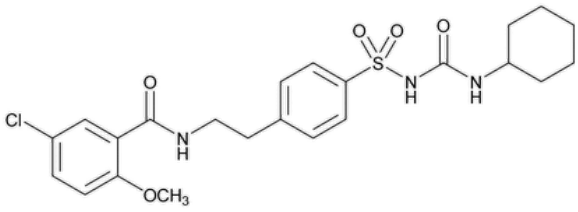
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jul-2021
Document Type: USP Monographs
DocId: GUID-5F4CD997-277A-4F7D-9D97-F4E08F68AB57_5_en-US
DOI: https://doi.org/10.31003/USPNF_M35380_05_01
DOI Ref: 069gc

Glyburide

Change to read:



$C_{23}H_{28}ClN_3O_5S$ 494.00

Benzamide, 5-chloro-*N*-[2-[4-[[[(cyclohexylamino)carbon yl]amino]-sulfonyl]phenyl]ethyl]-2-methoxy-.

1-[[*p*-[2-(5-Chloro-*o*-anisamido)ethyl]phenyl]sulfonyl]-3-▲cyclohexylurea▲ (ERR 1-Jul-2021) CAS RN®: 10238-21-8; UNII: SX6K58TVWC.

» Glyburide contains not less than 98.0 percent and not more than 102.0 percent of $C_{23}H_{28}ClN_3O_5S$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Glyburide RS

Identification—

A: *Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*.

B: The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for glyburide, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.

Loss on drying—Dry it at 105° for 6 hours: it loses not more than 1.0% of its weight.

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

Chromatographic purity—

Mobile phase—Prepare as directed in the *Assay*.

Test solution—To about 10 mg of Glyburide, accurately weighed, add 10 mL of acetonitrile, and shake to dissolve. Add 4 mL of water, and mix.

Chromatographic system—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L7. The flow rate is about 2 mL per minute. Chromatograph the *Test solution*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 3500 theoretical plates.

Procedure—Inject a volume (about 20 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the areas for the major peaks. Calculate the percentage of each impurity in the portion of Glyburide taken by the formula:

$$100(r_i/r_s)$$

in which r_i is the peak response for each impurity; and r_s is the sum of the responses of all of the peaks: not more than 1.5% of any impurity, which elutes before glyburide, is found; not more than 0.5% of any other individual impurity is found; and not more than 2.0% of total impurities is found.

Assay—

Mobile phase—Dissolve 2.6 g of monobasic ammonium phosphate in 450 mL of water. Add 550 mL of acetonitrile, filter, and degas. Adjust, if necessary, with phosphoric acid or sodium hydroxide to a pH of 5.25 ± 0.30. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Dissolve progesterone in acetonitrile to obtain a solution containing about 0.2 mg per mL.

Standard preparation—To about 10 mg of USP Glyburide RS, accurately weighed, add 20.0 mL of *Internal standard solution*, and shake vigorously to dissolve. Add 4.0 mL of water, and mix.

Assay preparation—To about 10 mg of Glyburide, accurately weighed, add 20.0 mL of *Internal standard solution*, and shake vigorously to dissolve. Add 4.0 mL of water, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L7. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.4 for glyburide and 1.0 for progesterone; the resolution, *R,* between glyburide and progesterone is not less than 5.0; and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the heights for the major peaks. Calculate the quantity, in mg, of $C_{23}H_{28}ClN_3O_5S$ in the portion of Glyburide taken by the formula:

$$W_S(R_U/R_S)$$

in which W_S is the weight, in mg, of USP Glyburide RS taken to prepare the *Standard preparation;* and R_U and R_S are the peak height ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GLYBURIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 27(4)

Current DocID: GUID-5F4CD997-277A-4F7D-9D97-F4E08F68AB57_5_en-US
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