

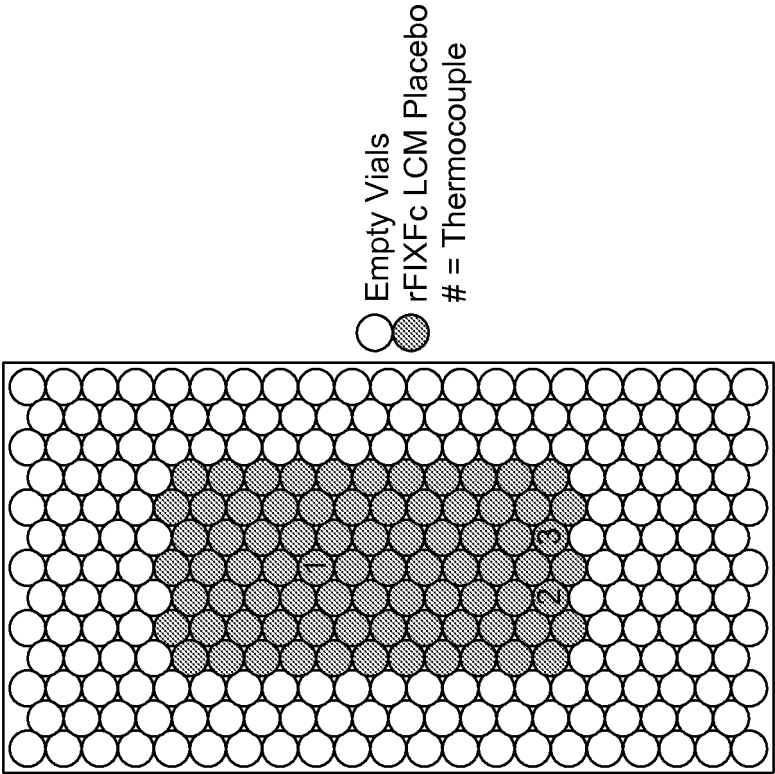


Fig. 1

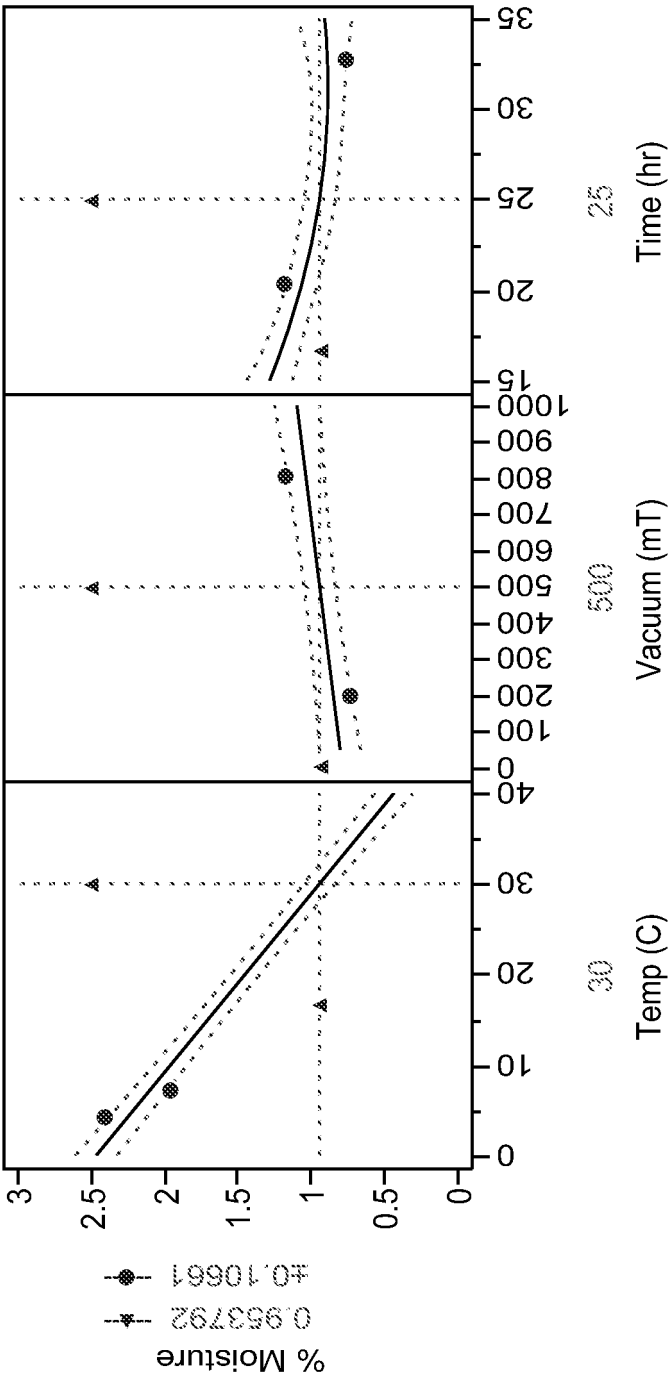


Fig. 2

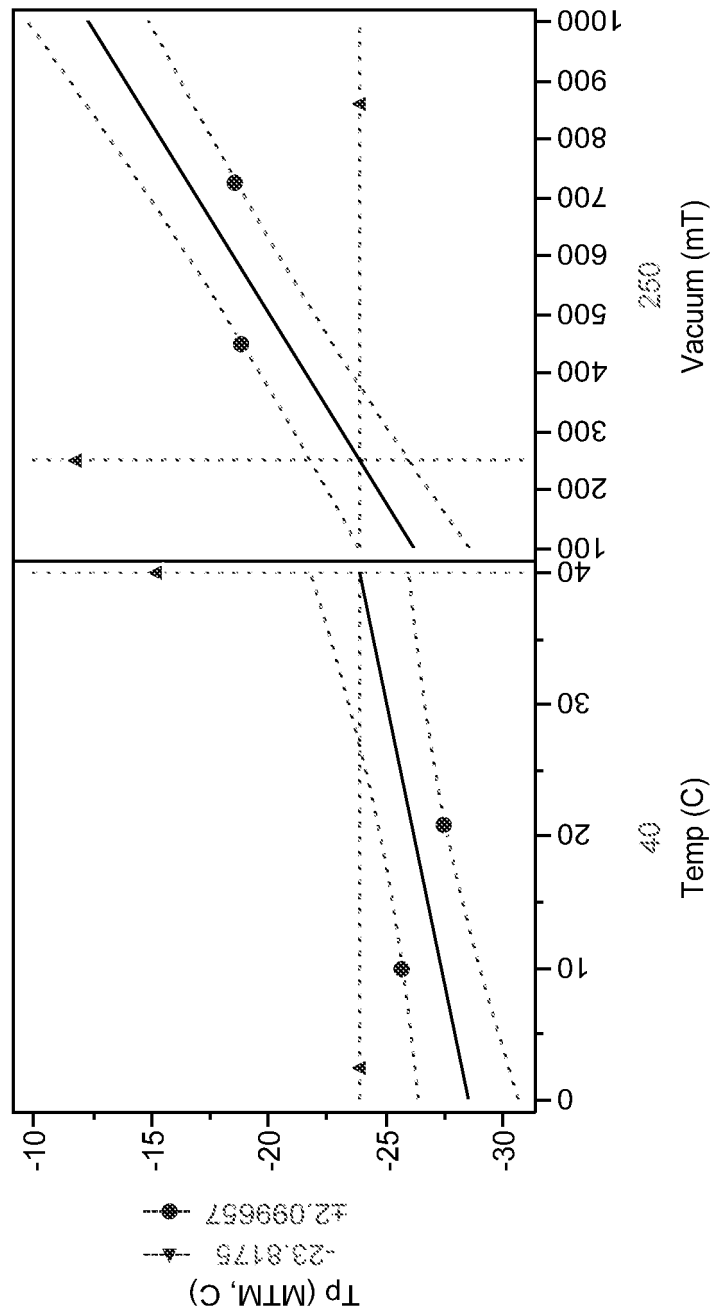


Fig. 3

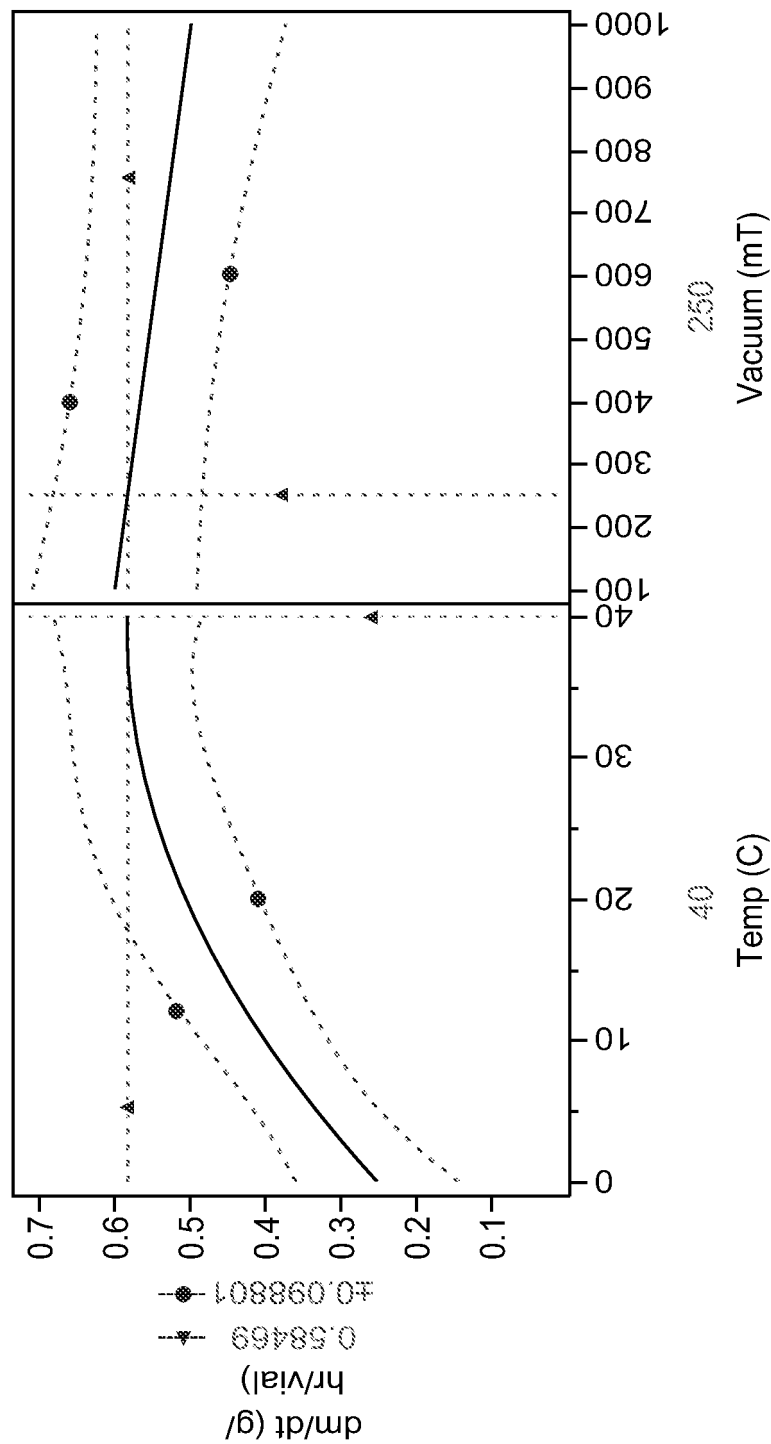


Fig. 4

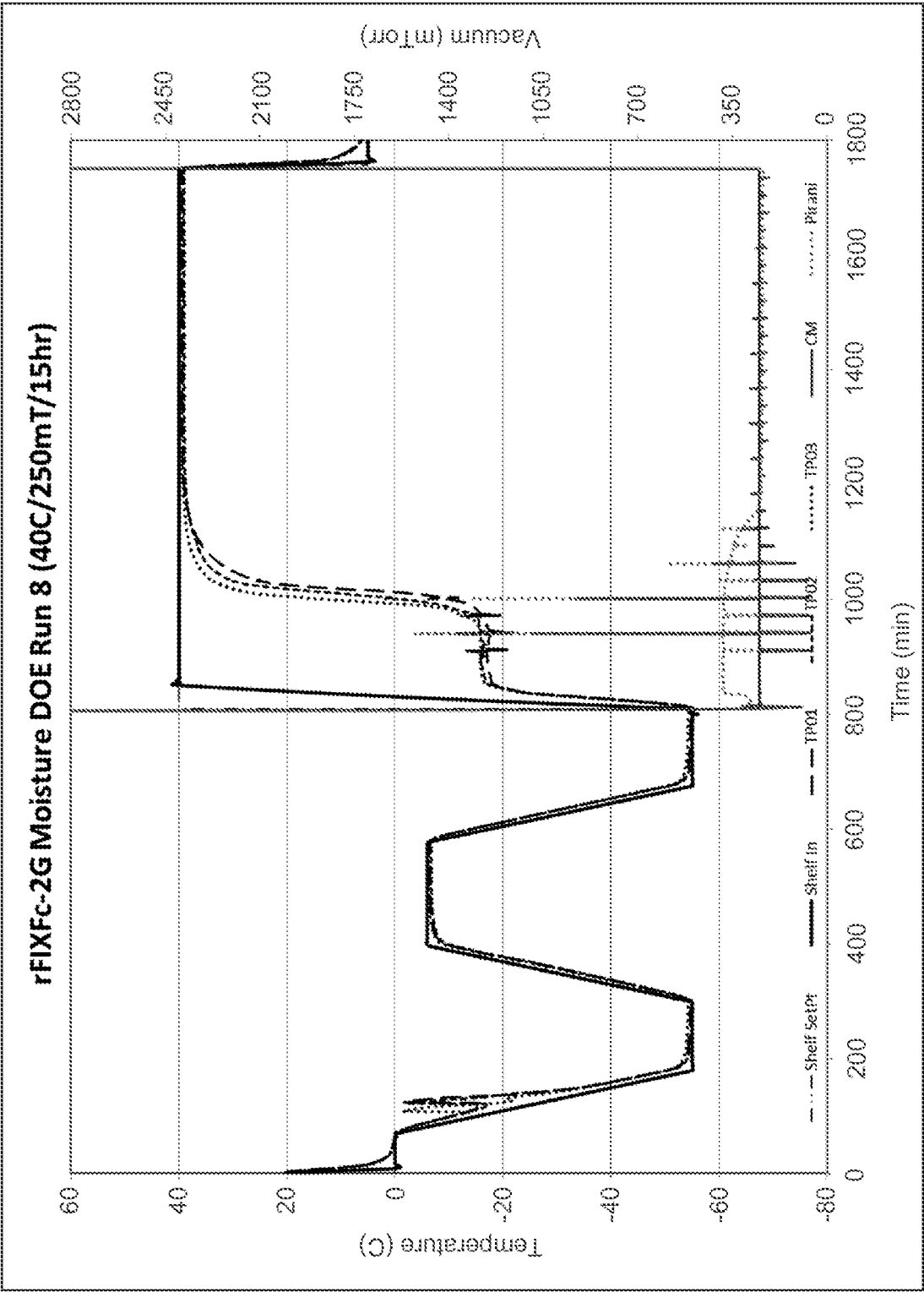


Fig. 5

WO 2015/148444

INTERNATIONAL SEARCH REPORT

PCT/US2015/022141

International application No.

PCT/US2015/022141

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-25, 29-42, 46-65, 69-87, 89-104
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

WO 2015/148444

INTERNATIONAL SEARCH REPORT

PCT/US2015/022141

International application No.

PCT/US2015/022141

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention provides, among other things, pre-lyophilization formulations, reconstituted formulations, and lyophilate powder compositions comprising a Factor IX (FIX) polypeptide. The present invention also provides lyophilization methods for producing lyophilate powder comprising a FIX polypeptide. The present invention is directed to a pre-lyophilization formulation comprising: (a) a Factor IX (FIX) polypeptide having FIX coagulation activity; (b) a buffering agent; (c) a stabilizing agent; (d) a bulking agent; and (e) a surfactant, wherein the formulation has a fill volume of less than about 5 mL, and wherein each of (a) - (e) are at an amount per vial (mg/vial) sufficient to allow (1) improved stability of the FIX polypeptide when lyophilized.