CONCLUSIONS AND SUGGESTIONS FOR FURTHER WORK
I. CONCLUSIONS

- The identified excipient was prepared from the seeds of *C. Roxburghii* by solvent extraction. The final extracted mucilage was freeze dried to obtain a fine gum powder. The selected novel excipient was evaluated for ideal excipient characteristics such as Bulk density, Tapped density, Angle of repose and Carr’s index and the results were comparable to the reference excipient (selected from IPEC - FDA). Further, by using FT-IR, MALDI-TOF, MALDI-ESI and DSC, the novel excipient was characterized as a mixed population of polymers and monosaccharides in variable amounts.

- It is common practice in the pharmaceutical industry to incorporate polymers and saccharides into the final drug product formulation to enhance stability. Since the identified novel excipient has polymers and saccharides, it was considered suitable for developing a lyophilized formulation for a PEGylated therapeutic protein.

- The suitability of the novel excipient as a surfactant and as a stabilizer was evaluated in comparison to a USFDA approved excipient for each function (i.e.) the novel excipient was tested instead of Sucrose as a stabilizer and Polysorbate 80 as a surfactant.

- Critical Thermal parameters such as $T_g$, $T_c$ and Teu from DSC profiles of the formulations were used to develop a lyophilization cycle for all formulation compositions. Lyophilization cycle parameters such as freezing rate, requirements for annealing, primary, secondary drying temperatures, duration and pressures were modified, depending on the ideal properties of the final lyophilized drug product. Physical appearance, reconstitution time, moisture content, quality of drug product characteristics by SEC (purity), SDS-PAGE (HMWP), DLS (hydrodynamic radius), DSC ($T_m$), Fluorescence analysis (λmax and Intensity of emission) and UV analysis (λmax and Intensity) were evaluated as critical quality attributes to finalize the lyophilization cycle.

- Additionally, comparative stability studies at stress condition (40°C), accelerated condition (25°C) and real time condition (5°C) were performed to evaluate the impact of the novel excipient on final product attributes. It was found that formulations...
containing the novel excipient performed on par with the formulations containing the proven USFDA approved excipients. All study results support the usage of novel excipient as stabilizer and surfactant.

1.1 SUGGESTIONS FOR FURTHER WORK

- Need to conduct the explorative pharmacokinetic and pharmacodynamics studies in suitable animal model as per the ICH guidelines
- Structural level identifications to be explored with suitable physio-chemical methods in order to establish exact chemical structure.
- Studies to be planned with another API to ascertain its role in pharmaceutical formulations.