Name	Relative Retention Time	Acceptance Criteria, NMT (%)
4-Epiminocycline[a]	0.38	4.0
Desmethyl minocycline[b,c]	0.46	—
Sancycline[b,d]	0.68	—
5a,6-Anhydrominocycline[b,e]	0.81	—
Hydroxymethylminocycline[b,f]	0.92	—
Minocycline	1.0	—
Any individual unspecified degradation product	—	0.2
Total degradation products[g]	—	2.0

[a] (4*R*,4a*S*,5a*R*,12a*S*)-4,7-Bis(dimethylamino)-3,10,12,12a-tetrahydroxy-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide.

[b] Process impurities are controlled in the drug substance and are not to be reported here. They are not included in total degradation products.

[c] (4*S*,4a*S*,5a*R*,12aS)-4-Dimethylamino-3,10,12,12a-tetrahydroxy-7-methylamino-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide.

[d] 6-Demethyl-6-deoxytetracycline; (4*S*,4a*S*,5a*R*,12a*S*)-4-Dimethylamino-3,10,12,12a-tetrahydroxy-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide.

[e] (4*S*,4a*S*,12a*S*)-4,7-Bis(dimethylamino)-3,10,11,12a-tetrahydroxy-1,12-dioxo-1,4,4a,5,12,12a-hexahydrotetracene-2-carboxamide.

[f] (4*S*,4a*S*,5a*R*,12a*S*)-4,7-Bis(dimethylamino)-3,10,12,12a-tetrahydroxy-*N*-(hydroxymethyl)-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide.

[g] Total degradation products does not include 4-epiminocycline.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Store in tightly closed containers at controlled room temperature.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩
  USP Minocycline Hydrochloride RS

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Not Applicable

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