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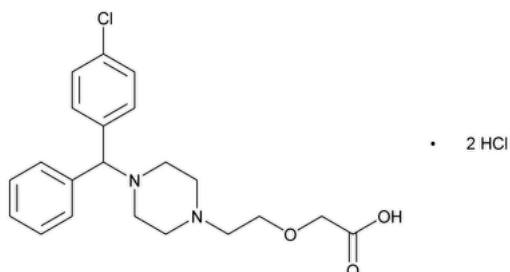
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# Cetirizine Hydrochloride

 $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$ 

461.81

(±)-[2-[4-[(4-Chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]acetic acid, dihydrochloride;

(±)-[2-[4-(p-Chloro-α-phenylbenzyl)-1-piperazinyl]ethoxy]acetic acid, dihydrochloride;

(2-[4-[(4-Chlorophenyl)phenylmethyl]piperazin-1-yl]ethoxy)acetic acid dihydrochloride CAS RN®: 83881-52-1; UNII: 640047KTOA.

## DEFINITION

Cetirizine Hydrochloride contains NLT 98.0% and NMT 102.0% of cetirizine hydrochloride ( $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$ ), calculated on the dried basis.

## IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
- **B. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Chloride:** Meets the requirements
- **C.** 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

**Mobile phase:** [Acetonitrile](#), [water](#), and [1 M sulfuric acid](#) (93: 6.6: 0.4)**Standard solution:** 0.5 mg/mL of [USP Cetirizine Hydrochloride RS](#) in *Mobile phase***Sample solution:** 0.5 mg/mL of Cetirizine Hydrochloride in *Mobile phase*

### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 230 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L3](#)**Flow rate:** 1 mL/min**Injection volume:** 10 μL**Run time:** NLT 3 times the retention time of the cetirizine peak

### System suitability

**Sample:** *Standard solution*

### Suitability requirements

**Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%

### Analysis

**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of cetirizine hydrochloride ( $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$ ) in the portion of Cetirizine Hydrochloride taken:

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

 $r_U$  = peak response of cetirizine from the *Sample solution* $r_S$  = peak response of cetirizine from the *Standard solution* $C_S$  = concentration of [USP Cetirizine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Cetirizine Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the dried basis

## IMPURITIES

### • RESIDUE ON IGNITION (281)

**Acceptance criteria:** NMT 0.2%

### • ORGANIC IMPURITIES, PROCEDURE 1

[NOTE—It is recommended that *Organic Impurities, Procedure 2* be performed if either cetirizine ethanol (2-[4-[(4-chloro phenyl)phenylmethyl]piperazin-1-yl]ethanol) or cetirizine acetic acid (2-[4-[(4-chloro phenyl)phenylmethyl]piperazin-1-yl]acetic acid) may be present in the test substance.]

**Mobile phase and Sample solution:** Prepare as directed in the Assay.

**System suitability solution:** 4 µg/mL each of [USP Cetirizine Hydrochloride RS](#) and [USP Cetirizine Related Compound A RS](#) in *Mobile phase*

**Sensitivity solution:** 0.1 µg/mL of [USP Cetirizine Hydrochloride RS](#) in *Mobile phase*

**Standard solution:** 0.5 µg/mL of [USP Cetirizine Hydrochloride RS](#) in *Mobile phase*

**Chromatographic system:** Proceed as directed in the Assay.

### System suitability

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

[NOTE—See [Table 1](#) for relative retention times.]

### Suitability requirements

**Resolution:** NLT 2.0 between cetirizine and cetirizine related compound A, *System suitability solution*

**Tailing factor:** NMT 2.0 for cetirizine, *System suitability solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

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

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each individual specified or unspecified impurity in the portion of Cetirizine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

$r_U$  = peak response of each individual specified or unspecified impurity from the *Sample solution*

$r_S$  = peak response of cetirizine from the *Standard solution*

$C_S$  = concentration of [USP Cetirizine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Cetirizine Hydrochloride in the *Sample solution* (mg/mL)

$F$  = relative response factor (see [Table 1](#))

**Acceptance criteria:** See [Table 1](#). The reporting threshold is 0.02%.

**Table 1**

| Name                                | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|-------------------------------------|-------------------------|--------------------------|------------------------------|
| 4-CBH <sup>a</sup>                  | 0.3                     | 1.4                      | 0.1                          |
| Cetirizine dimer <sup>b</sup>       | 0.5                     | 1.8                      | 0.1                          |
| 2-Chlorocetirizine <sup>c</sup>     | 0.85                    | 0.49                     | 0.1                          |
| Cetirizine related compound A       | 0.9                     | 0.95                     | 0.1                          |
| Cetirizine                          | 1.0                     | —                        | —                            |
| Deschlorocetirizine <sup>d</sup>    | 1.4                     | 0.45                     | 0.1                          |
| CBHP <sup>e</sup>                   | 1.45                    | 1.6                      | 0.1                          |
| Any individual unspecified impurity | —                       | 1.0                      | 0.10                         |