

GLYCOLS AS PATHOGEN INACTIVATING AGENTS

FIELD OF THE INVENTION

The present disclosure relates to uses, methods and compositions for the inactivation of pathogens in biological compositions.

BACKGROUND OF THE INVENTION

Use of biological compositions is important for developing and producing therapeutics (*e.g.*, the production of recombinant proteins). Biological compositions, such as blood compositions, save many lives by blood transfusion for instance, for patients having a blood disease, a haemorrhage, or undergoing a surgical procedure. However, the presence of pathogens in biological compositions presents a significant health risk.

Methods to inactivate pathogens in biological compositions have been developed. Classical pathogen inactivation methods include approaches based on heat treatment, solvent and/or detergent treatment, gamma irradiation, UV treatment, and leukodepletion. However, the efficiency and effectiveness of said methods varies because of the different sensitivities of pathogens and incompatibility of some methods with specific biological compositions.

There is a need for new pathogen inactivation methods and agents.

SUMMARY OF THE INVENTION

The present disclosure relates to uses, methods, agents and compositions for the inactivation of pathogens in biological compositions.

In a first aspect, the present invention refers to the use of a glycol as a pathogen inactivating agent in a biological composition, wherein the biological composition is selected from a group consisting of a blood composition, a milk composition, urine, sweat, sputum, feces, spinal fluid, and cellular or tissue extracts.

In a second aspect, the present invention refers to an in vitro method for inactivating a pathogen in a biological composition, said method comprising contacting said biological

composition with a glycol, wherein the biological composition is selected from a group consisting of a blood composition, a milk composition, urine, sweat, sputum, feces, spinal fluid, and cellular or tissue extracts.

In a third aspect, the present invention refers to a biological composition comprising glycol obtained by any of the methods of the present invention.

In one example~~aspect~~ the disclosure relates to the use of a glycol as a pathogen inactivating agent. In some example~~embodiments~~ the glycol is propylene glycol.

In one example~~aspect~~ the disclosure relates to methods for inactivating a pathogen in a biological composition, said method comprising contacting said biological composition

with a glycol. In some embodimentsexamples for inactivating a pathogen in a biological composition, the glycol is propylene glycol. In some embodimentsexamples for inactivating a pathogen in a biological composition, said biological composition is a blood composition or a milk composition. In some embodimentsexamples for inactivating a pathogen in a biological composition, said pathogen is selected from the group consisting of viruses, bacteria, fungi, protozoa, parasites, and prions. In some embodimentsexamples said virus is selected from the group consisting of X-MuLV, PRV, BVDV and TGEV virus. In some embodimentsexamples for inactivating a pathogen in a biological composition, said method results in a pathogen elimination equal or greater than $4\text{Log}_{10}\text{TCID}$ (Tissue Culture Infective Dose) according to the methods of Kärber and/or Spearman-Kärber. In some embodimentsexamples for inactivating a pathogen in a biological composition, the concentration of glycol after the contacting step is between 40 and 50% (w/w) of the biological composition. In some embodimentsexamples for inactivating a pathogen in a biological composition, the concentration of glycol after the contacting step is between 40 and 50% (v/v) of the biological composition. In some embodimentsexamples for inactivating a pathogen in a biological composition, said method is performed at a temperature between 15 and 25°C. In some embodimentsexamples for inactivating a pathogen in a biological composition, said method is performed at a pH between 7.0 and 8.0.

In one exampleaspect the disclosure relates to a biological composition comprising a glycol, wherein said biological composition is obtained by any of the methods described herein. In some embodimentsexamples said glycol is at a concentration between 40 and 50%. In some embodimentsexamples said glycol is propylene glycol. In some embodimentsexamples the biological composition is a milk composition or a blood composition.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings form part of the present specification and are included to further demonstrate certain aspects of the present disclosure. The disclosure may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein. The figures are illustrative only and are not required for enablement of the disclosure.

Figure 1 shows TEGV inactivation in an affinity chromatography eluate