(54) **CRYSTALLINE FORM OF LAMIVUDINE**

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A61K 31/70   (2006.01)
C07D 239/00   (2006.01)
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(52) **U.S. Cl.** **514/50**; 544/242; 514/247
(58) **Field of Classification Search** .... None
See application file for complete search history.

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(57) **ABSTRACT**

The disclosure herein relates to a new Lamivudine polymorphic form, methods of making the same, and pharmaceutical formulations thereof. A (−) cis-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one in the form of monoclinic crystals has characteristic powder X-ray diffractogram, as disclosed herein, is disclosed along with a process for preparation of the same. A pharmaceutical composition in solid dosage unit form comprising a therapeutically effective amount of a new Lamivudine polymorphic form in combination with a pharmaceutically acceptable carrier is also disclosed along with a pharmaceutical composition useful for treating HIV infections in humans.
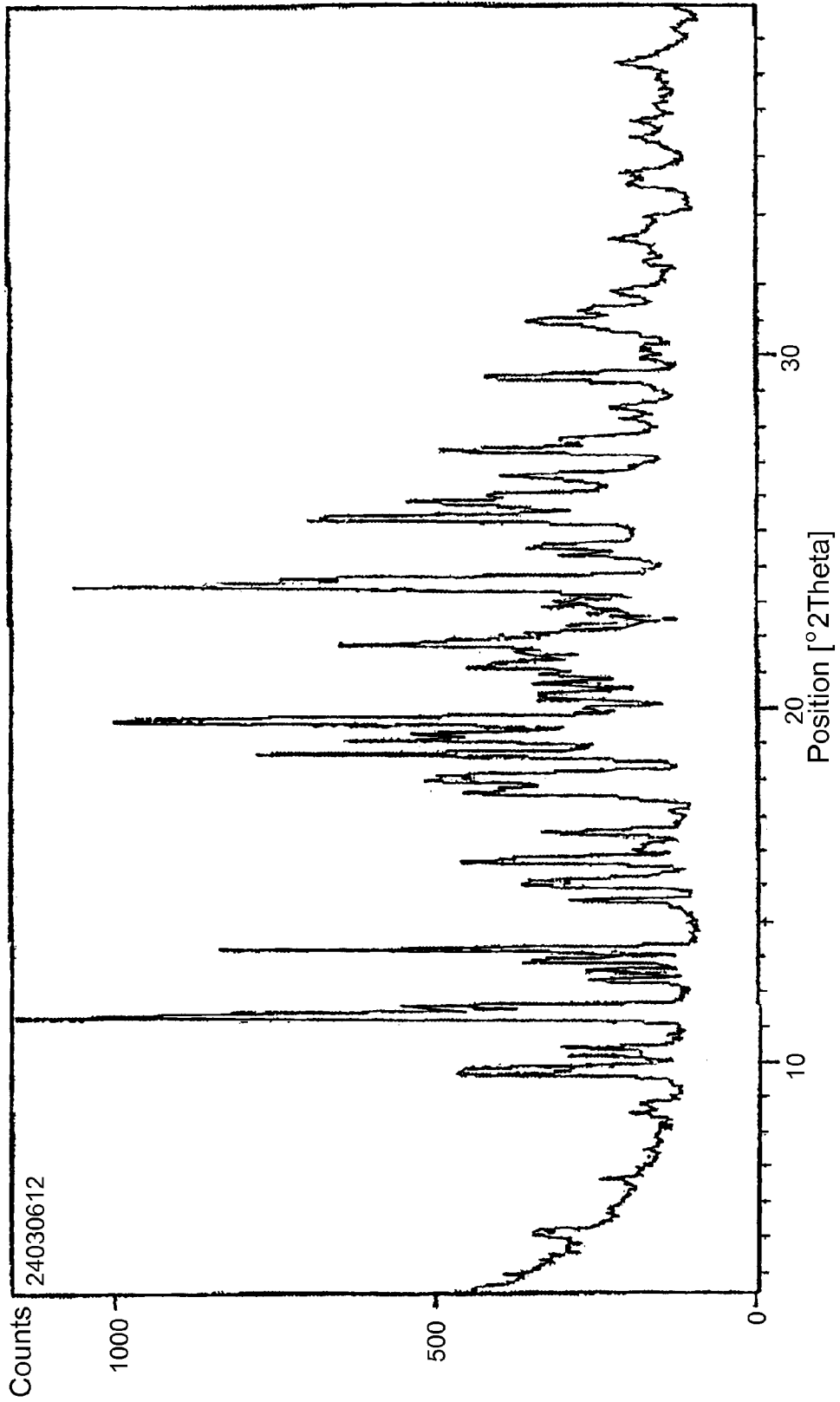
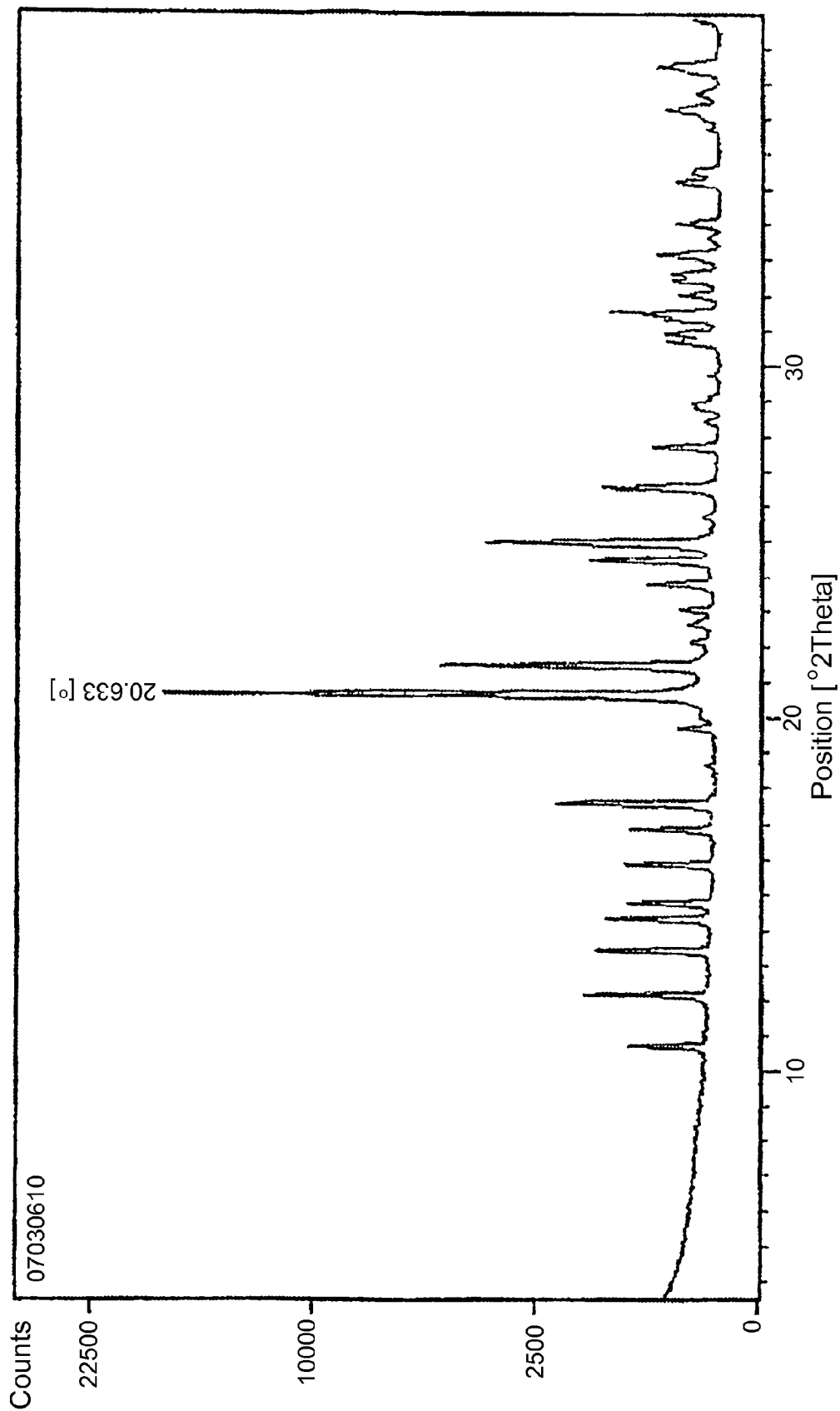**39 Claims, 16 Drawing Sheets**

FIG. 1

FIG. 2

07030610

20.633 [°]

Counts

22500

10000

2500

0

10

20

30

Position [°2Theta]

FIG. 3

FIG. 4

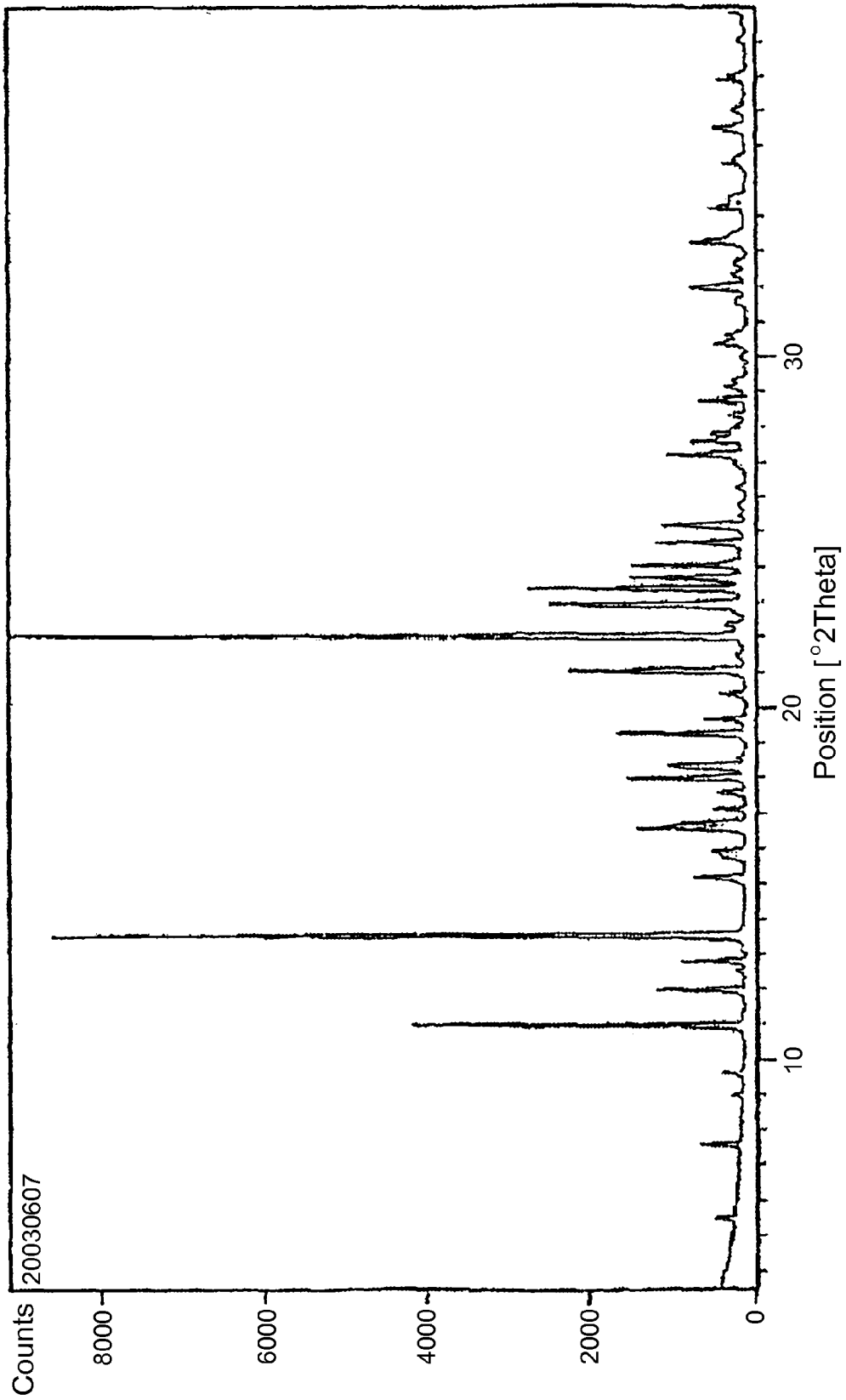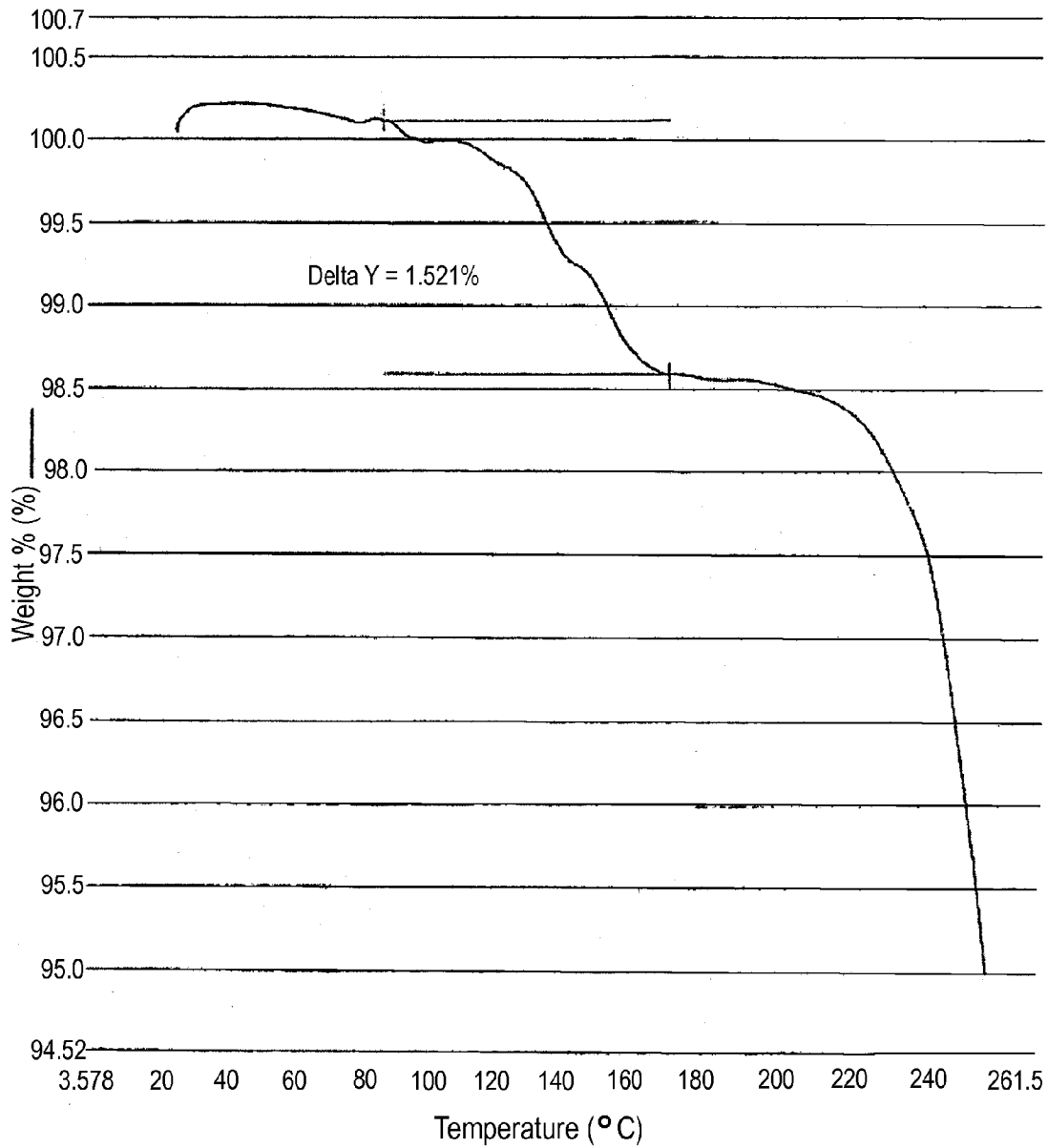Plot of Weight % (%) versus Temperature (°C). Delta Y = 1.521%

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