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FDP – 2B: THE NEW GENERATION OF CGMP COMPLIANT LYOPHILIZED PLATELET RICH PLASMA (PRP)

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SUMMARY

Introduction: Platelet Rich Plasma (PRP) is a fraction of peripheral blood by concentration of platelets that generates clinically useful levels of various growth factors such as platelet-derived growth factor (PDGF), fibroblast growth factors (FGF) and epithelial growth factor (EGF). However, due to intensive time and labour, it can be difficult to prepare an adequate and consistent amount of platelets. Thus, we have generated a new method of PRP which could be isolated beforehand and stored for further use. **Methods:** Fresh PRP with 2 billion cells/vial and freeze-dried PRP (FDP-2B) which were also stored in 2 billion cells/vial has been prepared from peripheral blood of 8 healthy human volunteers (300 mL/person) ages 20-50 years old. Every vial of the fresh PRP from each donor were sent for growth factor studies right after the processing from the whole blood while the rest of the vials from each donor were freeze-dried and stored at three different temperatures of 4,-20 and -80°C. The growth factors (PDGF, FGF and EGF) concentration were examined after freezing and tested on day 10th, 1 month and 3 month post freeze drying. **Results:** The successful samples processed for storage is 100%. All the three growth factors studied were present in both the fresh PRP(2B) and FDP-2B. However, it was observed that for every sample studied, the lyophilized PRP (FDP-2B) shows a significant increase ($p<0.05$) in all growth factors as compared to the fresh PRP. The results of our study suggest that freeze-drying is an effective technique in preserving PRP bioactivity. Furthermore, we have developed the product in a cGMP environment, taking into account the bacterial and fungal culture testing for each donor in order to improve the safety of the procedure and to ensure it is free from contamination. In conclusion, our results suggest that freeze-dried human PRP maintains the growth factor levels that are comparable to those of fresh PRP(2B), even after the storage with potential clinical value.