

[Document Name]Patent Claims

[Claim 1]

Crystalline 1:1 tranilast N-methylglucamine Form I salt.

[Claim 2]

A powder X-ray diffraction pattern having at least four peaks selected from 7.3, 8.4, 9.7, 12.2, 14.4 and a peak at  $16.2^{\circ} \pm 0.2^{\circ}$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 1, or an infrared spectrum having at least four peaks selected from 1662, 1589, 1507, 1423, 1378, 1272 and  $1244 \text{ cm}^{-1} \pm 1 \text{ cm}^{-1}$ ; Or an infrared spectrum substantially similar to FIG. 4. A crystalline 1:1 tranilast N-methylglucamine Form I salt.

[Claim 3]

Crystalline 1:1 tranilast N-methylglucamine Form II salt.

[Claim 4]

A powder X-ray diffraction pattern having at least four peaks selected from 10.8, 14.0, 14.6, 15.2, 15.9, 16.7 and a peak at  $18.9^{\circ} \pm 0.2^{\circ}$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 6, or an infrared spectrum having at least four peaks selected from 1655, 1585, 1519, 1417, 1377, 1301 and  $1258 \text{ cm}^{-1} \pm 1 \text{ cm}^{-1}$ ; Or an infrared spectrum substantially similar to FIG. 9. The crystalline 1:1 tranilast N-methylglucamine Form II salt of claim 1, wherein:

[Claim 5]

Crystalline 1:1 tranilast L-lysine salt.

[Claim 6]

A powder X-ray diffraction pattern having at least four peaks selected from 11.8, 12.3, 15.1, 16.0, 18.5, 20.9 and a peak at  $21.5^{\circ} \pm 0.2^{\circ}$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 11, or an infrared spectrum having at least four peaks selected from 1670, 1584, 1493, 1371, 1277, 1254 and  $1135 \text{ cm}^{-1} \pm 1 \text{ cm}^{-1}$ ; Or an infrared spectrum substantially similar to FIG. 14. A crystalline 1:1 tranilast L-lysine salt, comprising:

[Claim 7]

Crystalline 1:1 tranilast diethylamine salt.

[Claim 8]

A powder X-ray diffraction pattern having at least four peaks selected from 7.6, 12.7, 13.2, 14.5, 16.6, 18.0 and a peak at  $20.0^{\circ} \pm 0.2^{\circ}$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 15, or an infrared spectrum

having at least four peaks selected from 1669, 1618, 1579, 1495, 1419, 1361 and 1155 $\text{cm}^{-1} \pm 1\text{cm}^{-1}$ ; Or an infrared spectrum substantially similar to FIG. 18. A crystalline 1:1 tranilast diethylamine salt, comprising:

[Claim 9]

Crystalline 1:1 tranilast N-ethylglucamine salt.

[Claim 10]

A powder X-ray diffraction pattern having at least four peaks selected from 6.9, 11.1, 13.8, 15.2, 16.1, 16.8 and a peak at  $18.2^\circ \pm 0.2^\circ$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 19, or an infrared spectrum having at least four peaks selected from 1660, 1589, 1423, 1374, 1295, 1273 and 1244 $\text{cm}^{-1} \pm 1\text{cm}^{-1}$ ; Or an infrared spectrum substantially similar to FIG. 22. The crystalline 1:1 tranilast N-ethylglucamine salt of claim 1, wherein:

[Claim 11]

Crystalline 1:1 tranilast potassium monohydrate salt.

[Claim 12]

A powder X-ray diffraction pattern having at least four peaks selected from a peak at 7.9, 10.6, 11.7, 14.9, 17.0, 19.8 and  $20.61^\circ \pm 0.2^\circ$ , a powder X-ray diffraction pattern substantially similar to Figure 23, or a 100K / c space group at a temperature of about 295K or P21; Or an infrared spectrum having at least four peaks selected from 1670, 1583, 1492, 1422, 1370, 1155 and 1127 $\text{cm}^{-1} \pm 1\text{cm}^{-1}$ , or an infrared spectrum substantially similar to FIG. 29.

[Claim 13]

Crystalline 1:1 tranilast diethanolamine salt.

[Claim 14]

A powder X-ray diffraction pattern having at least four peaks selected from 7.5, 11.8, 12.5, 16.8, 18.5, 19.1 and a peak at  $19.9^\circ \pm 0.2^\circ$ ; Or a powder X-ray diffraction pattern substantially similar to Figure 30, or an infrared spectrum having at least four peaks selected from 1652, 1494, 1422, 1363, 1346, 1266 and 1233 $\text{cm}^{-1} \pm 1\text{cm}^{-1}$ ; Or an infrared spectrum substantially similar to Figure 33. A crystalline 1:1 tranilast diethanolamine salt, characterized by at least one of:

[Claim 15]

Crystalline 1:1 tranilast ethanolamine salt.

[Claim 16]

A powder X-ray diffraction pattern having at least four peaks selected from a 10.4, 11.4, 12.2, 14.5, 15.8, 19.5 and a peak at  $20.4^\circ \pm 0.2^\circ$ , a powder X-ray diffraction pattern substantially similar to FIG. 34, or a 293K / c space group at a temperature of about P21; Or an infrared spectrum having at least four peaks selected from 1668, 1585, 1375, 1359, 1277, 1255 and 1131 $\text{cm}^{-1} \pm 1\text{cm}^{-1}$ ; or an infrared

spectrum substantially similar to FIG. 39.

[Claim 17]

A pharmaceutical composition comprising the crystalline tranilast salt of any one of claims 1 to 16 and a pharmaceutically acceptable carrier.

[Claim 18]

The pharmaceutical composition of claim 17, wherein the composition is a topical formulation.

[Claim 19]

The pharmaceutical composition of claim 17, wherein the composition is an inhalable formulation.

[Claim 20]

A process for preparing a liquid pharmaceutical composition comprising dissolving the crystalline tranilast salt according to any one of claims 1 to 16 in a pharmaceutically acceptable solvent.

[Claim 21]

A liquid pharmaceutical composition prepared by the method of claim 20.

[Claim 22]

A method of treating an allergic, fibrotic or inflammatory disorder comprising administering to a patient in need thereof a therapeutically effective amount of a crystalline tranilast salt according to any one of claims 1 to 16 or a pharmaceutical composition according to any one of claims 17 to 19 and 21.

[Claim 23]

A method of inhibiting tumor growth and metastasis comprising the step of administering a therapeutically effective amount of the crystalline tranilast salt according to any one of claims 1 to 16 or the pharmaceutical composition according to any one of claims 17 to 19 and 21 to a patient in need thereof.

[Claim 24]

Use of a crystalline tranilast salt according to any one of claims 1 to 16 for the preparation of a liquid pharmaceutical composition by dissolution in a pharmaceutically acceptable solvent.