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ACTION

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(54) Title: METHOD FOR PRODUCING PURIFIED HEMATINIC IRON-SACCHARIDIC COMPLEX AND PRODUCT PRO-
DUCED

(57) Abstract: A method for separating and purifying the active hematinic species present in iron-saccharidic complexes comprising sodium ferric gluconate complex in sucrose, ferric hydroxide-sucrose complex and ferric saccharate complex and others of similar form and function, based on separation of the iron-saccharidic complex from one or more excipients and, preferably, lyophilization. Separation of the iron-saccharidic complex permits its analytical quantification; further concentration or purification as a new and useful product; preparation of redesigned formulations for new and useful pharmaceuticals; and/or lyophilization. The ability to separate the iron-saccharidic complex responsible for hematinic function, including its lyophilized form, also provides a means for preparing analytical material to verify and validate its pharmacological integrity, patient safety and clinical performance, as well as analytical monitoring, standardization and quality control inspection over hematinic manufacturing processes and establishment of standards for use therewith.