avoid previous impurities and/or to increase the yield of the ferric hydroxypyrone and/or to reduce the overall amount of solvent required for the reaction.

In a first aspect of the disclosure, there is provided a method of forming an iron hydroxypyrone compound comprising reacting a hydroxypyrone with a non-carboxylate iron salt in an aqueous solution and precipitating the iron hydroxypyrone compound from the aqueous solution having a pH of greater than 7, wherein the precipitated iron hydroxypyrone compound is separated and collected from the solution.

In a first embodiment~~aspect~~ of the disclosure~~invention~~, there is provided a method of forming an iron hydroxypyrone compound comprising reacting a hydroxypyrone with a non-carboxylate iron salt in an aqueous solution, and precipitating the iron hydroxypyrone compound from the aqueous solution and/or, preferably optionally, the aqueous solution has a pH of greater than 7, preferably a final pH greater than 7.

In a second embodiment~~aspect~~ of the disclosure~~invention~~, there is provided a method of forming an iron hydroxypyrone compound comprising reacting a hydroxypyrone with a non-carboxylate iron salt in an aqueous solution at a pH greater than 7 and precipitating the iron hydroxypyrone from the aqueous solution, wherein, optionally, the method does not comprise the use of an organic solvent and/or the solution does not comprise a buffer.

In a third embodiment~~aspect~~ of the disclosure~~invention~~, there is provided a method of forming an iron hydroxypyrone compound comprising reacting a hydroxypyrone in an aqueous alkaline solution with a non-carboxylate iron salt, or a mixture of a hydroxypyrone and a non-carboxylate iron salt, wherein the salt or mixture is added to the aqueous alkaline solution and, optionally, precipitating the iron hydroxypyrone from the aqueous alkaline solution.

In a fourth embodiment~~aspect~~ of the disclosure~~invention~~, there is provided a method of forming an iron hydroxypyrone compound comprising reacting an aqueous solution of a hydroxypyrone having a temperature of greater than 40°C to 100°C, with a non-carboxylate iron salt and, optionally, adding further hydroxypyrone and/or, optionally, precipitating the iron hydroxypyrone from the aqueous solution.

In a fifth embodimentaspect of the disclosureinvention, there is provided a method of forming an iron hydroxypyrone compound comprising reacting an aqueous solution of a hydroxypyrone having a temperature of greater than 40°C to 100°C with a non-carboxylate iron salt, optionally cooling, and reacting the solution with an aqueous alkaline solution comprising a hydroxypyrone and, optionally, precipitating the iron hydroxypyrone from the aqueous alkaline solution.

In another embodimentaspect of the disclosureinvention, there is provided a method of forming an iron hydroxypyrone compound comprising reacting a hydroxypyrone with a non-carboxylate

iron salt in an aqueous solution and precipitating the iron hydroxypyrone compound from the aqueous solution having a pH of greater than 7 or lower than or equal to 7 such as defined herein. Optionally, when the pH is lower than or equal to 7, as defined herein, the solution does not comprise a buffer as defined herein and/or the molar ratio of hydroxypyrone to iron salt used is greater than 3:1, such as 3.1:1, 3.5:1, 4:1 or higher.

In a secondsixth aspect of the disclosureinvention, there is provided a pharmaceutical composition comprising an iron hydroxypyrone compound and an iron hydroxide. The pharmaceutical composition is generally suitable for administration to a subject, such as a mammal, for example a human. The route of administration is typically oral.

In a third aspect, there is provided a composition as defined above, for use in medicine.

In a fourth aspect, there is provided a composition as defined above, for use in treating and/or preventing anaemia, or for increasing the level of iron in a subject's bloodstream.

In a fifth aspect, there is provided the use of the composition as defined above in the manufacture of a medicament for treating and/or preventing anaemia, or for increasing the level of iron in a subject's bloodstream.

The present disclosureinvention provides methods in which the iron hydroxypyrone, such as ferric trimaltol, can be precipitated from an aqueous solution or an aqueous alkaline solution. Furthermore, the non-carboxylate iron compound as a starting material can yield a sodium or potassium salt of high solubility to enable easy removal from the final product in the aqueous environment. The sodium or potassium salt may also be non-toxic, e.g chloride.

The method of the disclosureinvention can avoid the formation of black deposits and gums consisting of ferric chloride/ferric hydroxide polymers, as well as non-red precipitates, and mixed iron hydroxy and chloride species, such as, for example, $Fe(OH)_2$ (Maltol) and Fe (OH) $(Maltol)_2$.

In one embodiment, the disclosureinvention provides a method of forming an iron hydroxypyrone compound wherein iron hydroxide, such as ferric hydroxide, is present in an amount of less than or equal to about 10 wt.% based on the weight of the iron

hydroxypyrone compound, such as less than or equal to about 5 wt.% or about 2 wt.%.

In one embodiment of the disclosure~~invention~~, the iron hydroxypyrone compound is a pharmaceutically pure compound. For example, the iron hydroxypyrone compound may have a purity of greater than or equal to about 95, 96, 97, 98, 99 or 99.5 %. It is preferred that the iron hyrdoxypyrone compound which is precipitated or precipitated and isolated and, optionally, dried, has a purity of greater than or equal to about 95, 96, 97, 98, 99 or 99.5 %, preferably without further purification.

The term "precipitating" as used herein includes an active step of causing the iron hydroxypyrone to be precipitated by, for example, increasing the pH of the aqueous