

FDA some time back released a list which includes drug for Wilson's disease treatment named penicillamine which lacks the generic competition. The availability of the drug is very important as there are no alternatives for the treatment of Wilson's disease.

A brief update on the drug property

Penicillamine has a tendency to dimerised with own (dimer of Penicillamine) molecules in aqueous media as well as biological matrix. Also Penicillamine binds to cysteine in biological matrix. In body, Penicillamine converted in to Penicillamine-cysteine and Penicillamine disulfide. In body, major part of Penicillamine converted in to its metabolites and small portion remains as a free Penicillamine.



Challenges faced by the Industry to develop method for penicillamine.

A very important step in developing the method is to prevent dimerization of Penicillamine in solution as well as in biological matrix (used to prepare calibrators and QCs). The reason is Penicillamine is not stable at ambient temperature. It is required to add such buffer which can prevent dimerization of Penicillamine as well as it can prevent back conversion from Penicillamine metabolites to Penicillamine. The major challenge faced in the development of the method is its reproducibility an optimization.

The breakthrough to achieve precise and accurate method

Veeda team worked on the development to prevent dimerization and metabolism of Penicillamine. During re-optimization, different trials were taken to select such a buffer which would prevent dimerization of Penicillamine as well as prevent the back conversion of penicillamine disulfide and penicillamine-cysteine. After selecting a proper buffer for plasma samples, different experiments were done to check the both issue and no further problem was observed.

Using this new method, study sample analysis was carried out and 97.17% ISR samples were found within acceptance criteria. The new validated method for the estimation of penicillamine is suitable for assay of free penicillamine without causing dimerization of free penicillamine as well as without causing breakage of penicillamine metabolites to penicillamine with excellent incurred samples reanalysis reproducibility.

With the excellence and dedication of the team, Veeda have now in it's basket of method library - a robust, scientific and regulatory compliant method with a proven ISR reproducibility of more than 95%. We are glad to share the above success story with our clients and always welcome to get associated to with the industry on such developments in future.

About Veeda CR

Veeda CR is a Contract Research Organization committed to serve its customers with the Best-in-Class Scientific Expertise and Demonstrated Regulatory Compliance. Veeda CR is a trusted partner of choice for conduct of healthy Volunteer BA/BE studies, Patient based PK End-point and PD-End point studies.

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