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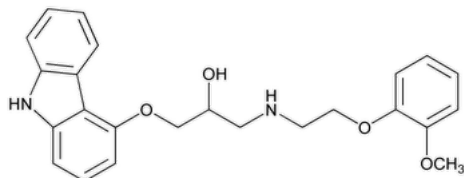
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Carvedilol

 $C_{24}H_{26}N_2O_4$

406.47

2-Propanol, 1-(9H-carbazol-4-yloxy)-3-[[2-(2-methoxyphenoxy)ethyl]amino]-, (±)-;

(±)-1-(Carbazol-4-yloxy)-3-[[2-(o-methoxyphenoxy)ethyl]amino]-2-propanol CAS RN®: 72956-09-3; UNII: 0K47UL67F2.

DEFINITION

Carvedilol contains NLT 98.0% and NMT 102.0% of $C_{24}H_{26}N_2O_4$, calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)
- **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

Buffer: 2.72 g/L of monobasic potassium phosphate. Adjust with dilute phosphoric acid to a pH of 2.0.**Mobile phase:** Acetonitrile and *Buffer* (31:69)**System suitability solution:** 0.05 mg/mL each of [USP Carvedilol RS](#) and [USP Carvedilol Related Compound A RS](#) in *Mobile phase***Standard solution:** 0.04 mg/mL of [USP Carvedilol RS](#) in *Mobile phase***Sample solution:** 0.04 mg/mL of Carvedilol in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 15-cm; 5-μm packing L7**Column temperature:** 55°**Flow rate:** 1 mL/min**Run time:** 60 min**Injection size:** 10 μL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 4.0 between carvedilol and carvedilol related compound A**Tailing factor:** NMT 1.5 for the carvedilol peak**Relative standard deviation:** NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*Calculate the percentage of carvedilol ($C_{24}H_{26}N_2O_4$) in the portion of the sample taken:

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

 r_U = peak response of carvedilol from the *Sample solution* r_S = peak response of carvedilol from the *Standard solution* C_S = concentration of carvedilol in the *Standard solution* (mg/mL) C_U = concentration of Carvedilol in the *Sample solution* (mg/mL)

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

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1% from 1 g
- **ORGANIC IMPURITIES, PROCEDURE 1:** [NOTE—On the basis of the impurities present, perform either *Organic Impurities, Procedure 1* or *Organic Impurities, Procedure 2*. *Organic Impurities, Procedure 2* is recommended when carvedilol related compound F is a potential impurity.]

Buffer and Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.05 mg/mL each of [USP Carvedilol RS](#) and [USP Carvedilol Related Compound C RS](#) in *Mobile phase*

Standard solution: 1 µg/mL each of [USP Carvedilol RS](#), [USP Carvedilol Related Compound A RS](#), [USP Carvedilol Related Compound B RS](#), [USP Carvedilol Related Compound D RS](#), and [USP Carvedilol Related Compound E RS](#), and 0.2 µg/mL of [USP Carvedilol Related Compound C RS](#) in *Mobile phase*

Sample solution: 1 mg/mL of Carvedilol in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Dual wavelength, UV 220 and 240 nm. Use 220 nm for quantitating carvedilol related compound E, and use 240 nm for carvedilol and all other related compounds.

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 55°

Flow rate: 1 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 17 between carvedilol and carvedilol related compound C

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carvedilol related compound A, carvedilol related compound B, carvedilol related compound C, carvedilol related compound D, carvedilol related compound E, and any other individual impurity in the portion of Carvedilol taken:

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

r_U = peak response of the corresponding related compound or any other impurity from the *Sample solution*

r_S = peak response of the corresponding related compound from the *Standard solution*. To calculate the percentage of any other individual impurity use the peak response of carvedilol.

C_S = concentration of the corresponding related compound in the *Standard solution* (mg/mL). To calculate the percentage of any other impurities for C_S , use the concentration of [USP Carvedilol RS](#).

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

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Carvedilol related compound E ^a	0.35	0.1
Carvedilol related compound A ^b	0.52	0.1
Carvedilol bisalkylpyrocatechol derivative (if present) ^c	0.70	0.15
Carvedilol	1.0	—
Carvedilol related compound C ^d	3.6	0.02