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Stability assessment of vitamin B12 in mixed parenteral B complex formulations and in syringes prior to patient administration

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Background and Aims: Cyanocobalamin (B12) stability in mixed parenteral formulations and in syringes prior to patient administration has not been investigated yet. In this research the effect of vitamin B1 and B6 on cyanocobalamin stability in commercial parenteral formulations has been investigated.
Methods: In this research commercial formulations were tested by screening test followed by an accelerated stability evaluation according to ICH guidelines. The amount of remaining vitamin B12 was analyzed using a newly introduced HPLC method and data were fitted to common degradation kinetic models in aqueous systems. Stability of vitamin B12 was assessed in medical grade syringes when mixed with B complex formulations to simulate the condition occurs just before patient administration. Shelf lives of were calculated according to recent guidelines using Excel software.
Results: The results proved that vitamin B1 aqueous solutions were more stable than vitamin B6 aqueous solutions and combination of cyanocobalamin and vitamin B1 resulted in a remarkable destruction of vitamin B12 .All prepared and commercial formulations showed extensive B12 loss at 40°C. The results indicated zero order kinetic models for all tested formulations.
Conclusions: Although poor stability of cyanocobalamin was resulted in mixtures with thiamine and pyridoxine during their label expiration date but mixing B12 injections with B complex formulations in medical grade syringes showed no significant degradation after an 8 hour assessment using HPLC analysis.

Keywords: B1; B6; HPLC; Physicochemical control; Buffers; Degradation kinetic