| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---|---|---|---|
| Doxepin related compound A[b] | 3.75 | 1.26 | 0.2 |
| Any individual impurity | — | 1.0 | 0.2 |
| Total impurities | — | — | 0.5▲ (USP 1-May-2021) |

[a] Process impurity included in the table for identification purposes only. Process impurities are controlled in the drug substance, and are not to be reported or included in the total impurities for the drug product.

[b] Dibenzo[*b*,*e*]oxepin-11(6*H*)-one.

## SPECIFIC TESTS

- **WATER DETERMINATION ⟨921⟩, *Method I***

  **Sample:** Contents of 1 Capsule

  **Acceptance criteria:** NMT 9.0%

## ADDITIONAL REQUIREMENTS

***Change to read:***

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. ▲Store at controlled room temperature.▲ (USP 1-May-2021)

***Add the following:***

▲- **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.▲ (RB 1-May-2021)

***Change to read:***

- **USP REFERENCE STANDARDS ⟨11⟩**

  USP Doxepin Hydrochloride RS

  ▲USP Doxepin Related Compound B RS

  11(*RS*)-(3-(Dimethylamino)propyl)-6,11-dihydrodibenzo[*b*,*e*]oxepin-11-ol.

  $C_{19}H_{23}NO_2$ 297.39

  USP Doxepin Related Compound C RS

  (*EZ*)-3-(Dibenzo[*b*,*e*]oxepin-11(6*H*)-ylidene)-*N*-methylpropan-1-amine hydrochloride.

  $C_{18}H_{19}NO \cdot HCl$ 301.81▲ (USP 1-May-2021)

**Page Information:**

Not Applicable

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