

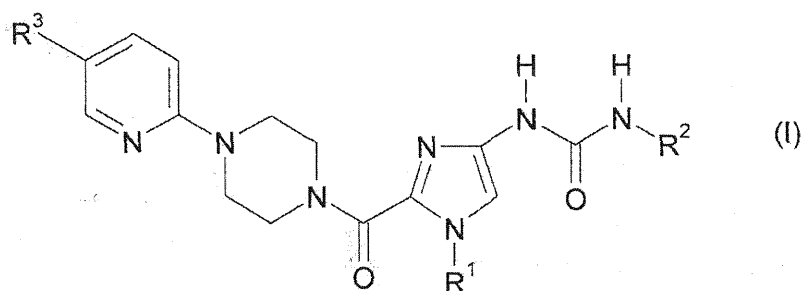
[0003] The compounds of Formula (I) are known from, e.g., WO 2006/089664 and were developed by the applicant as promising candidates for antivirally effective substances, in particular for combating infections with the human cytomegalovirus (HCMV). In development, it has been shown, however, that the substances in aqueous solvents as well as strongly polar solvents showed an inadequate solubility. The problems with respect to the solubility were still further intensified in that the compounds also showed inadequate solubility under the conditions existing in the human stomach (approximately 0.1 M HCl, pH ~ 1), in which the process can be started from the *in-situ* formation of an HCl salt.

SUMMARY

[0004] It is thus an object of the invention to describe salts that show a considerably improved solubility in comparison to the free base of the compounds of Formula (I). Further, these salts should also be stable over the long term under the usual storage conditions. In particular, the compounds should not show any elevated hygroscopy. Also, the salts in the presence of a dilute HCl solution should be converted only slowly into the HCl salt in order to ensure as quick and uniform a release as possible even under conditions as are present in the human stomach.

[0005] Surprisingly enough, it was discovered that the organic sulfonic acid salts of the compounds of Formula (I) show a superior solubility in comparison to the free base, as well as a broad spectrum of other salts of the compounds of Formula (I). Further, these salts also show the long-term stability that is necessary for use in medications. In addition, it has been shown that the salts according to the invention also show a high and uniform solubility under conditions that correspond to those in the human stomach.

[0005a] In a first aspect, there is provided a salt of a compound of the formula



in which

R^1 stands for methyl, ethyl, butyl, or cyclopropylmethyl,

R^2 stands for phenyl, whereby phenyl is substituted with a substituent that is selected from the group that consists of trifluoromethoxy and difluoromethoxy, and

R^3 stands for hydrogen, methyl, chlorine, methoxy, or trifluoromethyl,

with an organic sulfonic acid or a solvate or hydrate thereof.

[0005b] In a second aspect, there is provided a crystalline N-(1-methyl-2-{[4-(5-methylpyridin-2-yl)piperazin-1-yl]-carbonyl}-1*H*-imidazol-4-yl)-N'-[4-trifluoromethoxyphenyl]urea dimesylate, wherein the powder-XRD diffractogram shows characteristic peaks at approximately 6.37, 11.77, 12.56, 17.17, 18.81, 20.34, 21.47, 23.04, and 35.46 degrees 2theta.

[0005c] In a third aspect, there is provided a crystalline N-(1-methyl-2-{[4-(5-methylpyridin-2-yl)piperazin-1-yl]-carbonyl}-1*H*-imidazol-4-yl)-N'-[4-trifluoromethoxyphenyl]urea dimesylate, characterized by a powder-XRD diffractogram as essentially depicted in Fig. 1.

[0005d] In a fourth aspect, there is provided a method for the production of a salt of the compounds of Formula (I) as disclosed herein, which comprises the reaction of a compound of Formula (I) or an acid salt of a compound of Formula (I), which is not a salt of an organic sulfonic acid, with an organic sulfonic acid or a source of organic sulfonate ions in a solvent.

[0005e] In a fifth aspect, there is provided a salt as disclosed herein for use in a method for the treatment and/or prevention of diseases, in particular viral infections, preferably infections with HCMV or another representative of the group Herpesviridae.

[0005f] In a sixth aspect, there is provided a pharmaceutical agent that contains a salt as disclosed herein in combination with at least one inert, non-toxic, pharmaceutically suitable adjuvant.

[0005g] In a seventh aspect, there is provided the use of a salt as disclosed herein for the production of a pharmaceutical agent for the treatment and/or prevention of viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.

[0005h] In an eighth aspect, there is provided a pharmaceutical agent as disclosed herein for use in a method for the treatment and/or prevention of viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.

[0005i] In a ninth aspect, there is provided the use of a pharmaceutical agent as disclosed herein for the production of a medicament for the treatment and/or prevention of viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.

DETAILED DESCRIPTION

~~12. Use of a salt according to one of Claims 1 to 6 in a method for the treatment and/or prevention of diseases, in particular viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.~~

123. Pharmaceutical agent according to Claim 9 or 10 for use in a method for the treatment and/or prevention of viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.

~~14. Method for combating viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae, in humans and animals, which comprises the administration of an antivirally effective amount of at least one salt according to one of Claims 1 to 6, a pharmaceutical agent according to Claim 9 or 10, or a pharmaceutical agent obtained according to Claim 11 or 12 to a human or an animal, who (which) requires such a treatment.~~

13. Use of a pharmaceutical agent according to Claim 9 or 10 for the production of a medicament for the treatment and/or prevention of viral infections, preferably infections with HCMV, or another representative of the group Herpesviridae.