

## Title

(Chemical structure, check the USP Dictionary)

[Chemical formula]      [Molecular weight]

Chemical names      [CAS registry no.].

## DEFINITION

[Drug] contains NLT [\_\_.\_] % and NMT [\_\_.\_] % of CmHn\_p, calculated on the [dried] [anhydrous] [ignited] basis.

## 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:** [ ] mg/mL of [ ] 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)  
 $C_U$  = 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.]

## 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

#### 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:** [ ] mg/mL of [ ] 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 ___ <sup>a</sup>	—	—	[.]
{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, <sup>b</sup> [Drug] Butyl analog, <sup>c</sup> [Drug] 3-ketone. <sup>d</sup> 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	[.]

<sup>a</sup> Chemical name.

<sup>b</sup> Chemical name.

<sup>c</sup> Chemical name.

<sup>d</sup> 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 ____ <sup>a</sup>	—	—	[.]
{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, <sup>b</sup> [Drug] Butyl analog, <sup>c</sup> [Drug] 3-ketone. <sup>d</sup> 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	[.]

<sup>a</sup> Chemical name.

<sup>b</sup> Chemical name.

<sup>c</sup> Chemical name.

<sup>d</sup> 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:** [ ]  $\mu$ 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

- MICROBIAL ENUMERATION TESTS <61>

and/or

- TESTS FOR SPECIFIED MICROORGANISMS <62>: [Drug] meets the requirements of the tests for the absence of [*Salmonella* species] [*Escherichia coli*] [*Staphylococcus aureus*] [*Pseudomonas aeruginosa*].

or

The total aerobic microbial count does not exceed [ ] cfu/g (or mL), and the total combined molds and yeasts count does not exceed [ ] cfu/g (or mL). [The total aerobic microbial count is less than [ ] cfu/g (or mL).]

- **SPECIFIC GRAVITY <841>**: [ ]-[ ] [at °]
- **MELTING RANGE OR TEMPERATURE**, [Class \_\_\_\_] **<741>**: [ ]°-[ ]°
- **SPECIFIC ROTATION <781S>**: [ + ]-[ ] [ ]° to [ + ]-[ ] [ ]°  
**Sample solution**: [ ] mg/mL in [ ]
- **OPTICAL ROTATION, Angular Rotation <781A>**: [ + ]-[ ] [ ]° to [ + ]-[ ] [ ]°  
**Sample solution**: [ ] mg/mL in [ ]
- **CRYSTALLINITY <695>**: Meets the requirements
- **REFRACTIVE INDEX <831>**: [ ]-[ ] [at °]
- **ACIDITY**: [Dissolve \_\_\_\_ mg in \_\_\_\_ mL of \_\_\_\_]. [To \_\_\_\_ mL of \_\_\_\_], add [ ] of [ ] TS, and titrate with [ ] [to a \_\_\_\_ color]: NMT [ ] mL of [ ] N sodium hydroxide is required [to produce a \_\_\_\_ color] [for neutralization] [to produce a color change].
- **PH <791>**: [ ]-[ ] [in a solution (\_\_\_\_ in \_\_\_\_)]
- **LOSS ON DRYING <731>**: Dry a sample [in a vacuum] [at a pressure not exceeding \_\_\_\_ mm of mercury] at [ ]° for [ ] h: it loses NMT \_\_\_\_% of its weight.
- **LOSS ON IGNITION <733>**: When ignited at [ ] ( [for \_ h] [to constant weight] ), it loses [NMT \_\_\_\_%][ \_\_\_\_% – \_\_\_\_%] of its weight.
- **WATER DETERMINATION, Method [I]/[II] <921>**: [ ]%-[ ]%
- **OTHER REQUIREMENTS**: It meets the requirements of the test for [ ] under [ ]. [Where the following language is used, please see the example of Indocyanine Green: Where the label states that the drug substance is sterile, it meets the requirements for *Sterility Tests <71>* and *Labeling under Injections <1>*. Where the label states that [Drug] must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements under *Bacterial Endotoxins Test <85>*.]

#### 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