Spray Reagent* and heat the plate at 80°C for about 10 minutes.

7.14.2.7. Examine the plate under white light.

7.14.2.8. No secondary spot of the *Sample Solution* is larger or more intense than the principle spot of the *Standard Test Solution* (USP Spec: NMT 0.5%, JP Spec: NMT 0.2%).

7.15. **TRACE METALS:**

7.15.1. Refer to BSI-SOP-0420, Analytical Method for the Determination of ICH Q3D Elemental Impurities (Class 1, 2A, 2B, 3 & 4) by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) in Cytidine, Uridine, L-Arginine HCl, and L-Glutamine for sample preparation and analysis.

7.15.1.1. Heavy Metals and Iron will be reported from this analysis.

8. COMPENDIAL DIFFERENTIATIONS:

Table 2: Compendial Analyses Not Harmonized

USP- NF Compendia	JP Compendia
Chloride	Ammonium
Related Compounds	Chloride
Sulfate	Clarity and Color of Solution
	pH
	Related Substances
	Sulfate

Table 3: Compendia Harmonized Methods

Analysis Name
Identification A, IR (USP/JP)
Loss on Drying (USP/JP)
Optical Rotation, Specific Rotation @ 20°C
Residue on Ignition

Table 4: In-House Validated Methods in accordance with USP General Chapter:

Analysis Name
Assay (dried basis)
Trace Metals: Heavy Metals and Iron

Table 5: In-House Methods for Product Quality Description

Analysis Name
Appearance and Color

Table 6: Outside Approved Laboratory Testing (if required)

Analysis Name	
TAMC/TYMC Sample size required to be sent: ~35grams	MPL Suitability #21T409a