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(54) Title: NOVEL PHARMACEUTICAL COMPOSITIONS OF URIDINE TRIPHOSPHATE

(57) Abstract

Novel pharmaceutical compositions of uridine 5'–triphosphate (UTP) for use in promoting increased mucociliary clearance of retained mucous secretions of the human airways, middle/inner ears or sinuses are disclosed. Novel Formulation (I) comprises UTP and aqueous solution having a therapeutic concentration between 5 and 45 mg/mL, a controlled tonicity within the range of 250 to 100 mOsM, a pH between 7.0 and 7.5, and is sterile. The pH–adjusted composition is capable of long–term storage in the refrigerated state with a shelf life of up to 30 months. Formulation (I) may be delivered therapeutically either in a nebulized form or in a liquid form. Novel Formulation (II) comprises UTP in an aqueous solution having a therapeutic concentration approaching the limit of UTP's solubility at ambient temperature or in a suspension which exceeds drug solubility. This high concentration allows delivery of a therapeutic amount of UTP in very small volumes (50 to 100 μL) suitable for administration via portable hand–held devices such as metered dose inhalers. Formulation (II) has extended shelf life without the need for refrigeration after being dispensed to the patient.