Table 1 *(Continued)*

Time (min)	Solution A (%)	Solution B (%)
68	0	100
80	0	100

Diluent: Acetonitrile and tetrahydrofuran (3:2)
System suitability stock solution: 0.5 mg/mL of USP Adapalene RS, prepared as follows. Transfer USP Adapalene RS to a suitable volumetric flask, add tetrahydrofuran equivalent to 40% of the final volume, and sonicate to dissolve. Dilute with acetonitrile to volume.
System suitability solution: 0.2 mg/mL of USP Adapalene RS in *Diluent*, from *System suitability stock solution*
Standard solution: 1.0 µg/mL of USP Adapalene RS in *Diluent*, from *System suitability solution*
Sample solution: Nominally equivalent to 0.2 mg/mL of adapalene, prepared as follows. Transfer 5.0 g of Gel to a 25-mL volumetric flask. Add 10 mL of tetrahydrofuran and sonicate to disperse for 10 min. Add 10 mL of acetonitrile and sonicate for 10 min. Cool to room temperature and dilute with acetonitrile to volume. Pass a portion through a Teflon filter of 0.45-µm pore size and use the filtrate.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 235 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Column temperature: 40°
Flow rate: 1 mL/min
Injection volume: 20 µL
System suitability
Samples: *System suitability solution* and *Standard solution*
Suitability requirements
Tailing factor: NMT 2.0, *System suitability solution*
Relative standard deviation: NMT 5.0%, *Standard solution*
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of each individual impurity in the portion of Gel taken:

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

r_U = peak area of each impurity from the *Sample solution*
r_S = peak area of adapalene from the *Standard solution*
C_S = concentration of USP Adapalene RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of adapalene in the *Sample solution* (mg/mL)
Acceptance criteria: See *Table 2*. Disregard any peak less than 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Adapalene related compound A[a,b]	0.5	—
Adapalene	1.0	—
Adapalene related compound B[b,c]	1.3	—

[a] Methyl 6-bromo-2-naphthoate.
[b] This process impurity is controlled in the drug substance monograph. It is included in the table for identification only and it is not to be reported in the total impurities.
[c] Methyl 6-[3-(adamant-1-yl)-4-methoxyphenyl]-2-naphthoate.

Table 2 *(Continued)*

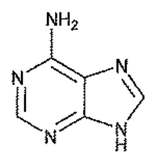
Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Any unspecified impurity	—	0.2
Total impurities	—	1.0

[a] Methyl 6-bromo-2-naphthoate.
[b] This process impurity is controlled in the drug substance monograph. It is included in the table for identification only and it is not to be reported in the total impurities.
[c] Methyl 6-[3-(adamant-1-yl)-4-methoxyphenyl]-2-naphthoate.

SPECIFIC TESTS
- **pH** ⟨791⟩: 4.0–6.0
- **Minimum Fill** ⟨755⟩: Meets the requirements
- **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩: The total aerobic microbial count is NMT 10^2 cfu/g. The total yeasts and molds count is NMT 10^1 cfu/g. It meets the requirements of the tests for the absence of *Escherichia coli*, *Salmonella* species, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* species.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature and protect from freezing.
- **USP Reference Standards** ⟨11⟩
  USP Adapalene RS

Adenine



$C_5H_5N_5$ 135.13
9*H*-Purin-6-amine;
1,6-Dihydro-6-iminopurine [73-24-5].

DEFINITION
Adenine contains NLT 98.0% and NMT 102.0% of adenine ($C_5H_5N_5$), calculated on the dried basis.

IDENTIFICATION
- **A. Infrared Absorption** ⟨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 solution: Dissolve 6.90 g of monobasic ammonium phosphate in about 800 mL of water. Adjust with ammonium hydroxide to a pH of 6.2, and dilute with water to 1 L.
  Mobile phase: See *Table 1*.

Table 1

Time (min)	Buffer Solution (%)	Acetonitrile (%)	Water (%)
0	5	5	90
20	5	5	90
20.1	10	10	80
30	10	10	80