

**USP Guideline for  
Submitting Requests for Revisions for *USP-NF***

**EXCIPIENTS MONOGRAPH TEMPLATE**

The following is a template to be used for drafting a monograph for an excipient. This is intended to serve as a guideline for writing monographs in *USP* style. It is incumbent on the writer to be familiar with *USP General Notices* and with the general tests chapters. Note that not all tests would appear in any one monograph and that not every variation of individual tests is shown. Only those sections used most often are included. Tests are listed in the order in which they should appear in a monograph.

NOTES—

- For assistance with wording for test texts in procedures that are used infrequently a search of the electronic/CD version of *USP-NF* is useful.
- All [ ] within the monograph template indicates number that should be used and are not all-inclusive. No space between [ ][ ] means that the two are exclusive, and only one is possible. All text in { } within the monograph template presents comments or instructions that are not to be included as part of the monograph.
- Note that a distinction should be made between tests for “Limit of \_\_\_\_\_” and “Content of \_\_\_\_\_.”

**Add the following:**

**Title**

(Chemical structure to come)

[Chemical formula] [Mol. wt.]

Chemical names [CAS registry no.].

>>[\_\_\_\_\_] contains not less than [\_. .] percent and not more than [\_. .] percent of  $C_mH_nO_p$  calculated on the [dried][anhydrous][ignited]basis {provided a test for *Loss on drying*, or *Water* or *Loss on ignition*, respectively, is given in the monograph.}[as is]. [It contains a suitable [antioxidant][stabilizer].]

**Packaging and storage**—Preserve in [well-closed][tight] [light-resistant] containers. [No storage requirements specified][Store at room temperature].

**Labeling**—Label it to indicate [ ]

{Refer to *General Notices* section under added substances. Where appropriate, label it to indicate that it is of animal or vegetable origin.}

**USP Reference standards** <11>—[USP [Article] RS.] [USP [Article] Related Compound [ \_ ] RS.]

**Identification**— { Need at least one ID test. If more than one ID test is incorporated, tests have to be alphabetized, e.g., **A**, **B**, etc., and ordered as follows: IR, UV, TLC, retention times comparison, and other tests. }

**A:** *Infrared Absorption* <197K> [or <197M> or <197F>].

**FOR <197S>:**

**A:** *Infrared Absorption* <197S>—

*Spectral range:* {IF DIFFERENT FROM 2.6 TO 15  $\mu\text{M}$  OR 3800 TO 650  $\text{CM}^{-1}$ }

*Cell:* {OTHER THAN 0.1-MM CELL}

*Solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation if necessary}

{When *Standard solution* is prepared differently than the *Test solution*.}

**A:** *Infrared Absorption* <197S>—

*Spectral range:* {IF DIFFERENT FROM 2.6 TO 15  $\mu\text{M}$  OR 3800 TO 650  $\text{CM}^{-1}$ }

*Cell:* {other than 0.1-mm cell}

*Test solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation if necessary}

*Standard solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation if necessary}

**B:** *Ultraviolet Absorption* <197U>—

*Spectral range:* {if a range other than 200 to 400 nm is specified}

*Solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation if necessary}

Absorptivities, calculated on the [dried][anhydrous][as is] basis, do not differ by more than .0%.

*Ratio:* {e.g.,  $A_{343}/A_{329}$ , between 1.00 and 1.15.}

**C:** *Thin-Layer Chromatographic Identification Test* <201>—

*Adsorbent:* {if different from 0.25-mm layer of chromatographic silica gel mixture}

*Test solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation if necessary}

*Standard solution:* About [ ]  $\mu\text{g}$  per mL in [solvent]

{Describe procedure for preparation, if necessary, only if its preparation differs from that of the *Test solution* or if there is more than one *Standard solution*}

*Application volume:* {mention only if it is different from 10  $\mu\text{L}$ }

*Developing solvent system:* {if other than a mixture of chloroform, methanol, and water (180:15:1)}

*Procedure,* {mention if there are differences from the chapter. See *Style Guide*.}

{If TLC is the only ID test, the heading for the section is as follows:

**D:** The retention time of the major peak in the chromatogram of the [Assay preparation] corresponds to that in the chromatogram of the [Standard preparation], as obtained in the [Assay].

**E:** A solution (1 in [ ]) meets the requirements of the [flame] test[s] for [sodium, calcium, etc.] [<191>].

**Specific gravity** <841>: between [ ] and [ ] [at  $^{\circ}$ ]. {No need to specify 25 $^{\circ}$ ; stated in the chapter.}

**Melting range** [ , *Class* \_\_\_ <741>]: between [ ] $^{\circ}$  and [ ] $^{\circ}$ .

OR

**Melting temperature** [ , Class \_\_\_\_ ]<741>: not lower than [ ]°.

**Viscosity** <911>: {Describe preparation of the sample, if necessary, and the apparatus employed when the apparatus is not among the ones mentioned under <911>} [its apparent viscosity is] between [ ] and [ ] [centipoises][centistokes], determined at [ ]° with a [suitable] [ ] viscosimeter.

{There is no need to say “its kinematic viscosity”; this is obvious if the viscosity is expressed in stokes or centistokes. Do not repeat the viscosity range if it is mentioned in the Definition.}

**Specific rotation** <781S>: between [ + ][ - ] [ ]° and [ + ][ - ] [ ]°.

*Test solution:* [ ] mg per mL, in [ ].

{As specified under <781>, there is no need to mention “on the anhydrous basis” or “on the dried basis” where *Water* or *Loss on drying*, respectively, are specified in the individual monograph.}

**Angular rotation** <781A>: between [ + ][ - ] [ ]° and [ + ][ - ] [ ]°.

*Test solution:* [ ] mg per mL, in [ ].

**Crystallinity** <695>: meets the requirements.

OR

{Where a phrase “where labeled as” or “where packaged as” is inserted, the phrase precedes “it meets the requirements.”}

**Crystallinity** <695>—Where labeled as being crystalline, it meets the requirements.}

**Refractive index** <831>: between [ . \_\_\_\_ ] and [ . \_\_\_\_ ] [at °]. {There is no need to specify temperature if it is 25°.}

**Microbial limits** <61>—The total aerobic microbial count does not exceed 1000 cfu per g or ml, and the total combined molds and yeasts count does not exceed 100 cfu per g or ml. Where required, meets the absence of specific microorganisms.

**Acidity**—[Dissolve \_\_ mg in \_\_ mL of \_\_][To \_\_ mL of \_\_], add [ ] of [ ] TS, and titrate with [ ] [to a \_\_ color][determining the endpoint potentiometrically]: not more than [ mL] of [ . \_\_\_\_ ] N sodium hydroxide is required [to produce a \_\_ color][for neutralization][to produce a color change.]

**pH** <791>: between [ ] and [ ], [in a solution in [ ].]

**Loss on drying** <731>—Dry it [in vacuum] [at a pressure not exceeding \_\_ mm of mercury] at [ ]° for [ ] hours: it loses not more than \_\_% of its weight. {If in vacuum, then it is implied that pressure does not exceed 20 mm of mercury. If other pressure conditions are set, e.g., 5 mm of mercury, specify in the individual monograph.}

**Water, Method [I][II]** <921>: between [ . \_\_\_\_ ]% and [ . \_\_\_\_ ]%.

OR

**Water, Method [III] [Procedure for Articles of Botanical Origin]** <921>—Dry it at [ ]° [at a pressure not exceeding \_\_ mm of mercury] for [ ] hours: it loses between [ . \_\_\_\_ ]% and [ . \_\_\_\_ ]% of its weight. {Where hydrated and anhydrous forms exist: “the anhydrous form loses ..., and the hydrated form loses ... of its weight.”}

**Loss on ignition** <733>—When ignited at [ ]° [for \_ hours][to constant weight], it loses [not more than \_\_%][between \_\_% and \_\_%] of its weight. {If a muffle furnace is used, there is no need to specify that there is a ±25° tolerance for maintaining the specified temperature.}

**Residue on ignition** <281>: not more than [ ] %.

**Chloride** <221>—A [ ]-g portion shows no more chloride than corresponds to [ ] mL of 0.020 N hydrochloric acid ([ ] %).

OR

**Chloride** <221>— {describe procedure if it differs from the one specified in the chapter} any turbidity formed is not greater than that produced in a similarly treated control solution containing [ ] mL of 0.020 N hydrochloric acid ([ ] %).

**Sulfate** <221>—A [ ]-g portion shows no more sulfate than corresponds to [ ] mL of 0.020 N sulfuric acid ([ ] %).

OR

**Sulfate** <221>— {describe procedure if it differs from the one specified in the chapter} any turbidity formed is not greater than that produced in a similarly treated control solution containing [ ] mL of 0.020 N sulfuric acid ([ ] %).

**Selenium** <291>: [ ]%.[ ]%, a [ ]-mg specimen mixed with [ ] mg of magnesium oxide being used.]

**Arsenic, Method [ ]** <211>: [ ] µg per g.

**Lead** <251>: [ ]% [ ] µg per g. {There are several monographs that contain qualitative tests for Lead, which, for example, involve detection of turbidity. In such cases do not cite <251>.}

**Heavy metals, Method [I]/[II]** <231>: [ ]% [ ] µg per g [ppm].

### Impurity—

{Generally, a test for Limit of impurity is used to measure organic impurity. The impurity is called out in the subsection. Measurement of Inorganic Impurities generally refers to a certain chapter or a chapter section, and names the test according to the heading in the chapter. Hence, the test is not necessarily “Limit of ...” For example, Lead <251> is usually a limit test, but is named after the heading of the chapter <251>.}

### Template #1

#### GENERIC TEMPLATE FOR HPLC WITH STANDARD SOLUTION

*Mobile phase*—Prepare a filtered and degassed solution of [ ] and [ ] of concentrations [ ] and [ ] mg per mL (or g per L), respectively in [ ]. [Adjust with [ ] to a pH of [ ].] Make adjustments, if necessary (see *System Suitability* under *Chromatography* <621>).

*System suitability solution*—Dissolve USP [ ] RS and USP [ ] Related compound [ ] RS in [ ] to obtain a solution having known concentration of about [ ] mg per mL of [drug] and about [ ] mg {or µg} per mL of related compound [ ].

*Quantitative limit solution*—Dissolve USP [ ] RS in [ ] [USP [ ] Resolution mixture RS] to obtain a solution having a known concentration of about [ ] [ ] mg {or µg} per mL.

OR

*Quantitative limit solution*—Dilute *System suitability solution* to obtain a solution having known concentration of about [ ] mg per mL of [ ] and about [ ] mg {or µg} per mL of related compound [ ].

*Standard solution*—Prepare a solution of USP [ ] RS and USP [ ] Related compound [ ] RS in [ ], of known concentrations of about [ ] mg per mL of [ ] and about [ ] mg [or µg] per mL of [ ].

*Test solution*—Dissolve [ ] in [ ] to obtain a solution having a known concentration of about [ ] mg (or µg) per mL.

*Chromatographic system* (see *Chromatography* <621>)—The liquid chromatograph is equipped with a [ ]-nm detector and a [ ]-mm × [ ]-cm column that contains packing L[ ]. The column temperature is maintained at [ ]°. The flow rate is about [ ] mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure*: [the relative retention times are \_\_\_ for \_\_\_ and \_\_\_ for \_\_\_;] [the resolution, *R*, between \_\_\_ and \_\_\_ is not less than \_\_\_.] [the column efficiency is not less than \_\_\_ theoretical plates] [the tailing factor is not more than \_\_\_] [and] [the relative standard deviation for replicate injections is not more than \_\_\_%].

*Procedure*—Separately inject equal volumes (about [ ] µL) of the *System suitability solution*, the

*Quantitative limit solution*, the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of [ ] in the portion of [excipient] taken by the formula:

$$[ ] CV/W(r_U / r_S),$$

in which *C* is the concentration, in µg per mL, of USP [ ] Related compound [ ] RS in the *Standard solution*; *W* is the amount of [excipient], in mg, taken to prepare the *Test solution*, *V* is the volume, in mL, of the *Test solution*, and *r<sub>U</sub>* and *r<sub>S</sub>* are the peak responses of [limited substance] obtained from the *Test solution* and the *Standard solution*, respectively: not more than [ . ]% is found.

## Template #2

{This following template is used when the impurity limits were established using relative response factors. If there are no USP Reference standards for impurities, skip the System suitability solution. If USP Reference standards for impurities (or Resolution mixtures) are available, they are used in the System suitability solution for identification of the impurities, not for quantitation.}

*Mobile phase*—Prepare a filtered and degassed solution of [ ] and [ ] of concentrations [\_.] and [\_.] mg per mL (or g per L), respectively in [ ]. [Adjust with [ ] to a pH of [ .].] Make adjustments, if necessary (see *System Suitability* under *Chromatography* <621>).

*System suitability solution*—Dissolve USP [ ] RS and USP [ ] Related compound [ ] RS in [solvent], {or USP [ ] Resolution mixture RS} to obtain a solution having concentrations of about [ ] mg per mL of [ ] and about [ ] mg {or µg} per mL of related compound [ ].

*Standard solution*—Dissolve USP [ ] RS in [solvent] to obtain a solution having a known concentration of about [ ] mg (or µg) per mL.

*Test solution*—Dissolve [ ] in [solvent] to obtain a solution having a known concentration of about [ ] mg (or µg) per mL.

*Chromatographic system* (see *Chromatography* <621>)—The liquid chromatograph is equipped with a [ ]-nm detector and a [ ]-mm × [ ]-cm column that contains packing L[ ]. The column temperature is maintained at [ ]°. The flow rate is about [ ] mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure* {if several components:} [identify the components using the Table 1,] {if only 2 components:} the relative retention times are \_\_\_ for \_\_\_ and \_\_\_ for \_\_\_; [the resolution, *R*, between \_\_\_ and \_\_\_ is not less than \_\_\_.] [the column efficiency is not less than \_\_\_ theoretical plates]; [the tailing factor is not more than \_\_\_]; and [the relative standard deviation for replicate injections is not more than \_\_\_%].

*Procedure*—Separately inject equal volumes (about [ ] μL) of the *System suitability solution*, the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of impurities in the portion of [excipient] taken by the formula:

$$[(1/F)CV/W(r_U / r_S)],$$

in which *F* is the relative response factor for each impurity, listed in Table [#]; *C* is the concentration, in μg per mL, of USP [ ] RS in the *Standard solution*; *W* is the amount of [excipient], in mg, taken to prepare the *Test solution*, *V* is the volume, in mL, of the *Test solution*, and *r<sub>U</sub>* is the peak responses of [limited substance] obtained from the *Test solution* and, *r<sub>S</sub>* are the peak response of [excipient] obtained from the *Standard solution*: in addition to not exceeding limits in the Table #, more than [ . ]% of total impurities is found.

Table [#]

Impurity name	Relative retention time	Relative Response factor	Limit, %
[Excipient] Related Compound [chemical name]	...	...	[ . ]
{List all identified impurities by ascending relative retention time. If possible, provide a short name for an impurity when no USP Reference standard is available, for example: [excipient] PVP <sup>2</sup> ; give full chemical names as footnotes}	...	{two decimal places if less than 1.0; one decimal place if more than 1.0}	[ . ]
[Excipient]	1.0	1.0	n/a
...	...	...	[ . ]
Any other individual unidentified impurity	—	1.0	[ . ]

**Template #3**

{This template is used when the limits for identified impurities were established without using relative response factors. Chromatographic system in this template addresses the use of a System suitability solution that contains more than two components or is prepared from a Resolution mixture.}

*Mobile phase*—Prepare a filtered and degassed solution of [ ] and [ ] of concentrations [\_.] and [\_.] mg per mL (or g per L), respectively in [ ]. [Adjust with [ ] to a pH of [ ].] Make adjustments, if necessary (see *System Suitability* under *Chromatography* <621>).

*System suitability solution*—Dissolve USP [ ] RS and USP [ ] RS in [ ], {or USP [ ] Resolution mixture RS} to obtain a solution having a known concentrations of about [ ] mg per mL of [ ] and about [ ] mg {or µg} per mL of related compound [ ].

*Test solution*—Dissolve [ ] in [ ] to obtain a solution having a known concentration of about [ ] mg (or µg) per mL.

*Quantitative limit solution*—Dissolve USP [ ] RS in [ ] to obtain a solution having a known concentration of about [ ] [ ] mg {or µg} per mL.

OR

*Quantitative limit solution*—Dilute *System suitability solution* to obtain a solution having known concentration of about [ ] mg per mL of [ ] and about [ ] mg {or µg} per mL of related compound [ ].

*Chromatographic system* (see *Chromatography* <621>)—The liquid chromatograph is equipped with a [ ]-nm detector and a [ ]-mm × [ ]-cm column that contains [ ] packing L[ ]. The flow rate is about [ ] mL per minute. Chromatograph the *System suitability solution*, record the peak responses as directed for *Procedure*, and identify the components using the Table 1 : [the resolution, *R*, between \_\_\_ and \_\_\_ is not less than \_\_. \_\_;] [the column efficiency is not less than \_\_\_ theoretical plates;] [the tailing factor is not more than \_\_\_] [; and] [the relative standard deviation for replicate injections is not more than \_\_. \_\_%.]

*Procedure*—Separately inject equal volumes (about [ ] µL) of the *System suitability solution*, the *Quantitative limit solution*, and the *Test solution* into the chromatograph, record the chromatogram, identify the impurities listed in Table 1, and measure the peak responses. Calculate the percentage of [excipient] related compound \_\_ in the portion of [excipient] taken by the formula:

$$100(r_i / r_s),$$

in which  $r_i$  is the individual peak response of [excipient] related compound \_\_, and  $r_s$  is the sum of the responses of all the peaks: in addition to not exceeding limits in the Table [#], more than [ . ]% of total impurity is found.

Table [#]

Impurity name	Relative retention time	Limit, %
[excipient] Related Compound [chemical name]	...	[ . ]
{List all indentified impurities. If possible, provide a short name for an impurity when	...	[ . ]

no USP Reference standard is available, for example: [excipient] PVP; give full chemical names as footnotes}		
[excipient]	1.0	n/a
...	...	[.]
Any other individual unidentified impurity	—	[.]

**GENERIC HPLC TEMPLATE WITH GRADIENT ELUTION—MOBILE PHASE AND CHROMATOGRAPHIC SYSTEM**

*Solution A* - Prepare a filtered and degassed mixture of [ ] and [ ] (\_\_\_:\_\_\_). [Adjust with [ ] to a pH of [ ].]

*Solution B* - Prepare a filtered and degassed mixture of [ ] and [ ] (\_\_\_:\_\_\_). [Adjust with [ ] to a pH of [ ].]

*Mobile Phase* – Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under *Chromatography* <621>).

*Chromatographic system* (see *Chromatography* <621>)—The liquid chromatograph is equipped with a [ ]-nm detector and a [ ]-mm × [ ]-cm column that contains [ ] packing L[ ]. The flow rate is about [ ] mL per minute. The chromatograph is programmed as follows (table below is an example; include isocratic and linear gradient steps as needed):

Time (minutes)	Solution A, %	Solution B, %	Elution
0 – t1	A1	B1	Isocratic
t1 – t2	A1→A2	B1→B2	Linear gradient
t2 – t3	A2	B2	Isocratic
...	...	...	...
t3 – t4	A2→A1	B2→B1	Linear gradient
t4 – t5	A1	B1	Re-equilibrator

**GENERIC TLC TEMPLATE**

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

*Test solution*—

*Standard solution[s]*—

*Application volume:* [ ] μL.

*Developing solvent system:* [a mixture of ... ( : : )].

*Procedure*—Proceed as directed for *Thin-Layer Chromatography* under *Chromatography* <621>. [Spray the plate with {specify spray reagent}.] {Alternatively, include any other instructions, e.g., exposure of the plate to the iodine vapors, drying or heating at a given temperature, etc.} Examine the plate under [short-wavelength UV light] {if 254 nm} [and then under] [long-wavelength UV light] {if 360 nm}: {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 in the chromatogram obtained from [ ], except for the principal spot, is not more intense than the spot in the chromatogram obtained from *Standard solution* [ ]: not more than 0.\_% of any individual impurity is found.”}

### Expressing limits in cases where more than one test procedures are necessary to quantitate the impurities:

#### Impurity—

Test 1—

*Mobile phase*—etc.

*Procedure*— ... Not more than [0.X]% of [excipient] related compound \_\_ is found.

Test 2—

*Mobile phase*—{as above}

*Procedure*—{as above} ..... Not more than [0.Y]% of [drug] related compound \_\_ is found; and not more than [\_.\_] % of total impurity is found, the results for *Test 1* and *Test 2* being added. {Notice that 0.X% and 0.Y% are different limits for individual impurities found in *Test 1* and *Test 2*.}

**Residual solvents, Method [ ] <467>**: meets the requirements.

**Content of [ ]**— {The distinguishing feature of this test, compared with the *Limit* test, is its specified range. For *Limit* tests, it is always “not more than.” Furthermore, if referring to a certain chapter or a chapter section, then name the test according to the heading in the chapter. Hence, the test is not necessarily “*Content of ...*” For example, *Water* <921> is usually a content test, but named after the heading of the chapter <921>.: [not less than \_\_\_%][between \_\_\_% and \_\_\_%] is found.

**Content of chloride**—{describe the procedure}: between \_\_ and \_\_ is found. {There is *Chloride* <221> test that cites the chapter and possibly describes some departures from the procedure specified in the chapter. Additionally, make sure that the test is not *Limit of chloride* test.}

**Nitrogen content, Method [I][II] <461>**—[Proceed as directed, starting with \_\_\_ [m]g of [Drug], accurately weighed]: [not less than \_\_\_%][between \_\_\_% and \_\_\_%] is found.

**Other requirements**—It meets the requirements of the test for [ ] under [excipient]. [Where the label states that [excipient] is sterile, it meets the requirements for *Sterility Tests* <71>, *Labeling* under *Injections* <1>, and *Bacterial endotoxins* under [Drug for Injection]. Where the label states that [excipient] must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under [Drug for Injection].]

#### Assay—

GENERIC HPLC TEMPLATE:

*Mobile phase*—Prepare a filtered and degassed mixture of [ ] and [ ] (\_\_\_:\_\_\_). [Adjust with [ ] to a pH of [ ]. Make adjustments if necessary (see *System Suitability* under *Chromatography* <621>).

*System suitability preparation*—Dissolve suitable quantities of [ ] and USP [Article] RS in [ ] to obtain a solution containing about [ ] [mg][Tg] per mL and [ ] [mg][Tg] per mL, respectively.

*Standard preparation*—Dissolve USP [ ] RS in [ ] to obtain a solution of known concentration of about [\_.\_] mg per mL.

*Assay preparation*—*Assay preparation*— Dissolve an accurately weighed quantity of [Article] in [ ], to obtain a solution having a known concentration of about [\_\_\_.\_\_] mg per mL.

*Chromatographic system* (see *Chromatography* <621>)—The liquid chromatograph is equipped with a [ ]-nm detector and [ ]-mm × [ ]-cm column that contains packing L[ ]. The flow rate is about [ ] mL per minute. [The column temperature is maintained at \_\_\_°.] Chromatograph the *System suitability preparation*, and record the peak responses as directed for *Procedure*: [the relative retention times are about \_\_\_ for \_\_\_ and 1.0 for \_\_\_ {name analyte}]; [the resolution,  $R$ , between \_\_\_ and \_\_\_ is not less than \_\_\_]; [the capacity factor,  $k'$ , is not less than \_\_\_]; [the column efficiency is not less than \_\_\_ theoretical plates]; [the tailing factor is not more than \_\_\_]; and [ the relative standard deviation for replicate injections is not more than \_\_\_%].

*Procedure*—Separately inject equal volumes (about [ ] TL) of the *System suitability preparation*, the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the [major] [analyte] peaks. Calculate the quantity, in mg, of [ ] {give chemical formula as shown in the Definition; if name of active ingredient is different from the drug name, name the active ingredient and add chemical formula in parentheses} in the portion of [Article] taken by the formula:

$$[ ] C(r_U/r_S),$$

in which  $C$  is the concentration, in mg per mL, of USP [excipient] RS in the *Standard preparation*; and  $r_U$  and  $r_S$  are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

#### GENERIC GAS CHROMATOGRAPHIC TEMPLATE WITH NO STANDARD PREPARATION:

*System suitability solution*—Dissolve USP [ ] RS and [ ] mg of USP [ ] RS in [ ] to obtain a solution of known concentration of about [ ] mg (µg) per mL.

*Assay preparation*—Dissolve [ ] in [ ] to obtain a solution of known concentration of about [ ] mg (µg) per mL.

*Chromatographic system* (see *Chromatography* <621>)—The gas chromatograph is equipped with a [flame-ionization] detector and contains a [ ]-mm × [ ]-m column packed with [ ]% liquid phase G[ ] on support S[ ]. The carrier gas is [ ], flowing at a rate of [ ] mL per minute. The chromatograph is programmed as follows. Initially the temperature of the column is equilibrated at [ ]°, then the temperature is increased at a rate of [ ]° per minute to [ ]°, and maintained at [ ]° for [ ] minutes. The injection port

temperature is maintained at [ ]°, and the detector is maintained at [ ]°. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: [the relative retention times are about \_\_ for \_\_ and 1.0 for \_\_\_\_;] [the resolution, *R*, between \_\_ and \_\_ is not less than \_\_. \_\_][;] [the capacity factor, *k'*, is not less than \_\_. \_\_][;] [the column efficiency is not less than \_\_ theoretical plates][;] [the tailing factor is not more than \_\_\_\_][; and] [the relative standard deviation for replicate injections is not more than \_\_. \_\_%].

*Procedure*—Inject a volume (about [ ] μL) of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the percentage of [ ] {give chemical formula as shown in the Definition; if name of active ingredient is different from the drug name, name the active ingredient and add chemical formula in parentheses} in the portion of [Article] taken by the formula:

$$100A/B,$$

in which *A* is the [analyte] peak response, and *B* is the sum of the responses of all the peaks in the chromatogram, except the solvent peak.

**GENERIC TITRATION TEMPLATE:**

Transfer about [ ] mg of [Article], accurately weighed, to a [ ]-mL beaker, and dissolve by stirring in [ ] mL of a mixture of [ ] and [ ] ( : ). Titrate with [ ] mL of [ ], determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* <541>). Each mL of [ ]N titrant is equivalent to [\_\_.] mg of [ ] {insert excipient chemical formula}.

Calculate the percentage of the drug substance in the portion taken using the following formula:

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

in which, *V*: Sample titrant volume (mL), *B*: Blank titrant volume (mL), *N*: Titrant normality, *F*: Equivalence Factor (mg sample/mL of *TN*), *TN*: Theoretical normality, *W*: Sample weight (mg), and *A*: Assay correction for LOD