CONCLUSION

Mother Nature has gifted India with great variety of flora and fauna. In recent years, plant based natural gums and mucilages are widely used as pharmaceutical excipients in the formulation of various conventional ad novel drug delivery systems. These natural gums and mucilages can be suitably modified to compete with the commercially available synthetic pharmaceutical excipients.

The endosperm of *Borassus flabellifer* fruit contains a high proportion of mucilage. Literature survey shown that extensive physical characterization, phytochemical screening and exploration of *Borassus flabellifer* fruit mucilage as versatile pharmaceutical excipients in pharmaceutical formulations has not been done. Hence, the present study was undertaken to enhance the use of *Borassus flabellifer* fruit mucilage as a natural plant based excipients to develop various pharmaceutical formulations and it will encourage cultivation and use of this mucilage in the pharmaceutical industry.

The research outcomes from the present study are as follows:

- The results indicated in the present study developed for the first time for BFM and this study was a primary platform to indicate the suitability of BFM as a pharmaceutical excipient.
- The powdered dry water soluble mucilage was extracted from *Borassus flabellifer* fruit for pharmaceutical use.
- The BFM was extracted using solvents such as distilled/demineralized water, PBS pH 4.0, pH 6.8 and pH 9.2 and alcohol was used (95% v/v) as non-solvent. The yield of the mucilage was varied depending on the solvents used. From the results it indicated that the solvents like distilled/demineralized water, phosphate buffer pH 9.2 could be used for extraction of BFM for better yield.
- The solubility behaviour of the BFM indicated that it is quickly soluble and forms neutral, viscous colloidal solution in warm water, sparingly soluble in cold water, whereas insoluble in organic solvents viz; ethanol, chloroform, ether etc.
- The low moisture content of BFM indicates that it can be used effectively in the formulation development of hygroscopic drugs.
- The low ash values indicated low levels of contamination of crude BFM during collection, processing and handling.
- The results indicated lower values for Carr’s index and angle of repose of BFM indicated that the BFM has a good flow with moderate compressibility.
The swelling characteristic of BFM was highest in water followed by phosphate buffer and least in 0.1N HCl. The results clearly indicated that the BFM can be used as binding agent, disintegrating agent, matrix forming material in solid oral formulations.

The results indicated that the extracted BFM has high viscosity and swelling characteristics due to this it could be considered for pharmaceutical suspension, emulsion and gel formulations as a suspending, emulsifying and gelling agents.

Since, the BFM is an acidic in nature and shown good swelling capability at alkaline pHs, it could be used as a polymer for colonic drug delivery system.

FTIR spectra of isolated BFM showed the principal absorption peaks at 1406 cm\(^{-1}\), 1652 and 1730 cm\(^{-1}\), 2931 cm\(^{-1}\), 3356 cm\(^{-1}\), 3396 cm\(^{-1}\), which indicate that isolated product, was mucilage. This is all consistent with a mucilage structure that is neither a starch nor cellulose.

The X-ray diffractogram of BFM shown that it is of low moisture and exhibit both amorphous and crystalline portions.

The DSC thermograms of BFM showed that the BFM has both amorphous and crystalline portions and it also showed that it is more resistant and stable to heat.

The TGA of BFM implies that it has excellent thermal stability.

The SEM of BFM exhibited fairly irregular, fragmented tiny granules and slightly elongated with rugged appearance.

The zeta potential of BFM was found to be -17.2, indicating that its value is towards the positive side. Thus it gives an indication that BFM can be used as a good mucoadhesive substance.

Phytochemical tests revealed that isolated BFM shown the absence of steroids, flavanoids, saponins, tannins, phenols, alkaloids and glycosides. Isolated BFM has given red color with ruthenium red it indicated that the obtained material was mucilage and it confirmed the purity of the mucilage obtained.

The toxicity studies of extracted BFM revealed no behavioral changes, no changes in body weight, no mortality; no toxic syndromes were reported, indicating the safety of the BFM.

From the results of the physicochemical characterization of isolated BFM shown all the desired characteristics of potential pharmaceutical excipients that could be used in the formulation of various pharmaceutical formulations.
The disintegrating property of the BFM was compared with synthetic super disintegrants viz; Croscarmellose sodium in the formulation of Metformin HCl FDT’s. The results indicated that the isolated natural disintegrant exhibited better disintegrating property at lower concentration viz; 1%w/w than the cross carmellose sodium, and it could be tried as disintegrant in the tablet formulations in place of synthetic superdisintegrants as BFM shows very good disintegrating properties.

The binding properties of extracted BFM powder were compared with starch paste, which was used as standard binder at 10% w/v concentration. The results indicated that BFM at 8%w/v showed better binding property when compared to tablets containing 10% w/v starch paste as standard binder. From the study it revealed that the isolated BFM can be used as a potential binding agent in the conventional tablet formulations.

To explore the gelling property of a BFM, different batches of diclofenac gels were prepared with different concentrations of mucilage (viz; 3.0, 4.0, 5.0 and 6.0 %w/w). The gelling property of BEM was compared with existing gum tragacanth as standard gelling agent. The results indicated that the gels formulated with 4.0%w/w of BFM was shown high gelling potential than that of gel containing 6% w/w of gum tragacanth. Thus it could be used as effective gelling agent in place of synthetic gelling agents.

The suspending properties of BFM were evaluated comparatively with tragacanth at four concentrations of in paracetamol suspension. The study revealed that BFM at 2.5%w/v concentration has excellent suspending properties in paracetamol suspension formulations, compared to the traditional suspending agent like gum tracaganth. BFM produced a stable and good quality ideal suspension.

The release retardant potential of BFM were studied by developing six batches of matrix tablets of diclofenac sodium by wet granulation method with different concentrations of BFM (2.5, 5, 7.5,10 and 12.5% w/w) and compared with guar gum as standard release retardant polymer. The results shown that BFM at 12.5%w/w concentration was capable to extend the release of the drug for 12 hrs. Thus BFM can be used as a potential natural source over the synthetic release retardant for sustaining the drug release from the formulation.

The film forming potential of BFM was evaluated by formulating matrix-type transdermal patches containing diclofenac sodium with different proportions of BFM by the solvent evaporation technique. The results shown that BFM can be
used as a film former in the formulation of transdermal patches due to its desired physical and mechanical properties.

➢ To investigate the effectiveness of the BFM as a polymer in the formulation of a floating tablets of ranitidine HCl. Its efficiency was compared with semi-synthetic polymer, HPMC K4M. The result indicated that the hydrophilic swellable BFM selected was more reliable as they released the drug slowly, extending it over a long period of time. More over the high swelling capacity of this polymer helped in maintaining the buoyancy with the minimal utilization of gas generating agent such as sodium carbonate. The formulation F3 shown a prolonged release of the drug. From the study, it shown that the BFM could be used for the development of floating tablets.

➢ To assess the potential of BFM as a biodegradable polymer for colonic drug delivery, colon targeted matrix tablets of olsalazine sodium were prepared by direct compression method using different concentrations viz; 5, 10, 15, 20 and 25% w/w of BFM. The in vitro and in vivo study indicated that the formulation F5 containing 25%w/w of BFM was capable of protecting the drug in upper GI tract while releasing significant of olsalazine sodium in SCF containing caecal content at the end of 24h under anaerobic conditions. Thus on the basis of the above mentioned findings it could be concluded that BFM could be successfully used in colon specific delivery system.

➢ To explore the mucoadhesive potential of BFM, five batches of sumatriptan succinate mucoadhesive tablets were prepared by using different drug-BFM ratio (viz: 1:025, 1:0.5, 1:0.75, 1:1 and 1:1.25). The results indicated that the mucoadhesive tablets formulated with 1:1.25 drug-BFM ratio (formulation F5) was shown all the desired properties and exhibited the extended cumulative percentage of drug release value (78.49%) after 10 hr. Thus it could be used as effective mucoadhesive property in place of synthetic mucoadhesive agents.

Future perspectives and recommendations

➢ Detailed Structural elucidation of extracted BFM can be attempted.

➢ Purified BFM has a brownish color so more research can be conducted into decolourisation of the BFM.

➢ More assessment should be done on drug – BFM interaction.

➢ The exploration of BFM in the formulation of particulate drug delivery systems like nanoparticles and microcapsules can be done.
➢ Further work should be done on using the BFM as a potential film coating agent.
➢ Possibility of the BFM for nasal drug delivery system can also be explored.
➢ Suitability of BFM for formulation ophthalmic drug delivery can also be attempted.
➢ Suitability of BFM for Osmotic drug delivery can also be attempted.
➢ Attempts can be done to alter the physicochemical properties of the BFM, and their pharmaceutical applications in the formulation of different conventional and novel dosage forms can be tried.

Since *Borassus flabellifer* fruit is readily available and widely distributed in nature and the isolation of mucilage involves simple and very fewer steps, it is comparatively inexpensive for large scale production of the active ingredient. The focus should be directed towards the development of these newer excipients, so that they can enter the pharmaceutical industry and newer formulations could be developed and formulation problems could be solved. In conclusion, BFM can be used as an effective natural pharmaceutical excipient in the development of various pharmaceutical dosage forms.