

| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) | | |
|--|-------------------------|--------------------------|------------------------------|------------|------------|
| | | | 7 mg/24 h | 14 mg/24 h | 21 mg/24 h |
| Nicotine related compound D | 0.85 | 1.6 | 5.6 | 3.2 | 2.6 |
| Nicotine | 1.00 | — | — | — | — |
| Nicotine related compound B ^g | 1.19 | 1.9 | 0.5 | 0.5 | 0.5 |
| Any other unspecified impurity | — | 1.0 | 0.6 | 0.5 | 0.5 |
| Total impurities | — | — | 8.3 | 5.8 | 4.4 |

^a 3-Pyridine carboxylic acid.

^b Process impurity; controlled in drug substance and not to be included in total impurities.

^c (S)-3-(Pyrrolidin-2-yl)pyridine; also known as nornicotine.

^d (S)-1-Methyl-5-(pyridin-3-yl)pyrrolidin-2-one; also known as cotinine.

^e (S)-3-(Piperidin-2-yl)pyridine; also known as anabasine.

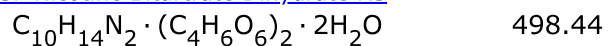
^f (S)-1,2,3,6-Tetrahydro-2,3'-bipyridine; also known as anatabine.

^g 3-(1-Methyl-1*H*-pyrrol-2-yl)pyridine; also known as nicotyrine.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in the hermetic, light-resistant, unit-dose pouch.
- **LABELING:** The labeling indicates the *Drug Release Test* with which the product complies.
- **USP REFERENCE STANDARDS (11).**

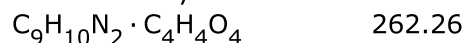
[USP Nicotine Bitartrate Dihydrate RS](#)



[USP Nicotine Related Compound D RS](#)

3-(4,5-Dihydro-3*H*-pyrrol-2-yl)pyridine fumarate;

Also known as Myosmine.

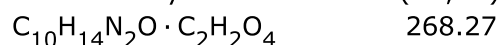


[USP Nicotine Related Compound E RS](#)

(1*RS*,2*S*)-1-Methyl-2-(pyridin-3-yl)pyrrolidine 1-oxide oxalate;

Also known as Nicotine *N*-oxide.

[NOTE—This may be a mixture of (1*R*,2*S*) and (1*S*,2*S*) isomers.]



Page Information:

Not Applicable

DocID:

© 2020 The United States Pharmacopeial Convention *All Rights Reserved.*