

## Optimization of Anti-Rh D Immunoglobulin Stability in the Lyophilization Processes

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### Abstract

#### Objective

Anti-Rh D IgG is used for the prevention of anti-D antibody production in Rh<sup>-</sup> individuals who have been exposed to Rh<sup>+</sup> red blood cells. The stability of IgG preparations as a solution is low, with a shelf life of a year or more. Formulation of anti-Rh D IgG as a lyophilized preparation would decrease its degradation rate and increases its shelf life. The objective of this study was to formulate the anti-Rh D as a lyophilized preparation using different formulations and optimize the lyophilization processes.

#### Materials and Methods

The effect of various formulations on the stability of anti-Rh D was evaluated using accelerated stability test. In this method the amount of transmittance (T %) at 585 nm for the lyophilized preparations had inverse relationship with aggregation of anti-Rh D. To improve stability, the most stable formulation was selected and different concentrations of sucrose in the presence of sodium-potassium phosphate buffer 25 mM pH 7.5. Then, the bioactivity was determined, using the ELAT test and also, the amount of moisture measured in this formulation.

#### Results

Among different formulations, the one with anti-Rh D 5 mg/ml, tween 80 0.1%, glycine 0.15 M, manitol 7% and sucrose 60 mM in sodium-potassium phosphate buffer 25 mM pH 7.5 was the most stable formulation ( $P < 0.05$ ). The result of biological test of ELAT showed that bioactivity of more than 93% meets the requirement set by British Pharmacopoeia. The amount of moisture measured in this formulation was less than 3%.

#### Conclusion

It was concluded that this formulation could be introduced as a candidate for the formulation of anti-Rh D in a lyophilized dosage form.

**Keyword:** Anti-Rh D IgG, Bioactivity, Formulation, Lyophilization, Protein stability

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