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ACTION

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(54) Title: STERILE LYOPHILIZED IFOSFAMIDE AND ASSOCIATED METHODS

(57) Abstract: The present invention provides a stable, sterile, pharmaceutical product that consists essentially of lyophilized ifosfamide and solutions thereof. The lyophilized ifosfamide of the present invention is suitable for pharmaceutical use, and can be stored in one or more aseptically sealed containers. The present invention further provides a method of ifosfamide and subjecting it to a primary drying stage. The primary drying stage includes applying a vacuum to remove solvent while raising the temperature to a primary drying temperature, to produce a first intermediate. The first intermediate is subjected to a secondary drying stage, which includes applying a vacuum to further remove solvent while raising the temperature to a secondary drying temperature, to produce the pharmaceutical product. The method of the present invention can be applied toward the production of stable, sterile, essentially pure dosage forms of ifosfamide (e.g., a sterile single-dose ifosfamide product) with doses that are within about 5 % of the label claim. The lyophilized ifosfamide of the present invention can be administered to a patient using standard therapeutic methods for delivering ifosfamide.