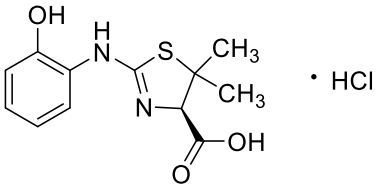
CLAIMS

1. A compound of Formula I:



Formula I (Compound 1),

comprising about 0.0001 % to about 0.30% w/w of at least one impurity selected from the group consisting of 2-Cl-BO (2-chlorobenzoxazole), BO-Imp-1 (2-hydroxybenzoxazole), BO-Imp-2 (2'H-[2,3'-bi-1,3-benzoxazol]-2'-one), BO-Imp-3 (2-aminophenol), BO-Imp-4 (2-[bis(1,3-benzoxazol-2-yl) amino]phenol), BO-Imp-5 (2-[(1,3-benzoxazol-2-yl)amino]phenol), and Cmp1 Imp-3 (propan-2-yl (4*R*)-2-(2-hydroxyanilino)-5,5-dimethyl-4,5-dihydro-1,3-thiazole-4-carboxylate).

2. The compound of claim 1, which comprises about 0.010% to about 0.020% w/w of BO-Imp-1 and about 0.002% to about 0.004% w/w of BO-Imp-5.

3. The compound of claim 1, which comprises about 0.01% to about 0.10% w/w of BO-Imp-1 and about 0.05% to about 0.3% w/w of Cmp1 Imp-3.

4. The compound of claim 3, which comprises less than 0.05% w/w of each of BO-Imp-2, BO-Imp-3, BO-Imp-4, and BO-Imp-5.

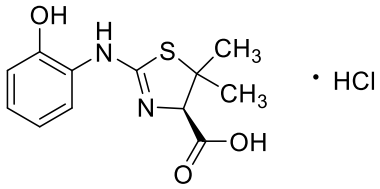
5. The compound of claim 1, which has an enantiomeric purity of at least about 98%.

6. The compound of claim 1, for use in treating painful diabetic neuropathy or post-surgical pain.

7. A pharmaceutical composition comprising the compound of claim 1.

8. The pharmaceutical composition of claim 7, wherein the pharmaceutical composition comprises at least one pharmaceutically acceptable carrier.

9. A crystalline form of the compound of Formula I:



Formula I (Compound 1),

wherein the crystalline form is characterized by an X-ray powder diffraction (XPRD) pattern comprising approximate peak positions (degrees 2θ ± 0.2), when measured using Cu K_α radiation, of 9.6, 15.2, 18.0, 19.4, 23.0, and 31.4, when the XPRD is collected from about 2 to about 42 degrees 2θ.

10. The crystalline form of claim 9, wherein the crystalline form is characterized by an XPRD pattern comprising approximate peak positions (degrees 2θ ± 0.2) of 9.6, 15.2, 15.8, 17.5, 18.0, 19.4, 21.9, 23.0, 24.5, 25.1, 26.4, and 31.4.

11. The crystalline form of claim 9, for use in treating painful diabetic neuropathy or post-surgical pain.