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Formulation, Development, and Characterization of Lyophilized Para-Amino Salicylate Sodium Injection for an Effective Treatment for Multi-Drug Resistance-Tuberculosis

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Abstract : The purpose of this study was to the development and manufacture of stable lyophilized injection formulation of Para-Amino Salicylate sodium, a drug that used in the treatment of multi-drug resistance tuberculosis. The drug was unstable in the aqueous solution and it shows high impurity level. Lyophilization technique in the pharmaceutical industries used in the formulation of thermolabile and moisture sensitive drug. For the formulation purpose, initial drug-excipients compatibility study was conducted and on the basis of percentage impurity level, present excipients were selected. Drug- Excipients compatibility study result shows that sodium metabisulphite increases the percentage of impurity level found that 0.12%, 0.15%, 0.06%, 0.09%, where the composition of API with sodium sulphite and other excipients reduces the impurities level. For the development of an effective formulation that provides stable, less impure and improved physicochemical characteristic of the model, several formulation methodologies were adopted.Compatibility study with reconstitution fluids was conducted for formulation (F-I, & F-II), the result shows that reconstitution with 0.9% Sodium chloride& 5% Dextrose injections, the reconstituted solution becomes hypertonic, where water for injection gives an isotonic solution. Accelerated stability perusal result for related substance during time period of initial to 6th month stability result indicates formulation (F-I, 0.05%, 0.13%), (F-II, 0.08%, 0.16%), and assay percentage (F-I, 102.14%, 98.61%), (F-II, 100.49%, 96.27%). Related substance (impurity) and Assay result indicate that formulation F-I shows less impurity level and high assay percentage as compared to formulation F-II. Accelerated stability 6th-month result indicates that Para-Amino Salicylate Sodium lyophilized injection found to be physically and chemically stable.

Keywords: Lyophilized, Para-Amino Salicylate sodium, Thermolabile, Hypertonic, Isotonic.

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