ISO 9001

MQ12-007H

SUMMARY OF STUDIES INVESTIGATING SBECD DECOMPOSITION
RESULTS

Summary

- The start of decomposition is indicated well by the decrease in pH. The initial decomposition is detectable when pH reaches the 4.2 – 4.4 values.
- More vigorous decomposition occurs when the pH is below 4.0.
- When the pH at the start of stress studies is greater than 4.7, the decomposition initiated by the stress is less expressed.
- The total area of peaks corresponding to UV 254 nm in stress-treated samples is proportional to the area of peak of decomposition product and pH.
- Sodium content of the decomposed samples and the area of decomposition products are proportional to each other.
- The secure pH range associated with the decomposition is when the in-process control sample and the final products' pH is greater than 5.8. Higher the pH, the more stable the product. (The upper limit is pH (30%w/v solution) 6.8 according to USP-NF monograph.). Above pH (15%w/v solution) 6, the pH measurement needs to be implemented with continuous N_2 bubbling according to the EP monograph.
- Samples under air and oxygen atmosphere decompose similarly, the decomposition product content unambiguously depends on the water content of the sample.
- No significant decomposition was observable in SBECD API product after 2 weeks of storage under an inert atmosphere at 70°C.
- Freeze-dried samples were prepared, taken before spray-drying from 3 batches, parallel to the spray-dried samples, then stored at 70°C. Checking their pH after 33 days, no change was detected. After this, the samples were stored further at room temperature, and new measurements were carried out after 1 and 3 months. There is no evidence indicating the decomposition of the samples.

Date: 14th of February 2023

Quality Assurance
CycloLab Ltd.