in the portion of constituted solution or suspension taken by
the formula:

\[(L / D)(C(R_U / R_S))\]

in which \(L\) is the labeled quantity, in mg of cefuroxime
\((C_tH_{16}N_4O_8S)\), in the container, or in the volume of con-
stituted solution or suspension taken; \(D\) is the concentra-
tion, in mg of cefuroxime \((C_tH_{16}N_4O_8S)\) per mL, of Assay pre-
paration 1 or Assay preparation 2, based on the labeled quan-
tity in the container or in the portion of constituted solution
or suspension taken, respectively, and the extent of dilu-
tion; \(C\) is the concentration, in mg of cefuroxime \((C_tH_{16}N_4O_8S)\)
per mL, of the Standard preparation; and \(R_U\) and \(R_S\) are
the peak response ratios of cefuroxime to the internal standard
obtained from the Assay preparation and the Standard pre-
paration, respectively. Where the test for Uniformity of dosage
units has been performed using the Procedure for content
uniformity, use the average of these determinations as the
Assay value.

## Celecoxib

\[C_{17}H_{14}F_{3}N_{3}O_{2}S\]

4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide;

\(\rho\)-[5-p-Tolyl-3-(trifluoromethyl)pyrazol-1-yl]benzenesulfonamide \([169590-42-5]\).

**DEFINITION**

Celecoxib contains NLT 98.0% and NMT 102.0% of
\(C_{17}H_{14}F_{3}N_{3}O_{2}S\), calculated on the anhydrous basis.

**IDENTIFICATION**

- **A. INFRARED ABSORPTION** \([197]\): [NOTE—Methods \((197A), (197K)\), or \((197M)\) under Infrared Absorption may be
  used.]

  [NOTE—If the spectra obtained show differences, dis-
  solve the substance to be examined and the Reference
  Standard separately in isopropyl alcohol, evaporate to
  dryness, and record the new spectra.]

- **B.** The retention time of the major peak of the Sample
  solution corresponds to that of the Reference Standard, as
  obtained in the Assay.

**ASSAY**

- **PROCEDURE**

  Buffer: 2.7 g/L of monobasic potassium phosphate ad-
  justed with phosphoric acid to a \(pH\) of 3.0 ± 0.2
  Mobile phase: Methanol, acetonitrile, and Buffer \((3:1:6)\)
  Diluent: Methanol and water \((3:1)\)
  System suitability solution: 0.5 mg/mL of USP
  Celecoxib RS and 2.4 µg/mL each of USP Celecoxib Rel-
  ated Compound A RS and USP Celecoxib Related Com-
  pound B RS in Diluent
  Standard solution: 0.5 mg/mL of USP Celecoxib RS in
  Diluent
  Sample solution: 0.5 mg/mL of Celecoxib in Diluent

  **Chromatographic system**

  (See Chromatography \((621)\), System Suitability.)
  Mode: LC
  Detector: UV 215 nm
  Column: 4.6-mm x 25-cm; 5-µm packing L11
  Column temperature: 60°
  Flow rate: 1.5 mL/min
  Injection size: 25 µL
  Run time: About 1.5 times the celecoxib peak elution

  **System suitability**

  Samples: System suitability solution and Standard
  solution

## IMPURITIES

### Inorganic Impurities

- **HEAVY METALS**: NMT 20 ppm

  Diluent: Acetone and water \((17:3)\)
  Standard solution: Dilute 1.0 mL of Standard Lead
  Solution, prepared as directed under Heavy Metals \((231)\),
  Special Reagents, with Diluent to 20 mL
  Sample solution: Dissolve 0.50 g of Celecoxib in 20 mL
  of Diluent.
  Blank solution: 20 mL of Diluent

  **Analysis**

  Samples: Standard solution and Blank solution

  To each solution, add 2 mL of \(\text{pH} 3.5\) Acetate Buffer,
  prepared as directed under Heavy Metals \((231)\),
  Method 1. Mix, and add to each solution 1.2 mL of
  thioacetamide–glycerin base TS. Mix immediately, and
  allow to stand for 2 min. Pass the solutions through a
  filter of 0.45-µm pore size. Compare the spots on the
  filters obtained from each of the solutions.

  **Acceptance criteria:** The brownish-black color of the
  spot resulting from the Sample solution is not more in-
  tense than that of the spot resulting from the Standard
  solution. The test is invalid if the Standard solution does
  not show a brownish-black color compared to the
  Blank solution.

- **RESIDUE ON IGNITION** \((281)\): NMT 0.2%, using a platinum
  crucible

### Organic Impurities

- **PROCEDURE**

  Buffer, Mobile phase, Diluent, System suitability solu-
  tion, Sample solution, and Chromatographic sys-
  tem: Proceed as directed in the Assay.

  **Standard solution**: 0.5 µg/mL of USP Celecoxib RS in
  Diluent

  **System suitability**

  Samples: System suitability solution and Standard
  solution

  **Suitability requirements**

  Resolution: NLT 1.8 between celecoxib related com-
  pound A and celecoxib and NLT 1.8 between
  celecoxib and celecoxib related compound B, System
  suitability solution

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

  **Analysis**

  Samples: Standard solution and Sample solution

  Calculate the percentage of \(C_{17}H_{14}F_{3}N_{3}O_{2}S\) in the por-
  tion of Celecoxib taken:

  \[\text{Result} = \left(\frac{r_U}{r_S}\right) \times \left(\frac{C_S}{C_U}\right) \times 100\]

  \(r_U\) = peak response for each impurity in the
  Sample solution

  \(r_S\) = peak response from the Standard solution

  \(C_S\) = concentration of the Sample solution (mg/mL)

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

  **Acceptance criteria:** 98.0%–102.0% on the anhydrous
  basis
Oxidized Cellulose

DEFINITION
Oxidized Cellulose contains NLT 16.0% and NMT 24.0% of carboxyl groups (COOH), calculated on the dried basis. It is sterile.

IDENTIFICATION

• Sample solution: 200 mg in 10 mL of 0.25 N sodium hydroxide

Analysis 1: Shake the Sample solution for 1 min. Add 10 mL of water, and shake.

Acceptance criteria 1: The Sample solution shows no more than a slight haze and is substantially free from fibers and foreign particles.

Analysis 2: Allow the resulting solution to stand for 10 min.

Acceptance criteria 2: Any swollen fibers initially present are no longer visible.

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celecoxib related compound A</td>
<td>0.9</td>
<td>0.4</td>
</tr>
<tr>
<td>Celecoxib</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Celecoxib related compound B</td>
<td>1.1</td>
<td>0.10</td>
</tr>
<tr>
<td>Individual unspecified impurity</td>
<td>—</td>
<td>0.10</td>
</tr>
<tr>
<td>Total impurities</td>
<td>—</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Analysis 3: Acidify the resulting solution with 3 N hydrochloric acid.

Acceptance criteria 3: A flocculent white precipitate is formed.

ASSAY

• PROCEDURE

Solution A: 20 mg/mL of calcium acetate

Sample: 500 mg, previously dried under vacuum over phosphorus pentoxide for 18 h

Blank: 50.0 mL of Solution A

Titrmetric system

(See Titrimetry (541).)

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Place the Sample in a 125-mL conical flask. Add 50.0 mL of Solution A, swirl until the sample is completely covered, allow the mixture to stand for 30 min, then add phenolphthalein TS. Titrate the solution with Titrant. Perform a blank determination, and make any necessary correction. Each mL of Titrant is equivalent to 4.502 mg of carboxyl groups (COOH).

Acceptance criteria: 16.0%–24.0% on the dried basis

IMPURITIES

• Residue on Ignition (281): NMT 0.15%

• Limit of Nitrogen

Solution A: 40 mg/mL of boric acid

Solution B: Methyl red TS and bromocresol green TS (1:4)

Sample: 1 g, previously dried under vacuum over phosphorus pentoxide for 18 h

Titrmetric system

(See Titrimetry (541).)

Mode: Direct titration

Titrant: 0.02 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Place a 125-mL conical flask, containing 30 mL of Solution A and 6 drops of Solution B, beneath the condenser of the distillation apparatus so that the tip of the condenser is well below the surface of the resulting solution. To a 500-mL Kjeldahl flask, add the Sample, and add 1 g of Devarda’s alloy, 100 mL of recently boiled water, a small lump of paraffin, and 100 mL of 1 N sodium hydroxide. Connect the Kjeldahl flask to the condenser by a suitable trap bulb. Heat the mixture in the flask until 45–50 mL of distillate has collected in the receiver. Rinse the condenser, and titrate the resulting solution with Titrant to a pale pink endpoint. Perform a blank determination, and make any necessary correction. Each mL of Titrant is equivalent to 0.2801 mg of nitrogen.

Acceptance criteria: NMT 0.5%

• Limit of Formaldehyde

Solution A: Formaldehyde in water (1 in 40,000)

Standard: 0.50 mL of Solution A

Sample: 500 mg

Instrumental conditions

(See Spectrophotometry and Light-Scattering (851).)

Mode: Vis

Analytical wavelength: 570 nm

Blank: Mixture of 0.5 mL of water and 10 mL of chromotropic acid TS

Analysis: Transfer the Sample to a 500-mL iodine flask. Add 250 mL of water, and allow to stand for NLT 2 h with intermittent shaking. Pipet 0.50 mL each of the supernatant from the resulting solution and the Standard into two separate glass-stoppered test tubes. To each test tube add 10 mL of chromotropic acid TS. Stopper the tubes loosely, and heat in a boiling water bath for 30 min. Cool, and determine the absorbance of each solution against the Blank.

Acceptance criteria: 0.5%; the absorbance of the Sample is NMT the Standard.