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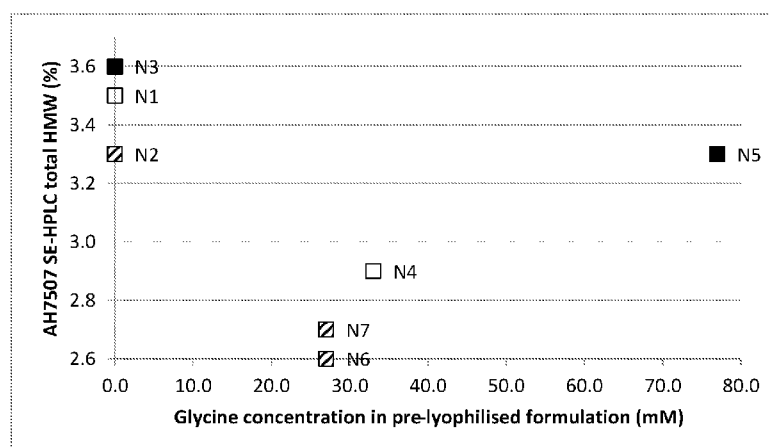
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(54) Title: IMPROVED FORMULATIONS OF RECOMBINANT HUMAN BILE SALT-STIMULATED LIPASE

Figure 8



(57) Abstract: The present invention relates to improved formulations of recombinant human bile salt stimulated lipase (rhBSSL), including those suitable for forming a lyophilized formulation of rhBSSL, lyophilized formulations of rhBSSL per-se, unit dose forms of rhBSSL and reconstituted formulations of rhBSSL. The formulations of the present invention comprises rhBSSL, a crystalline bulking agent and an amorphous stabilizer that is a different chemical entity to said crystalline bulking agent. The formulations of the present invention have one or more desired properties, including those that relate to stability, decreased aggregation and/or formation of insoluble aggregates in solution. The lyophilized formulations of the present invention have pharmaceutical utility, particularly for the administration of rhBSSL to human infants.