lated Compound B RS in a suitable volumetric flask, in 50% of the total volume of acetonitrile, and dilute with *Solution A* to volume.
Standard solution A: 0.002 mg/mL of USP Acebutolol Hydrochloride RS in *Solution A*
Standard solution B: 0.004 mg/mL of USP Acebutolol Related Compound I RS in *Solution A*
Standard solution C: 0.002 mg/mL of USP Acebutolol Related Compound A RS in *Solution A* from *Standard stock solution 1*
Standard solution D: 0.004 mg/mL of USP Acebutolol Related Compound B RS in *Solution A* from *Standard stock solution 2*
System suitability solution: 0.4 µg/mL each of USP Acebutolol Hydrochloride RS and USP Acebutolol Related Compound I RS in *Solution A* from *Standard solution A* and *Standard solution B*
Sample solution: 2 mg/mL of Acebutolol Hydrochloride in *Solution A*
Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	98	2
2	98	2
30.5	10	90
41	10	90

Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 240 nm
Column: 4.0-mm × 12.5-cm; 5-µm packing L1
Column temperature: 40°
Flow rate: 1.2 mL/min
Injection volume: 25 µL
System suitability
Samples: *Standard solution A* and *System suitability solution*
Suitability requirements
Resolution: NLT 7.0 between acebutolol and acebutolol related compound I, *System suitability solution*
Relative standard deviation: NMT 2.0%, *Standard solution A*
Analysis
Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Sample solution*
Calculate the percentage of acebutolol related compound A, acebutolol related compound B, and acebutolol related compound I 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 acebutolol related compound A or acebutolol related compound B or acebutolol related compound I from the *Sample solution*
r_S = peak response of acebutolol related compound A or acebutolol related compound B or acebutolol related compound I from *Standard solution B*, *Standard solution C*, or *Standard solution D*
C_S = concentration of USP Acebutolol Related Compound A RS or USP Acebutolol Related Compound B RS or USP Acebutolol Related Compound I RS in *Standard solution B*, *Standard solution C*, or *Standard solution D* (mg/mL)
C_U = concentration of Acebutolol Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of any unspecified impurity 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 any unspecified impurity from the *Sample solution*
r_S = peak response of acebutolol from *Standard solution A*
C_S = concentration of USP Acebutolol Hydrochloride RS in *Standard solution A* (mg/mL)
C_U = concentration of Acebutolol Hydrochloride in the *Sample solution* (mg/mL)
Acceptance criteria: See *Table 2*. Disregard peaks below 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Acebutolol related compound B[a]	0.72	0.2
Acebutolol related compound I[b]	0.91	0.2
Acebutolol	1.00	—
Acebutolol related compound A[c]	1.48	0.1
Any unspecified impurity	—	0.10
Total impurities[d]	—	0.5

[a] *N*-{3-Acetyl-4-[2-hydroxy-3-(isopropylamino)propoxy]phenyl}acetamide.
[b] *N*-{3-Acetyl-4-[3-(ethylamino)-2-hydroxypropoxy]phenyl}butyramide.
[c] *N*-(3-Acetyl-4-hydroxyphenyl)butyramide.
[d] Total impurities include specified and unspecified impurities.

SPECIFIC TESTS
• **pH** ⟨791⟩
Sample: 10 mg/mL of Acebutolol Hydrochloride in water
Acceptance criteria: 4.5–7.0
• **Loss on Drying** ⟨731⟩
Analysis: Dry at 105° for 3 h.
Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS
• **Packaging and Storage:** Preserve in tight containers and store at controlled room temperature.
• **USP Reference Standards** ⟨11⟩
USP Acebutolol Hydrochloride RS
USP Acebutolol Related Compound A RS
N-(3-Acetyl-4-hydroxyphenyl)butyramide.
$C_{12}H_{15}NO_3$ 221.25
USP Acebutolol Related Compound B RS
N-{3-Acetyl-4-[2-hydroxy-3-(isopropylamino)propoxy]phenyl}acetamide.
$C_{16}H_{24}N_2O_4$ 308.37
USP Acebutolol Related Compound I RS
N-{3-Acetyl-4-[3-(ethylamino)-2-hydroxypropoxy]phenyl}butyramide.
$C_{17}H_{26}N_2O_4$ 322.40

Acebutolol Hydrochloride Capsules

DEFINITION
Acebutolol Hydrochloride Capsules contain the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of acebutolol ($C_{18}H_{28}N_2O_4$).