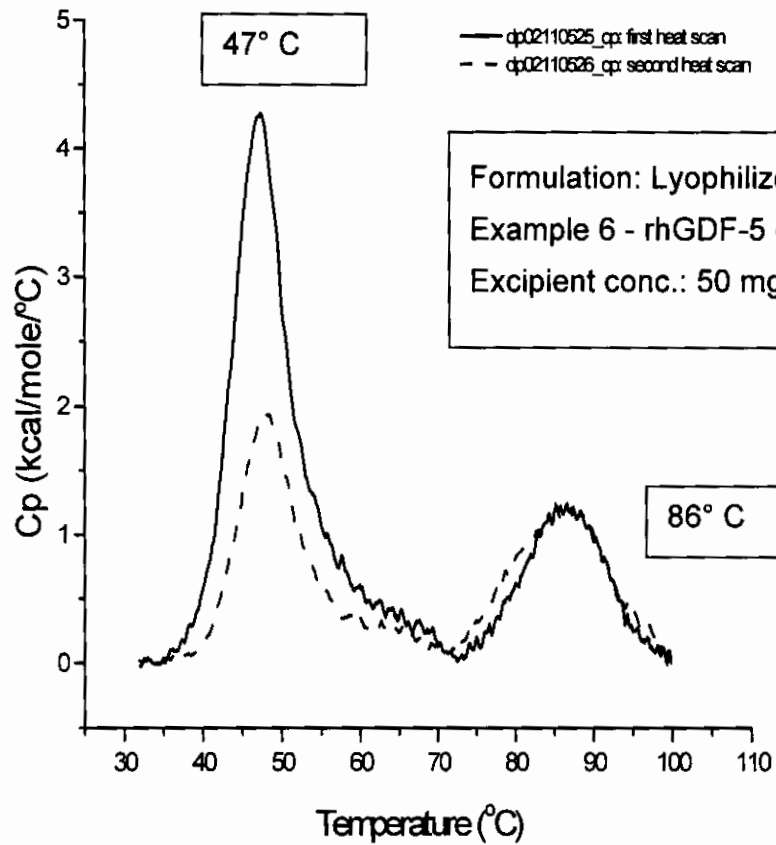
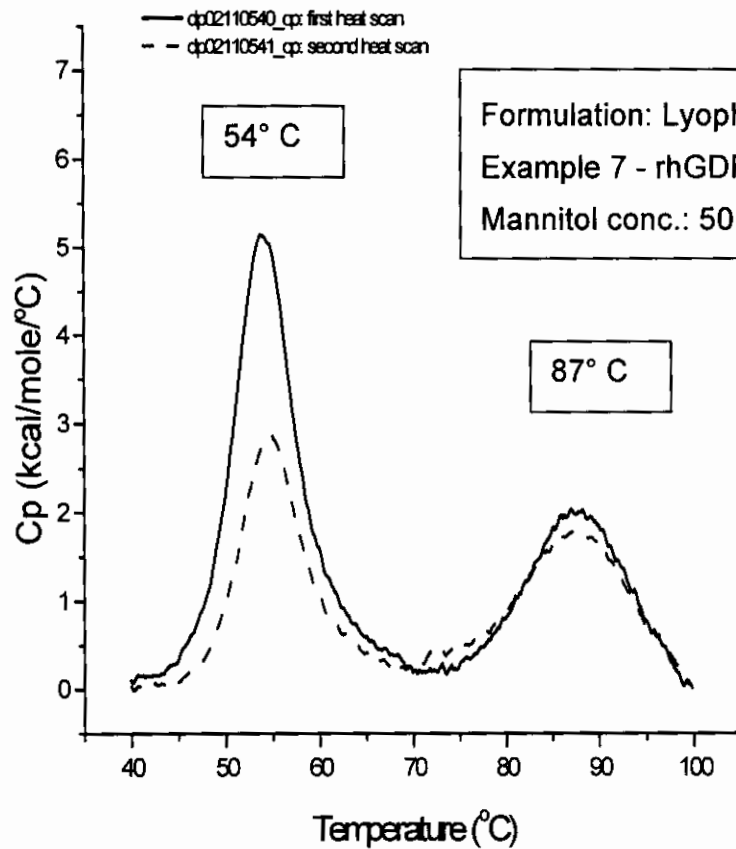


Figure 1: DSC profile of rhGDF-5 /trehalose formulation, example 6



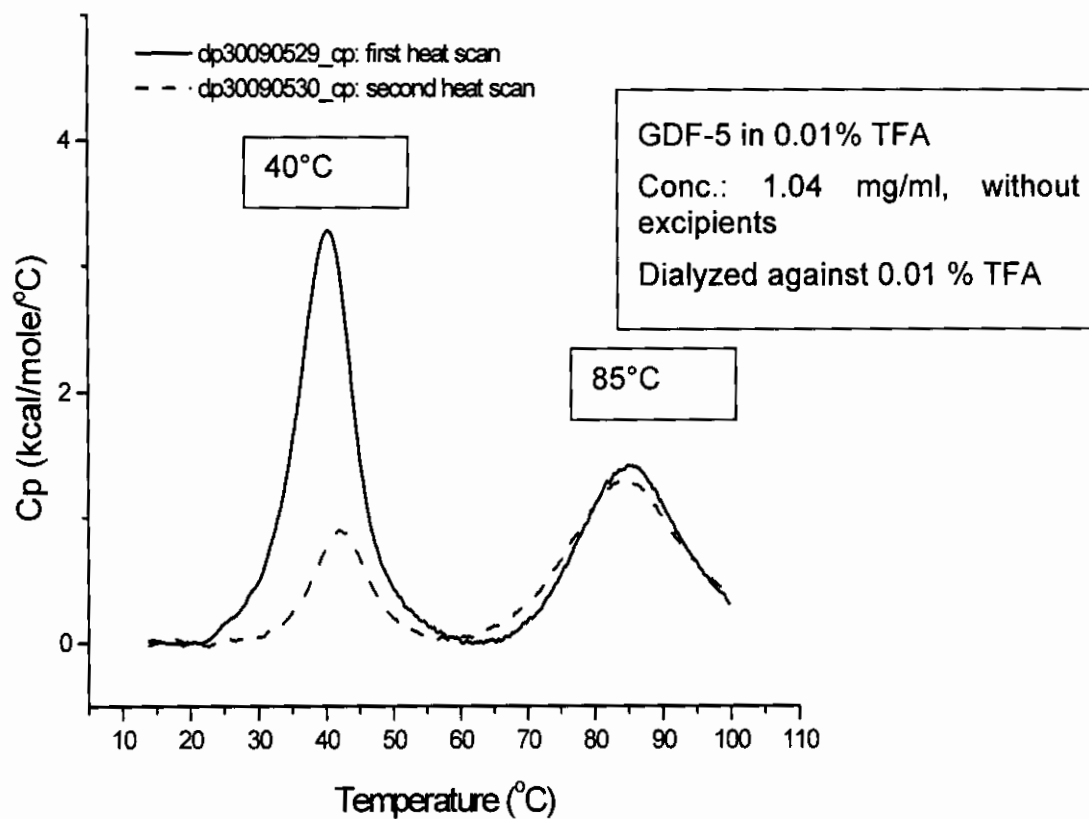
The lyophilized formulation was reconstituted with water. The final concentration
5 was 0.33 mg/ml of protein + 3.3 % trehalose.

Figure 2: DSC profile of rhGDF-5 /mannitol formulation, example 7



The lyophilized formulation was reconstituted with water. The final concentration
5 was 0.33 mg/ml of protein + 3.3 % Mannitol.

Figure 3: DSC profile of rhGDF-5 native protein



Bulk GDF-5, 3.8 mg/ml in 10 mM HCl was dialyzed against 0.01 % TFA. Final
5 protein concentration was 1.04 mg/ml.

Figure 4: Polarized light Microscopy of the trehalose/GDF-5 formulation, example 6, showing the desirable amorphous state of the trehalose.

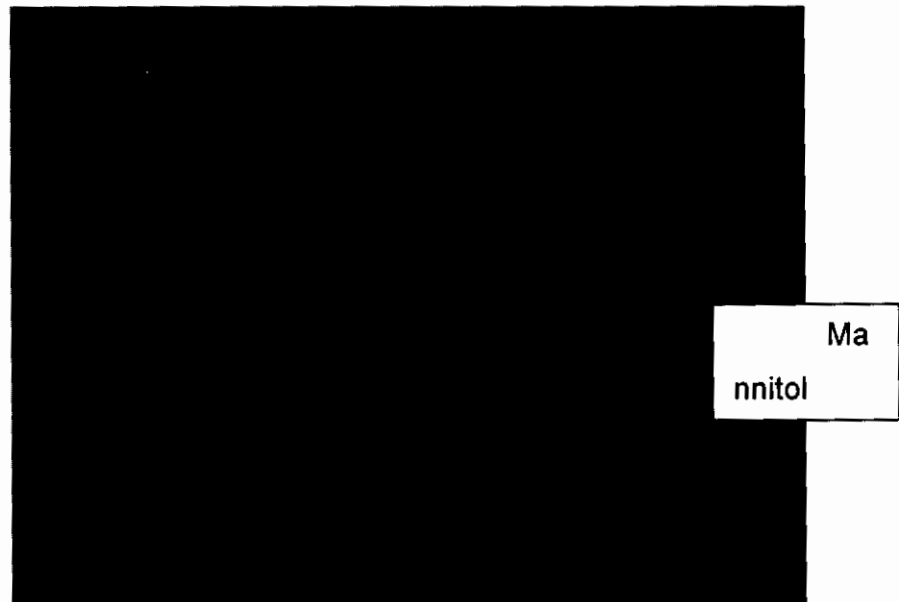


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Lyophilized formulation: example 6, rhGDF-5 conc.: 0.5 mg/vial, trehalose 50 mg/
0.5 mg of rhGDF-5, pH 2.9

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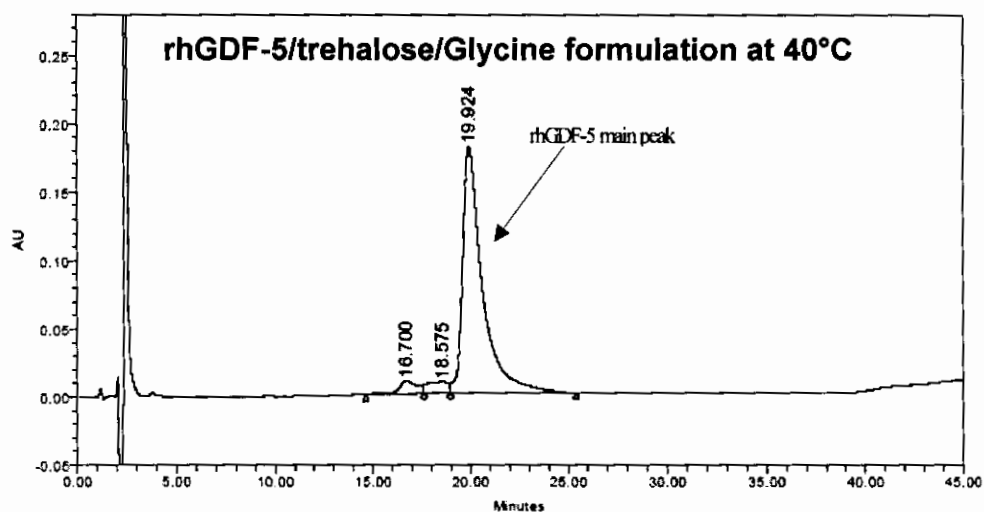
Figure 5: Polarized light Microscopy of the Mannitol/GDF-5 formulation, example 7, showing the undesirable crystallized state of mannitol.



5

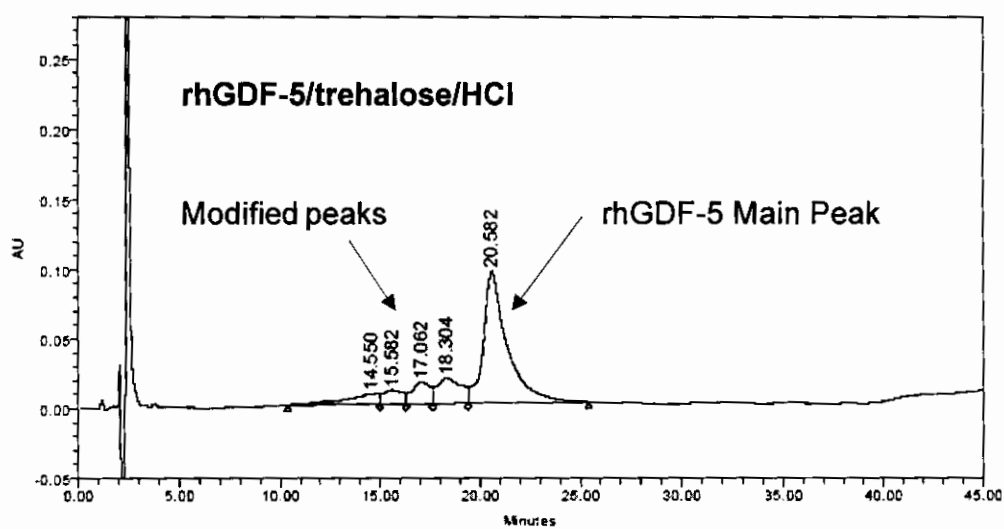
Lyophilized formulation: example 7, rhGDF-5 conc.: 0.5 mg/vial, Mannitol 50 mg/0.5 mg of rhGDF-5, pH 2.9

Figure 6: rpHPLC of the rhGDF-5/trehalose/Glycine formulation after 6 months at 40°C/75% RH.



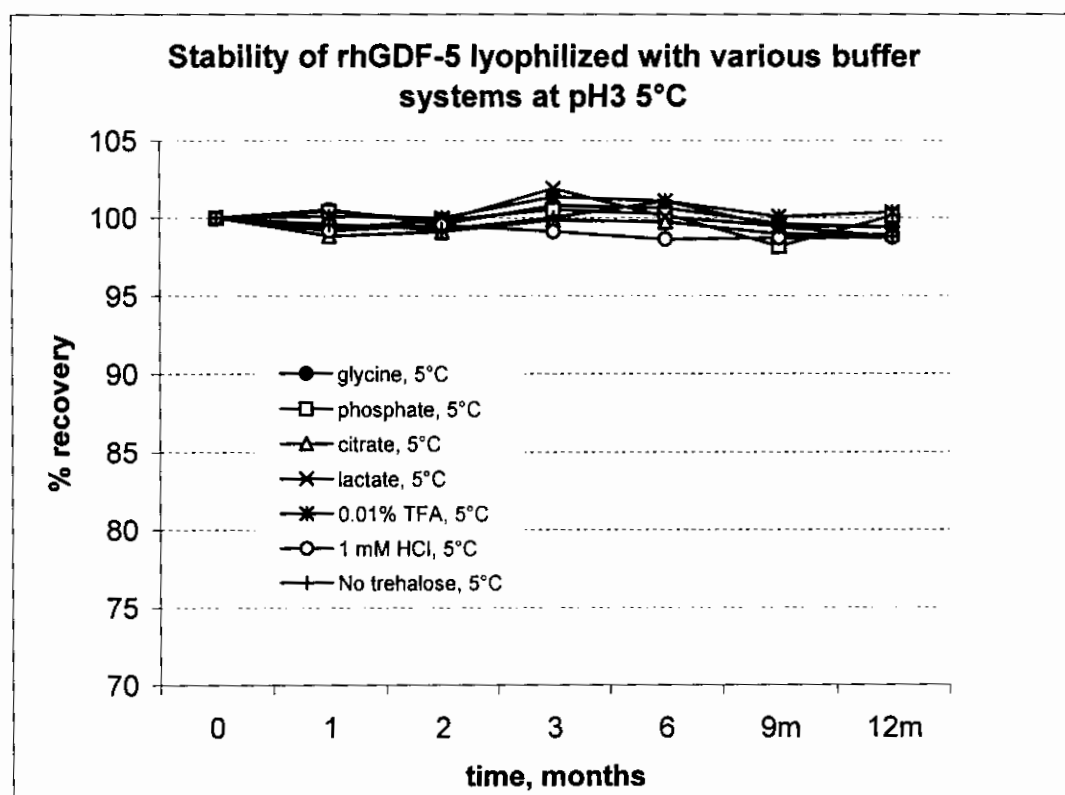
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Figure 7: rpHPLC of the rhGDF-5/trehalose/HCl formulation after 6 months at 40°C/75% RH.



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Figure 8: Stability of rhGDF-5 lyophilized with various buffer systems at pH3 5°C.



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Figure 9. Stability of rhGDF-5 Lyophilized with various buffer systems at pH 3 after storage at 25°C.

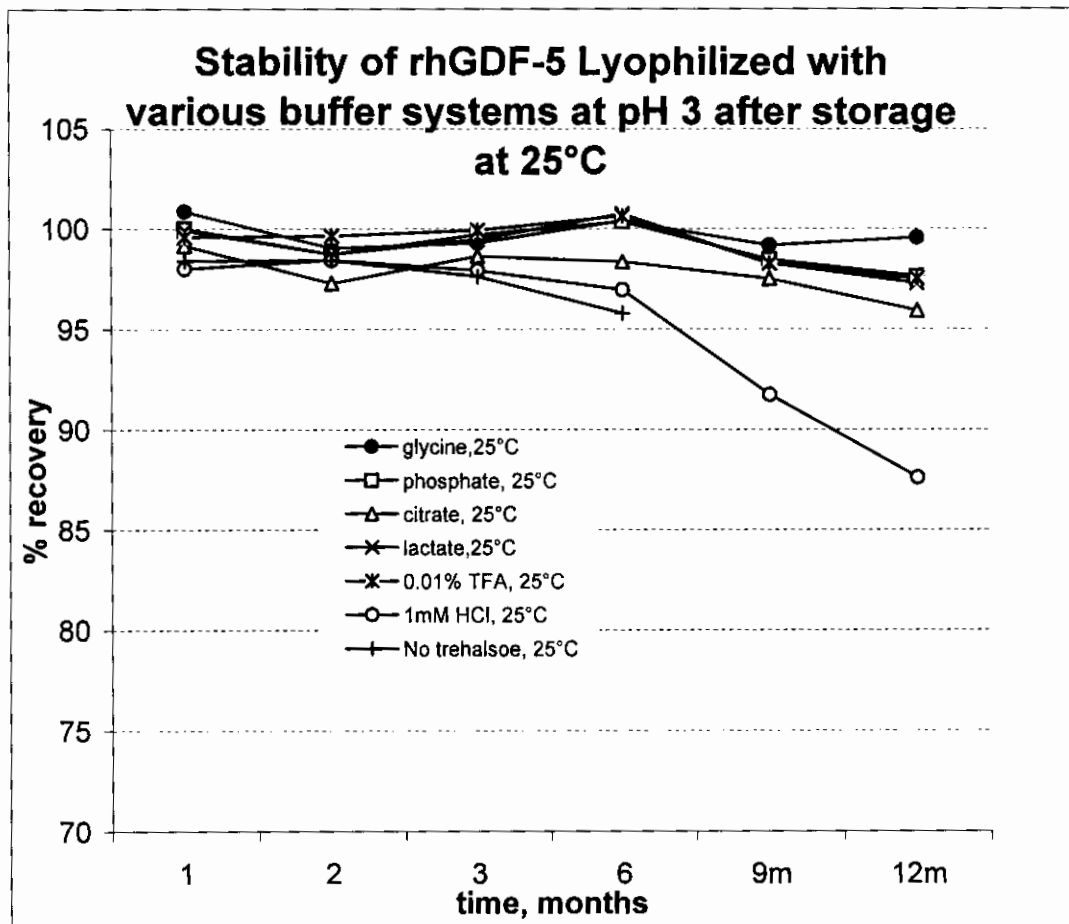


Figure 10. Stability of rhGDF-5 Lyophilized with various buffer systems at pH 3 after storage at 40°C.

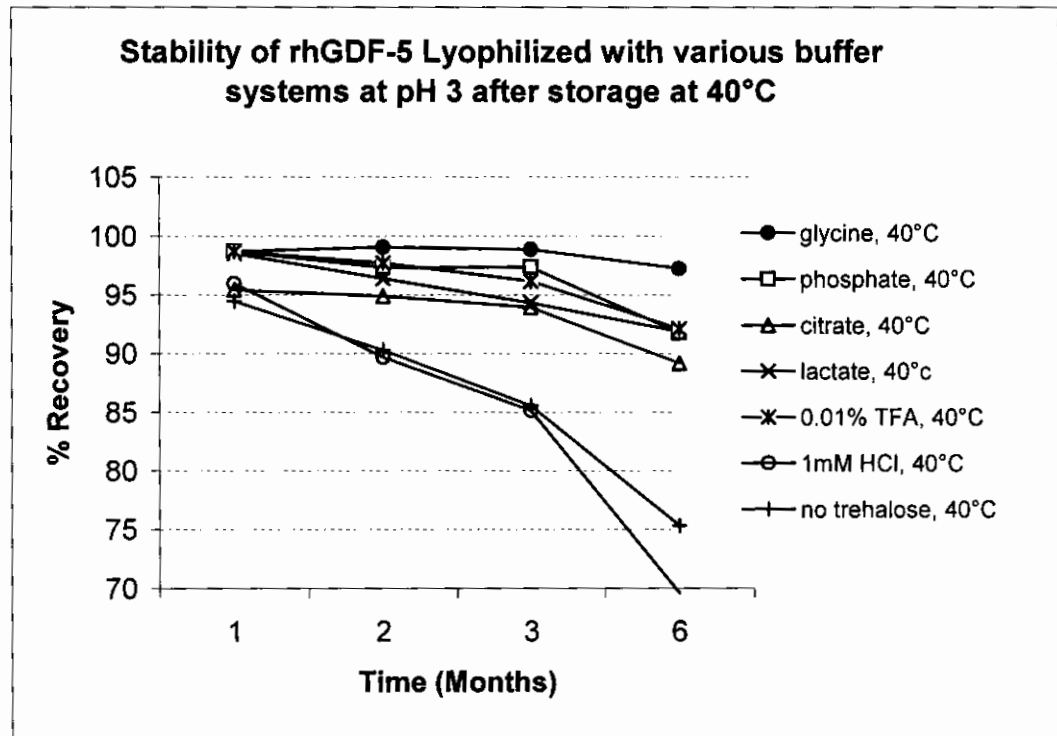
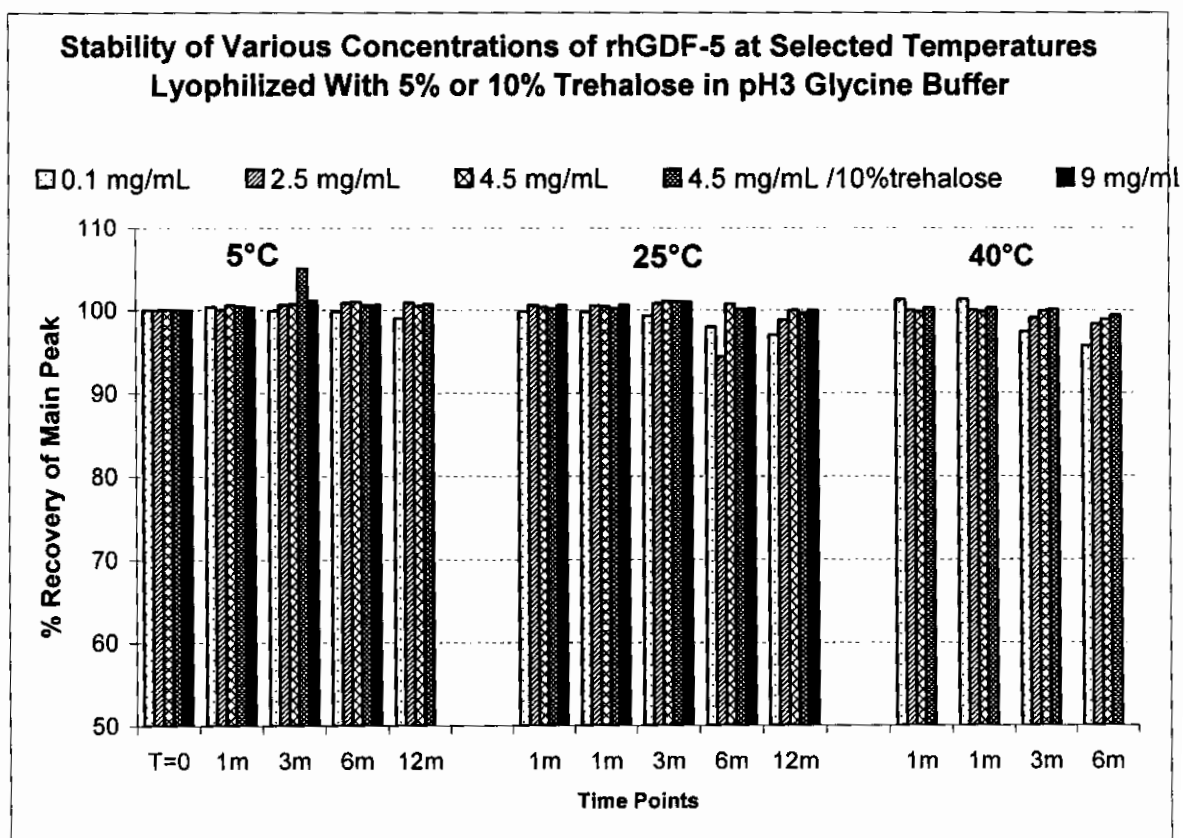


Figure 11. Stability of Various Concentrations of rhGDF-5 at Selected Temperatures Lyophilized With 5% or 10% Trehalose in pH3 Glycine Buffer.



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