

## Title

### DEFINITION

[Drug Product] 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 \_\_\_\_%.

**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 [Tablets] 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**

- **DISINTEGRATION <701>**  
**Medium:** [solvent]; [900] mL  
**Time:** [ ] min
- **DISSOLUTION <711>**  
[**Test 1:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.]  
**Medium:** [solvent] [simulated gastric fluid (without enzyme)]; [900] mL  
**Apparatus [1][2]:** [ ] [50] [100] rpm  
**Time:** [ ] min  
**Detection:** UV [ ] nm  
**Sample solution:** Sample per *Dissolution <711>*. Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.  
**Standard solution:** USP [ ] RS in *Medium*  
**Analysis:** Determine the amounts of [name] (C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub>), [name] (C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub>), and [name] (C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub>) dissolved, by using the procedure set forth in the Assay [, except to use \_\_,] [making any necessary volumetric adjustments]  
**Tolerances:** NLT [ ]% (Q) of the labeled amount of C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub> is dissolved.
- **DISSOLUTION, Method [A][B] <711>**  
**Apparatus [1][2]:** [50] rpm  
**Times:** 60 min for *Acid Stage*; 60 min for *Buffer stage*  
**Analysis:** Transfer 1 [Tablet, Capsule] to the apparatus. Proceed as directed for *Acid stage* [ {description is included if different from the chapter procedure}]. Continue as directed for *Buffer stage* [ {description is included if different from the chapter procedure }]. Determine the amount of C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub> dissolved after [ ] min by [assaying] a filtered portion of the solution under test [as directed under *Antibiotics—Microbial Assays <81>*].  
**Tolerances:** NLT [ ]% (Q) of the labeled amount of C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub> is dissolved.  
**or**
- **DISSOLUTION, Method B <711>**  
**Acid stage**  
**Medium:** [solvent]; [900] mL  
**Apparatus [1][2]:** [{special description of paddle construction, if given;}] [50] rpm  
{Time is not specified as a subhead.}  
**Analysis:** {Description is included if different from that in the chapter.} At the end of [ ] h, remove each Tablet, or the major portion thereof if the Tablet is not intact, from the individual vessels, and subject them to the test in the *Buffer stage*. Determine the amount of [chemical formula] dissolved by using... {Directions similar to those in the test for *Dissolution, Method A*.}  
**Buffer stage**  
**pH [\_.] [phosphate] buffer:** Dissolve {give directions for its preparation}.  
**Medium:** pH [\_.] [phosphate] buffer; [900] mL  
**Apparatus [1][2]:** [50] rpm  
**Analysis:** {Description is included if different from that in the chapter.} At the end of [ ] min, determine the amount of C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub> dissolved by using... {Directions should be similar to those in the *Dissolution, Method A*.}  
**Tolerances:** NLT [ ]% (Q) of the labeled amount of C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub> is dissolved.
- **UNIFORMITY OF DOSAGE UNITS <905>:** Meet the requirements for [*Weight Variation*] [*Content Uniformity*]  
**OR**
- **UNIFORMITY OF DOSAGE UNITS <905>:** Meet the requirements  
**Procedure for content uniformity:** {Directions should be similar to those in the Assay.}

**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 [ ] [ ] <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 [Tablets] 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	—	{two decimal places if less than 1.0; one decimal place if more than 1.0}	[.]

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
full chemical names as footnotes.)			
[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:** [ ] μL

**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<sub>F</sub> 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