the total combined molds and yeasts count is not more than 100 cfu per g.

Loss on drying ⟨731⟩**—**Dry it at 105° for 2.5 hours: it loses not more than 15.0%.

Total ash ⟨561⟩**:** not less than 4.0% and not more than 14.0%, calculated on the dried basis.

Arsenic, *Method II* ⟨211⟩**:** not more than 3.0 µg per g.

Lead ⟨251⟩**—**Prepare a *Test Preparation* as directed, using a 2.0-g portion of Gellan Gum. Use 4 mL of *Diluted Standard Lead Solution* (4 µg of Pb) for the test: the limit is not more than 2.0 µg per g.

Limit of isopropyl alcohol—Proceed as directed under *Limit of isopropyl alcohol* for *Xanthan Gum,* using about 5 g of Gellan Gum, accurately weighed, for the *Test solution:* not more than 750 µg per g is found.

Assay—Proceed with Gellan Gum as directed for *Procedure* under *Alginates Assay* ⟨311⟩, using about 1.2 g of undried Gellan Gum, accurately weighed.

Pharmaceutical Glaze

» Pharmaceutical Glaze is a specially denatured alcoholic solution of Shellac containing between 20.0 and 57.0 percent of anhydrous shellac and is made with either dehydrated alcohol or alcohol containing 5 percent of water by volume. The solvent is a specially denatured alcohol approved for glaze manufacturing by the Internal Revenue Service. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of shellac. It may contain waxes, and it may contain Titanium Dioxide as an opaquing agent.

Packaging and storage—Preserve in tight, lined metal or plastic containers, protected from excessive heat, preferably at a temperature below 25°.

Labeling—Label it to indicate the shellac type (see under *Shellac*) and concentration, the composition of the solvent, and the quantity of titanium dioxide, if present. Where titanium dioxide or waxes are present, the label states that the Glaze requires mixing before use.

Acid value—Accurately weigh, by difference, a quantity of Glaze containing about 2 g of shellac, dissolve in 50 mL of alcohol that has been neutralized to phenolphthalein with 0.1 N sodium hydroxide, add additional phenolphthalein TS, if necessary, and titrate with 0.1 N sodium hydroxide VS to a pink endpoint. [NOTE—For Glaze containing orange shellac, titrate slowly, stirring vigorously, until a glass rod dipped into the titrated solution produces a color change when touched to a drop of thymol blue TS on a spot plate.] Express the acid value in terms of the number of mg of potassium hydroxide required per g of dried shellac. It meets the requirement for *Acid value* under *Shellac*.

Wax—Accurately weigh, by difference, a quantity of Glaze containing about 10 g of shellac into a 200-mL tall-form beaker. Add, with stirring, 150 mL of hot water containing 2.5 g of sodium carbonate, and proceed as directed in the test for *Wax* under *Shellac*, beginning with "immerse the beaker." It meets the requirement for *Wax* under *Shellac.*

Identification, Heavy metals, and Rosin—Pour the remainder of the solution in the volumetric flask, retained from the *Assay*, onto a clean glass plate, and place the plate in a nearly vertical position. After drainage is complete, allow the resulting film to dry in a well-ventilated place at 20° for 1 hour, then place the plate in an oven at a temperature of 43° for 16 to 24 hours. Cool, and scrape the film from the plate with a sharp blade, discarding the thick edges: it responds to the *Identification* test and meets the requirements of the tests for *Heavy metals*, and *Rosin* under *Shellac.*

Assay—When testing Glaze that does not contain titanium dioxide, transfer an accurately weighed quantity of Glaze, containing about 17 g of shellac, to a 100-mL volumetric flask, add alcohol to volume, and mix. Pipet 3 mL into a tared dish containing about 10 g of washed sand and a small glass rod. [NOTE—The tare weight includes the combined weights of the dish, the washed sand, and the glass rod. Retain the remaining solution in the volumetric flask for the tests for *Identification*, *Heavy metals*, and *Rosin*.] Stir until a uniform mixture is obtained, allow the glass rod to remain in the dish, dry at 105° for 1 hour in an explosion-proof oven, cool, and weigh: the weight of shellac in the quantity of Glaze taken is obtained by subtracting the tare weight from the final weight of the dried dish and contents. When testing Glaze that contains titanium dioxide, transfer an accurately weighed quantity, containing about 10 g of solids, to a beaker, and add about 10 mL of alcohol. Filter off the pigment with the aid of vacuum. Wash the filter with alcohol, and transfer the combined filtrate and washing, with the aid of alcohol, to a 200-mL volumetric flask, add alcohol to volume, and mix. Pipet 6 mL into a tared dish containing about 10 g of washed sand and a small glass rod. Proceed as directed above, beginning with the *Note*.

Gluconolactone—*see Gluconolactone General Monographs*

Liquid Glucose

[8027-56-3].

» Liquid Glucose is a product obtained by the incomplete hydrolysis of starch. It consists chiefly of dextrose, dextrins, maltose, and water.

Packaging and storage—Preserve in tightly closed containers. No storage requirements specified.

Labeling—Label it to indicate the natural source of starch. Label it to indicate its nominal dextrose equivalent.

USP Reference standards ⟨11⟩**—**
USP Dextrose RS

Identification—It meets the requirements of the *Assay for reducing sugars (dextrose equivalent)*.

Acidity—To a solution of 5.0 g in 15 mL of water add 5 drops of phenolphthalein TS: not more than 0.60 mL of 0.10 N sodium hydroxide is required to produce a pink color.

Water, *Method Ia* ⟨921⟩: not more than 21.0%, determined on a 100-mg specimen.

Residue on ignition ⟨281⟩: not more than 0.5%.

Sulfite—Dissolve 5 g in 50 mL of water, add 0.2 mL of 0.1 N iodine, then add 0.5 mL of starch TS: a blue color is produced.

Heavy metals ⟨231⟩**—**Mix 2.0 g with water to make 25 mL: the limit is 0.001%.

Starch—Dissolve 5 g in 50 mL of water, boil the solution for 1 minute, cool, and add 0.2 mL of 0.1 N iodine: no blue color is produced.

Assay for reducing sugars (dextrose equivalent)—

Standard solution—Dissolve an accurately weighed quantity of USP Dextrose RS in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 6 mg per mL.

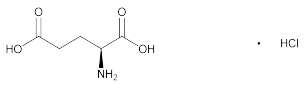
Test solution—Transfer a quantity of Liquid Glucose, equivalent to about 3.0 g of reducing sugars (dextrose equivalent), to a 500-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Transfer 25.0-mL portions of alkaline cupric tartrate TS to each of two boiling flasks. Bring the contents of one flask to boiling within about 2 minutes while titrating with *Standard solution* to within 0.5 mL of the anticipated endpoint. Boil gently for 2 minutes. Continue to boil gently, add 2 drops of methylene blue solution (1 in 100), and complete the titration within 1 minute by adding the *Standard solution* dropwise or in small increments until the blue color disappears, determined by viewing against a white background in daylight or under equivalent illumination. If more than 0.5 mL of the titrant was required after the addition of the indicator, repeat the titration, adding the necessary volume of titrant before adding the indicator. Bring the contents of the second flask to boiling, and similarly titrate with the *Test solution*. Calculate the dextrose equivalent, on the anhydrous basis, taken by the formula:

$$[100 / (1 - 0.01A)] (500)(C_S / W)(V_S / V_U)$$

in which A is the percentage *Water* of the Liquid Glucose taken; 500 is the volume, in mL, of the *Test solution; W* is the weight, in mg, of Liquid Glucose taken to prepare the *Test solution;* C_S is the concentration, in mg per mL, of USP Dextrose RS in the *Standard solution;* and V_U and V_S are the titrated volumes, in mL, of the *Test solution* and the *Standard solution,* respectively. The dextrose equivalent is not less than 90% and not more than 110% of the labeled value.

L-Glutamic Acid, Hydrochloride



$C_5H_9NO_4 \cdot HCl$ 183.59
L-2-Aminoglutaric acid, hydrochloride;
2-Aminopentanedioic acid, hydrochloride [138-15-8].

DEFINITION
L-Glutamic Acid, Hydrochloride, contains NLT 98.5% and NMT 101.5% of $C_5H_9NO_4 \cdot HCl$, calculated on the dried basis.

IDENTIFICATION
- **INFRARED ABSORPTION** ⟨**197K**⟩

ASSAY
- **PROCEDURE**

Sample: 100 mg of L-Glutamic Acid, Hydrochloride, previously dried

Analysis: Dissolve the *Sample* in 0.5 mL of water, add 15.0 mL of 0.1 N perchloric acid VS, and heat on a water bath for 30 min. After cooling, add 45 mL of glacial acetic acid, and titrate the excess perchloric acid with 0.1 N sodium acetate, determining the endpoint potentiometrically. Perform a blank determination (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 18.36 mg of $C_5H_9NO_4 \cdot HCl$.

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES
Inorganic Impurities
- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.25%
- **HEAVY METALS,** *Method I* ⟨**231**⟩**:** NMT 5 ppm

SPECIFIC TESTS
- **OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩**:** +25.2° to +25.8°, determined at 20°

Sample solution: 100 mg/mL, in 2 N hydrochloric acid
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 80° for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Store in well-closed, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP L-Glutamic Acid, Hydrochloride RS

Glutaral Disinfectant Solution

» Glutaral Disinfectant Solution contains not less than 100.0 percent and not more than 110.0 percent, by weight, of the labeled amount of $C_5H_8O_2$.

Packaging and storage—Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

Identification—

2, 4-Dinitrophenylhydrazine reagent—Prepare as directed in the *Identification* test under *Glutaral Concentrate*.

Procedure—Add 5 mL of Disinfectant Solution to 20 mL of *2, 4-Dinitrophenylhydrazine reagent*, mix by swirling, allow to stand for 5 minutes, and proceed as directed for *Procedure* in the *Identification* test under *Glutaral Concentrate*, beginning with "Collect the precipitate on a filter."

pH ⟨791⟩: between 2.7 and 3.7.

Assay—

Buffer—Dissolve 2.59 g of monobasic potassium phosphate and 6.77 g of anhydrous dibasic sodium phosphate in 500 mL of water in a 1000-mL volumetric flask, dilute with water to volume, and mix.

Hydroxylamine hydrochloride solution—Prepare a solution of hydroxylamine hydrochloride in *Buffer* containing 70 µg per mL.

Standard preparation—Transfer an accurately weighed quantity of Glutaral Concentrate, previously assayed as directed in the *Assay* under *Glutaral Concentrate*, equivalent to about 2.5 g of glutaraldehyde, to a 100-mL volumetric flask, dilute with water to volume, and mix. Dilute an accurately measured volume of this solution quantitatively and stepwise with water to obtain a solution having a known concentration of about 50 µg per mL.

Standard preparation blank solution—Transfer 10.0 mL of *Standard preparation* and 10.0 mL of *Buffer* to a 50-mL volumetric flask, dilute with water to volume, and mix.

Assay preparation—Transfer an accurately weighed portion of Disinfectant Solution, equivalent to about 100 mg of glutaraldehyde, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with water to volume, and mix.

Assay preparation blank solution—Transfer 10.0 mL of *Assay preparation* and 10.0 mL of *Buffer* to a 50-mL volumetric flask, dilute with water to volume, and mix.

Reagent blank solution—Transfer 10.0 mL of *Buffer* and 10.0 mL of *Hydroxylamine hydrochloride solution* to a 50-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Transfer 10.0 mL each of the *Standard preparation* and the *Assay preparation* to separate 50-mL volumetric flasks, to each add 10.0 mL of *Hydroxylamine hydrochloride solution*, dilute with water to volume, mix, and allow each to stand for 25 minutes. Concomitantly determine the absorbances of both solutions and of the respective blank solutions at the wavelength of maximum absorption at about 238 nm, with a suitable spectrophotometer, using the *Reagent blank solution* to