Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Quetiapine related compound H	0.57	1.0	0.2
Quetiapine desethoxy[b]	0.87	—	—
Quetiapine	1.0	—	—
Quetiapine related compound B[b]	1.9	—	—
Any individual unspecified degradation product	—	1.0	0.2
Total degradation products	—	—	0.4

[a] Counter ion peak, not to be included in the total degradation products.
[b] Process impurity controlled in the drug substance. Included for identification purposes only. Not reported for the drug product and not included in the total degradation products.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store 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 Quetiapine Fumarate RS

USP Quetiapine Related Compound H RS

4-(Dibenzo[*b,f*][1,4]thiazepin-11-yl)-1-[2-(2-hydroxyethoxy)ethyl]piperazine 1-oxide.

$C_{21}H_{25}N_3O_3S$ 399.51

USP Quetiapine System Suitability RS

It contains quetiapine fumarate and at least 0.1% of each of the following impurities:

Quetiapine related compound B: 11-(Piperazin-1-yl)dibenzo[*b,f*][1,4]thiazepine; Quetiapine related compound G: Dibenzo[*b,f*][1,4]thiazepin-11(10*H*)-one; and Quetiapine desethoxy: 2-[4-(Dibenzo[*b,f*][1,4]thiazepin-11-yl)piperazin-1-yl]ethanol.

Page Information:

Not Applicable

Current DocID: