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Montelukast Sodium Chewable Tablets

DEFINITION

Montelukast Sodium Chewable Tablets contain Montelukast Sodium equivalent to NLT 92.5% and NMT 107.5% of the labeled amount of montelukast (C₃₅H₃₆ClNO₃S).

[NOTE—Avoid exposure of samples containing montelukast to light.]

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:** 197U

Diluent: [Methanol](#) and [water](#) (3:1)

Standard solution (for 4-mg Chewable Tablets): 0.026 mg/mL of [USP Montelukast Dicyclohexylamine RS](#) in *Diluent*

Standard solution (for 5-mg Chewable Tablets): 0.033 mg/mL of [USP Montelukast Dicyclohexylamine RS](#) in *Diluent*

Sample solution: Nominally (*L*/200) mg/mL of montelukast, where *L* is the label claim of montelukast in mg/Chewable Tablet prepared as follows. Transfer 1 Chewable Tablet to a suitable volumetric flask, add 25% of the flask volume of [water](#), and let stand for 5–10 min until the Chewable Tablet has disintegrated. Add 55% of the flask volume of [methanol](#), shake well, and sonicate for 70 min with occasional shaking. Cool to room temperature, dilute with [methanol](#) to volume, and mix well. Centrifuge a portion of the resulting solution to obtain a clear solution.

Wavelength range: 210–400 nm

Acceptance criteria: The *Sample solution* exhibits maxima only at the same wavelengths as the *Standard solution*.

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

ASSAY

- **PROCEDURE**

Diluent: [Methanol](#) and [water](#) (3:1)

Solution A: 0.2% (v/v) [Trifluoroacetic acid](#) in [water](#)

Solution B: [Methanol](#) and [acetonitrile](#) (3:2)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	48	52
5	45	55
12	45	55
22	25	75
23	25	75
25	48	52
30	48	52

Standard solution: 0.33 mg/mL of [USP Montelukast Dicyclohexylamine RS](#) in *Diluent*

System suitability solution: Transfer 10 mL of the *Standard solution* to a clear 10-mL volumetric flask, add 4 µL of [hydrogen peroxide](#), and mix well. Expose the flask for at least 4 h to ambient light or 10 min to a 4 klx cool white light. [NOTE—Montelukast is partially converted to the *cis*-isomer under these conditions.]

Sensitivity solution: 0.33 µg/mL of [USP Montelukast Dicyclohexylamine RS](#) in *Diluent* from the *Standard solution*

Sample solution (for 4-mg Chewable Tablets): Nominally 0.24 mg/mL of montelukast prepared as follows. Transfer 13 Chewable Tablets to a suitable volumetric flask, add 75% of the flask volume of *Diluent*, and shake vigorously for 60 min. Dilute with *Diluent* to volume. Pass a



portion of the resulting solution through a suitable filter of 0.45-µm pore size, discarding the first mL of filtrate. Use the filtrate.

Sample solution (for 5-mg Chewable Tablets): Nominally 0.25 mg/mL of montelukast prepared as follows. Transfer 10 Chewable Tablets to a suitable volumetric flask, add 75% of the flask volume of *Diluent*, and shake vigorously for 60 min. Dilute with *Diluent* to volume. Pass a portion of the resulting solution through a suitable filter of 0.45-µm pore size, discarding the first mL of filtrate. Use the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 255 nm

Columns

Guard: 3.0-mm × 4-mm; packing [L11](#)

Analytical: 4.6-mm × 10-cm; 3-µm packing [L11](#)

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: 2 times the retention time of montelukast

System suitability

Samples: *Standard solution*, *System suitability solution*, and *Sensitivity solution*

[NOTE—The relative retention times for the *cis*-isomer and montelukast are about 0.92 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the *cis*-isomer and montelukast, *System suitability solution*

Relative standard deviation: NMT 2% for five injections, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of montelukast ($C_{35}H_{36}ClNO_3S$) in the portion of Chewable Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Montelukast Dicyclohexylamine RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of montelukast, 586.18

M_{r2} = molecular weight of montelukast dicyclohexylamine, 767.50

Acceptance criteria: 92.5%–107.5%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.5% (w/v) [Sodium dodecyl sulfate](#) in [water](#); 900 mL. Do not deaerate.

Apparatus 2: 50 rpm

Time: 20 min

Solution A: 0.2% (v/v) [Trifluoroacetic acid](#) in [water](#)

Solution B: 0.2% (v/v) [Trifluoroacetic acid](#) in [acetonitrile](#)

Mobile phase: *Solution A* and *Solution B* (1:1)

Standard stock solution (for 4-mg Chewable Tablets): 0.30 mg/mL of [USP Montelukast Dicyclohexylamine RS](#) in [methanol](#) (equivalent to 0.23 mg/mL of montelukast)

Standard stock solution (for 5-mg Chewable Tablets): 0.35 mg/mL of [USP Montelukast Dicyclohexylamine RS](#) in [methanol](#) (equivalent to 0.27 mg/mL of montelukast)

Standard solution: ($L/900$) mg/mL of montelukast in *Medium* from the *Standard stock solution*, where L is the label claim in mg/Chewable Tablet of montelukast

Sample solution: Pass a portion of the solution under test through a suitable filter or centrifuge to obtain a clear solution.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 389 nm

Column: 3.0-mm × 10-cm; 5-µm packing [L11](#)

Column temperature: 50°