▲Table 7▲ (TBD) *(continued)*

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Total degradation products	—	0.50

[a] Process impurities; do not include in total degradation products.
[b] (*RS*,*E*)-1-{2-[2-Hydroxy-3-(propylamino)propoxy]phenyl}-3-phenylprop-2-en-1-one.
[c] 1-[2-[(2*RS*)-2,3-Dihydroxypropoxy]phenyl]-3-phenylpropan-1-one.
[d] 2-Phenylchroman-4-one.
[e] 1,1′-[Propyliminobis(2-hydroxypropane-3,1-diyl)oxy-2,1-phenylene]bis(3-phenylpropan-1-one).
[f] 1-[2-(3-Chloro-2-hydroxypropoxy)phenyl]-3-phenylpropan-1-one.
[g] 1-[2-[[(*RS*)-Oxiranyl]methoxy]phenyl]-3-phenylpropan-1-one.
[h] 1-(2-Hydroxyphenyl)-3-phenylpropan-1-one.
[i] 1,1′-(2,2′-(2-Hydroxypropane-1,3-diyl)bis(oxy)bis(2,1-phenylene))bis(3-phenylpropan-1-one).

Change to read:

- **Content of Propafenone Related Compound A**

Buffer: Dissolve 3.4 g of dibasic potassium phosphate in 1000 mL of water, and adjust with phosphoric acid to a pH of 2.5 ± 0.05.
Solution A: Methanol and *Buffer* (45:55); pass through a suitable filter of 0.2-µm pore size.
Solution B: Methanol and *Buffer* (75:25); pass through a suitable filter of 0.2-µm pore size.
Mobile phase: See ▲*Table 8*.

Table 8▲ (TBD)

Time (min)	Solution A (%)	Solution B (%)
0	100	0
4.0	100	0
7.0	50	50
10.0	0	100
12.0	0	100
12.5	100	0
15.0	100	0

Diluent: Methanol and water (80:20)
Standard solution: 2.0 µg/mL of USP Propafenone Related Compound A RS in *Diluent*
Sensitivity solution: 0.2 µg/mL of USP Propafenone Related Compound A RS in *Diluent* from the *Standard solution*
Sample solution: Nominally 1 mg/mL of propafenone hydrochloride prepared as follows. Transfer a suitable amount of finely powdered contents from NLT 20 Capsules to an appropriate volumetric flask. Add about 75% of the final volume of *Diluent* and sonicate with intermittent shaking for 20 min. Dilute with *Diluent* to volume and pass through a suitable filter of 0.45-µm pore size. Discard the first 4 mL of the filtrate.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 250 nm
Column: 2.1-mm × 10-cm; 1.7-µm packing L1
Column temperature: 60°
Flow rate: 0.4 mL/min
Injection volume: 4 µL
System suitability
Samples: *Standard solution* and *Sensitivity solution*
Suitability requirements
Tailing factor: NMT 2.0, *Standard solution*
Relative standard deviation: NMT 6.0%, *Standard solution*
Signal-to-noise ratio: NLT 10, *Sensitivity solution*
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of propafenone related compound A in the portion of Capsules taken:

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

r_U = peak response of propafenone related compound A from the *Sample solution*
r_S = peak response of propafenone related compound A from the *Standard solution*
C_S = concentration of USP Propafenone Related Compound A RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of propafenone hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: See ▲*Table 9*.

Table 9▲ (TBD)

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Propafenone	1.0	—
Propafenone related compound A[a]	1.9	0.20

[a] *N*-{2-Hydroxy-3-[2-(3-phenylpropanoyl)phenoxy]propyl}-*N*-propylformamide.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Keep in tight containers and store at controlled room temperature.
- **Labeling:** When more than one test for *Dissolution* is given, the *Labeling* section states the test for *Dissolution* used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩
USP Propafenone Hydrochloride RS
USP Propafenone Related Compound A RS
N-{2-Hydroxy-3-[2-(3-phenylpropanoyl)phenoxy]propyl}-*N*-propylformamide.
$C_{22}H_{27}NO_4$ 369.45
USP Propafenone Related Compound B RS
(*RS*,*E*)-1-{2-[2-Hydroxy-3-(propylamino)propoxy]phenyl}-3-phenylprop-2-en-1-one.
$C_{21}H_{25}NO_3$ 339.43