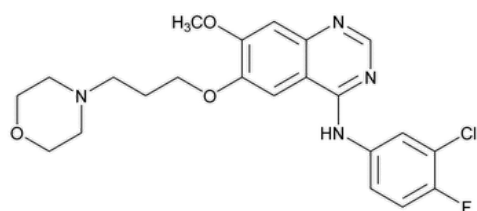


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Add the following:

▲Gefitinib



$C_{22}H_{24}ClFN_4O_3$ 446.91

4-Quinazolinamine, N-(3-chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholinyl)propoxy]-;

N-(3-Chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholinyl)propoxy]-4-quinazolinamine;

(3-Chloro-4-fluorophenyl)[7-methoxy-6-[3-(morpholin-4-yl)propoxy]quinazolin-4-yl]amine CAS RN®: 184475-35-2; UNII: S65743JHBS.

DEFINITION

Gefitinib contains NLT 98.0% and NMT 102.0% of gefitinib ($C_{22}H_{24}ClFN_4O_3$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197D
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: 9.7 g/L of [ammonium acetate](#) in [water](#)

Solution B: 0.2% [trifluoroacetic acid](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (38:62)

Diluent: [Acetonitrile](#) and *Solution B* (40:60)

System suitability solution: 0.35 mg/mL of [USP Gefitinib RS](#) and 0.25 mg/mL of [USP Dichloroaniline RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution: 0.35 mg/mL of [USP Gefitinib RS](#) in *Diluent*. Sonicate to dissolve.

Sample solution: 0.35 mg/mL of Gefitinib in *Diluent*. Sonicate to dissolve.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 247 nm

Column: 3.0-mm × 10-cm; 3-μm packing [L1](#)

Column temperature: 60°

Flow rate: 0.9 mL/min

Injection volume: 5 μL

Run time: NLT 5 times the retention time of gefitinib

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 5.0 between dichloroaniline and gefitinib, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of gefitinib ($C_{22}H_{24}ClFN_4O_3$) in the portion of Gefitinib taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of gefitinib from the *Sample solution*

r_S = peak response of gefitinib from the *Standard solution*

C_S = concentration of [USP Gefitinib RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Gefitinib in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution A: 0.7 µg/mL of [USP Gefitinib RS](#) in *Diluent*

Standard solution B: 0.7 µg/mL each of [USP Gefitinib Related Compound A RS](#) and [USP Gefitinib Related Compound B RS](#) in *Diluent*

Sensitivity solution: 0.18 µg/mL of [USP Gefitinib RS](#) from *Standard solution A* in *Diluent*

System suitability

Samples: *System suitability solution, Standard solution A, Standard solution B, and Sensitivity solution*

[NOTE—The relative retention times in [Table 1](#) are provided as information that could aid in peak assignment.]

Table 1

Name	Relative Retention Time
Gefitinib related compound A	0.13
Dichloroaniline	0.7
Gefitinib	1.0
Gefitinib related compound B	1.26

Suitability requirements

Resolution: NLT 5.0 between dichloroaniline and gefitinib, *System suitability solution*

Relative standard deviation: NMT 5.0% for gefitinib, *Standard solution A*; NMT 5.0% for gefitinib related compound A and gefitinib related compound B, *Standard solution B*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution A, Standard solution B, and Sample solution*

Calculate the percentage of gefitinib related compound A and gefitinib related compound B in the portion of Gefitinib taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of gefitinib related compound A or gefitinib related compound B from the *Sample solution*

r_S = peak response of gefitinib related compound A or gefitinib related compound B from *Standard solution B*

C_S = concentration of [USP Gefitinib Related Compound A RS](#) or [USP Gefitinib Related Compound B RS](#) in *Standard solution B* (mg/mL)

C_U = concentration of Gefitinib in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity in the portion of Gefitinib taken: