

Category :**Hematology: bleeding\transfusion**

A174 - Biochemical quality of octaplaslg frozen and freeze-dried products

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Introduction:

OctaplasLG[®] is a solvent/detergent-treated, coagulation active plasma product for treating complex coagulation factor deficiencies, such as coagulopathy due to severe hepatic failure or massive transfusion, and as a substitution therapy in coagulation factor deficiencies in situations where specific factor concentrates are not available, or in emergency situations where precise laboratory diagnosis is not possible. OctaplasLG[®] is supplied frozen; the thawed product is stable during refrigerated storage for up to 5 days. Recently, a new freeze-dried form was developed (OctaplasLG[®] Lyo) to further increase ease of logistics and utilization.

Methods:

Three OctaplasLG[®] Lyo batches for process performance qualification were manufactured at Octapharma AB, freeze-dried and reconstituted with sterilized water. Twelve batches of frozen OctaplasLG[®] were used for comparison; batches were assessed directly after thawing, as well as after storage of the thawed product at 2–8 °C for ≤6 days. All batches were assessed for global coagulation parameters, important coagulation factors and protease inhibitors, and activation markers of coagulation and fibrinolysis.

Results:

Frozen OctaplasLG[®] and freeze-dried OctaplasLG[®] Lyo demonstrate identical quality profiles upon thawing and reconstitution, respectively; all parameters were in line with levels mandated by the European Pharmacopoeia. In addition, OctaplasLG[®] Lyo exhibited comparable/higher quality for temperature-sensitive parameters, such as levels of factor V, factor VIII, and protein S, compared to thawed OctaplasLG[®] after 6 days refrigerated storage (Figure 1).

Conclusion:

OctaplasLG[®] frozen and freeze-dried products have equally high biochemical quality. The key features of the new freeze-dried version (OctaplasLG[®] Lyo) are the fast reconstitution time and flexibility of storage conditions (refrigerated/room temperature), which has advantages in emergency situations and in ex-hospital settings.

Image :

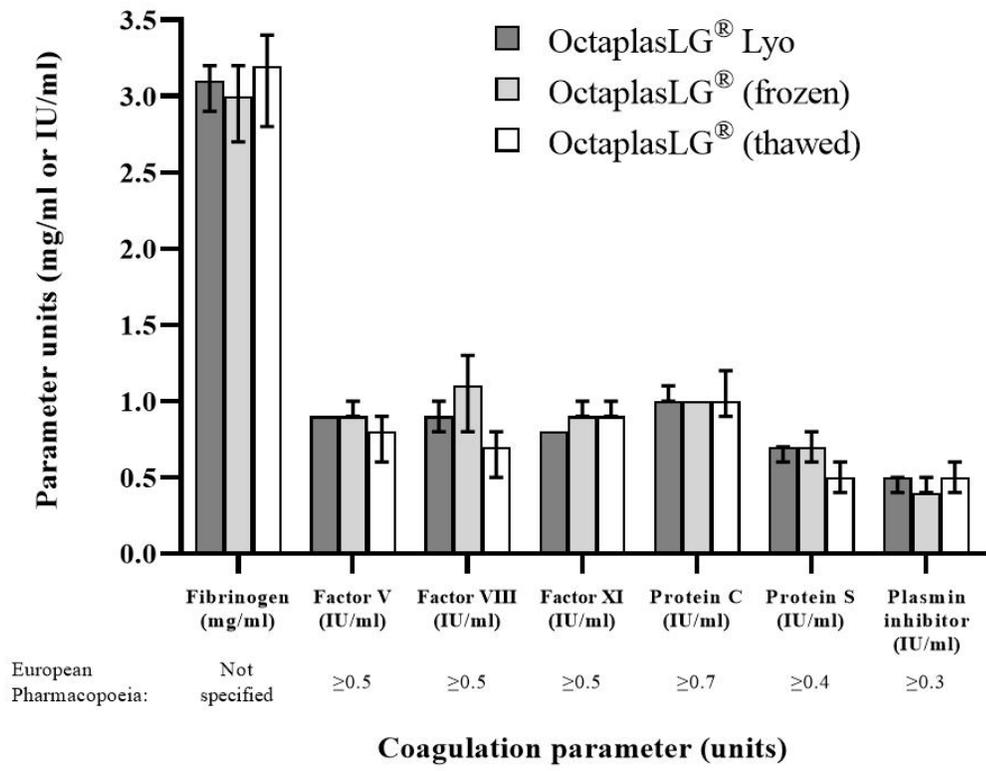


Figure 1. Quality of OctaplasLG[®] and OctaplasLG[®] Lyo products