

Title

DEFINITION

[Drug] Injection is a sterile solution of [drug substance name] in [solvent, e.g., Water for Injection] and contains NLT [_._]% and NMT [___._]% of CmHn_p

IDENTIFICATION

- **A. INFRARED ABSORPTION <197K>** [or <197M> or <197F>]

or

INFRARED ABSORPTION <197S>

Analytical wavelength: {if more than a single wavelength, use **Wavelength range** as the subsection head}

Cell: {if other than 0.1-mm cell is used}

Standard solution: [] (g/mL in [solvent])

Sample solution: [] (g/mL in [solvent])

- **B. Ultraviolet Absorption <197U>**

Analytical wavelength: {if more than a single wavelength, use **Wavelength range** as the subsection head}

Sample solution: [] (g/mL in [solvent {if water, no need to state; in General Notices}])

Acceptance criteria: Absorptivities, calculated on the [dried][anhydrous] basis, do not differ by more than _.0%.

Ratio: Ax/Ay, []-[]

- **C. Thin-Layer Chromatographic Identification Test <201>**

Adsorbent:

Standard solution: [] (g/mL in [solvent])

Sample solution: [] (g/mL in [solvent])

Application volume: [] (L)

Developing solvent system:

Spray reagent:

Analysis

- **D.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the **Assay**.
- **E.** A solution of [] μg/mL (or mg/mL) meets the requirements of the [flame] test[s] for [sodium, calcium, etc.] [<191>].

ASSAY {Chromatographic Assay}

- **PROCEDURE**

Mobile phase: Solvent 1, solvent 2, and solvent 3 ([]:[]:[]). {Solvents should be in the order of Organic:Aqueous. If more than one organic constituent, then list them in the order of prevalence.}

System suitability solution: [] mg/mL of [drug {usually a USP Reference Standard}] and [] mg/mL of related compound [] in [if water, no need to state; per General Notices]

Quantitative limit solution: [] mg/mL of USP [] RS in []

or

Quantitative limit solution: [] mL/mL of *System suitability solution* in []

Standard solution: [] mg/mL of USP [] RS in []

Sample solution: equivalent to [] mg/mL of [], from [Injection] in []

Chromatographic system

(See *Chromatography* <621>, *System Suitability*.)

Mode: LC or GC

Detector: [detector type] [] nm

Column: []-mm × []-cm; packing L[]

Temperature: []° **or** [See the temperature program table.](#)

Flow rate: [] mL/min

Injection size: [] μL

Injection type: {for GC}

System suitability

Sample: *System suitability solution* and *Standard solution* [sometimes *Internal standard solution*]

Suitability requirements

Resolution: NLT [] between ___ and ___

Column efficiency: NLT [] theoretical plates

Tailing factor: NMT []

Relative standard deviation: NMT ___% for [{number of} replicate injections]

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of [drug] in the portion of [] taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

F = any monograph correction factor when a value is provided, such as a unit conversion

Acceptance criteria: [___.]%-[___.]% on the [] basis

ASSAY {Titration Assay}

• PROCEDURE

Sample solution:

Titrimetric system

(See *Titrimetry* <541>.)

Mode: Direct titration or residual titration

Titrant:

Back-titrant:

Endpoint detection: Potentiometric, colorimetric, or coulometric

Analysis

Samples:

Each mL of [] N titrant is equivalent to [___.] mg of [] {insert Drug chemical formula}.

Or

Calculate the percentage of the [drug substance] in the portion taken {equations for titrations are not needed if "Each mL [] N titrant is equivalent to [___.] mg of ..." is written into the text}:

$$\text{Result} = [(V - B) \times N \times F \times 100] / [TN \times W \times (100 - A)/100]$$

V = sample titrant volume (mL)

B = blank titrant volume (mL)

N = titrant normality ({units})

F = equivalence factor (mg sample/mL of TN)

TN = theoretical normality

W = sample weight (mg)

A = assay correction for LOD

Acceptance Criteria: [___.]%-[___.]% on the [] basis

ASSAY {Microbiological Assay}

• PROCEDURE

Sample solution: {Describe as required. Use template for the HPLC Assay above, but specify the appropriate buffer as directed in *Antibiotics—Microbial Assays* <81>.}

Analysis: Proceed as directed for [] under *Antibiotics—Microbial Assays* <81>. Use a volume of *Assay Preparation* diluted quantitatively to yield a *Sample solution* having a concentration assumed to be equal to the median dose level of the Standard.

OTHER COMPONENTS (may not be in all monographs; included in those monographs that have *Content of... tests*)

- **CONTENT OF []**: [NLT ____%] [between __% and __%]
- **CONTENT OF CHLORIDE**: [NLT ____%] [__%– __%]
- **NITROGEN DETERMINATION, Method [I] [II] <461>**: [Proceed as directed, starting with ____ [m]g of [drug]: [NLT ____%] [Between __% and __%,] is found.]

PERFORMANCE TESTS

- **DELIVERABLE VOLUME <698>**: For [Injection] [For Injection] packaged in [package type] containers, meets the requirements

IMPURITIES

Inorganic Impurities

- **RESIDUE ON IGNITION <281>**: NMT []%
- **CHLORIDE AND SULFATE, Chloride <221>**: A []-g portion shows no more chloride than corresponds to [] mL of 0.020 N hydrochloric acid ([]%).
- **CHLORIDE AND SULFATE, Sulfate <221>**: A []-g portion shows no more sulfate than corresponds to [] mL of 0.020 N sulfuric acid ([]%).
- **SELENIUM <291>**: [_.__%].[_.__%, a __-mg specimen mixed with __ mg of magnesium oxide being used.]
- **ARSENIC, Method [] <211>**: [] ppm
- **LEAD <251>**: [ppm]
- **HEAVY METALS, Method [I] [II] <231>**: [ppm]

Organic Impurities {include only degradation products and product specific impurities}

• **PROCEDURE 1**

Mobile phase: Solvent 1, solvent 2, and solvent 3 ([]:[]:[])

System suitability solution: [] mg/mL of [drug {usually a USP Reference Standard}] and [] mg/mL of related compound [] in []

Quantitative limit solution: [] mg/mL of USP [] RS in []

or

Quantitative limit solution: [] mL/mL of *System suitability solution* in []

Standard solution: [] mg/mL of USP [] RS in []

Sample solution: equivalent to [] mg/mL of [], from [Injection] in []

Chromatographic system

(See *Chromatography <621>*, *System Suitability*.)

Mode: LC or GC

Detector: [detector type] [] nm

Column: []-mm × []-cm; packing L[]

Temperature: []° **or** [See the temperature program table](#) [for GC].

Flow rate: [] mL/min

Injection size: [] μL

Injection type: [for GC]

System suitability

Sample: *System suitability solution* **or** *Standard solution*

Suitability requirements

Resolution: NLT [] between ____ and ____

Column efficiency: NLT [] theoretical plates

Tailing factor: NMT []

Relative standard deviation: NMT __. __%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of [limited substance] in the portion of [Drug] taken:

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

r_U = peak response of [limited substance] from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria

Individual impurities: See *Impurity Table 1*. {Create an impurity table if there are more than three named impurities. A table will be numbered "1", even if only 1 impurity table is in the document.}

Total impurities: NMT []%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
[Drug] related compound ^a	—	—	[.]
{All identified impurities should be listed. If possible, provide a short name for an impurity when no USP Reference standard is available, for example: [Drug] Z-isomer, ^b [Drug] Butyl analog, ^c [Drug] 3-ketone. ^d Give full chemical names as footnotes.}	—	{two decimal places if less than 1.0; one decimal place if more than 1.0}	[.]
[Drug]	1.0	1.0	—
Any other individual, unidentified impurity	—	1.0	[.]

^a Chemical name.

^b Chemical name.

^c Chemical name.

^d Chemical name.

or

Solution A: Solvent 1, solvent 2, and solvent 3 ([]:[]:[]). Adjust with [] to a pH of [].

Solution B: Solvent 1, solvent 2, and solvent 3 ([]:[]:[]). Adjust with [] to a pH of [].

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	A1	B1
T1	A1	B1
T2	A2	B2

Example of GC Temperature program table

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	6
40	30	80	14
80	30	200	3

Chromatographic system

(See *Chromatography <621>*, *System Suitability*.)

Mode: LC or GC

Detector: [detector type] [] nm

Column: []-mm × []-cm; packing L[]

Temperature: []° **or** [See the temperature program table](#) {for GC}.

Flow rate: [] mL/min

Injection size: [] (L

Injection type: {for GC}

System suitability

Sample: System suitability solution or Standard solution

Suitability requirements

Resolution: NLT [] between ___ and ___

Column efficiency: NLT [] theoretical plates

Tailing factor: NMT []

Relative standard deviation: [], NMT []%

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of [limited substance] in the portion of [Drug] taken:

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

r_U = peak response of [limited substance] from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria

Individual impurities: See *Impurity Table 1*. {The table will be numbered with "1", even if only one table.}

Total impurities: NMT []%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT %
[Drug] related compound ___ ^a	—	—	[.]
{All identified impurities should be listed. If possible, provide a short name for an impurity when no USP Reference standard is available, for example: [Drug] Z-isomer, ^b [Drug] Butyl analog, ^c [Drug] 3-ketone. ^d Give full chemical names as footnotes.}	—	{two decimal places if less than 1.0; one decimal place if more than 1.0}	[.]
[Drug]	1.0	1.0	—
Any other individual, unidentified impurity	—	1.0	[.]

^a Chemical name.

^b Chemical name.

^c Chemical name.

^d Chemical name.

IMPURITIES {TLC Impurities procedure}

Organic Impurities

• [Test]

Standard solution:

Sample solution:

Adsorbent: {e.g., 0.25-mm layer of chromatographic silica gel mixture. We have to specify it here but not in the ID test. Chapter <201> mentions it, but <621> does not.}

Application volume: [] μ L

Developing solvent system: Solvent 1, Solvent 2, and Solvent 3 ([]:[]:[])

Spray reagent:

Analysis: Proceed as directed for *Chromatography* <621>, *Thin-Layer Chromatography*.

[Spray the plate with _____. Examine the plate under [short-wavelength UV light] [and then under] [long-wavelength UV light].

{When listing several spots on a TLC plate, cite in the order of increasing R_F value.}

{When stating a quantitative result, indicate:}

Any spot obtained from [], except for the principal spot, is not more intense than the spot of the *Standard solution* []: NMT 0._% of any individual impurity is found.

SPECIFIC TESTS

• **BACTERIAL ENDOTOXINS TEST <85>:** Contains NMT [] USP Endotoxin Unit/mg of []

• **STERILITY <71>:** Meets the requirements when tested as directed for [] under *Test for Sterility of the Product to Be Examined* {If the original "Injection" monograph states test type (membrane filtration (default) or direct inoculation), then the test type is included.}

• **ANTIMICROBIAL PRESERVATIVE <341>:** {If present in original monographs.} Proceed as directed for [name of the antimicrobial agent] under *Antimicrobial Agent Content* -<341>: NMT [_._] % is found.

- **PARTICULATE MATTER IN INJECTIONS<788>**: Meets the requirements for small-volume injections
- **INJECTIONS <1>**: Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in [well-closed] [tight] [light-resistant] containers [, and store at ____].
- **LABELING**: There should be no changes from the classic monograph. {Example: Label the article to indicate whether it is the anhydrous form or the hemihydrate form, and label it to indicate with which impurity procedures it complies.}
- **USP REFERENCE STANDARDS <11>** {ALPHABETICAL ORDER}
USP [Drug] RS
USP [Drug] Related Compound [___] RS