6.6 Regulatory Consideration of Alginate

According to US Pharmacopoeia, alginate is explained as a polymannuronate even on the presence of glucuronate, and the building block structure of alginate is now well known [54]. Before the use of alginate in the pharmaceutical and biotechnology field, its regulatory aspect must be addressed, mainly regarding long-term safety, toxicity [55–59], reproducibility of the product, and its characterization and functionality, which includes product specification, product stability, and validation of analytical methods. The use of alginate in human studies must require a regulatory approval by the FDA [60]. Drug master file (DMF) contains all the information regarding the manufacturing, specification, and safety of the product. Regulatory considerations regarding alginate in different pharmacopoeia are discussed in Table 6.1 [61, 62].

6.7 Applications

1. Pharmaceutical field—The application of alginate in industry is based on its ability to retain water and swelling, viscosifying, and stabilizing properties.

Dosage form—The presence of free carboxyl group exhibits mucoadhesive property and allows it to interact with the mucin, which makes it a good excipient for buccal, nasal, ocular, and gastrointestinal dosage form. This interaction is due to the hydrogen and electrostatic bonding. pH has a great impact on the mucoadhesive character as only an ionized carboxyl group is capable of interacting with mucin.

In tablet—Alginate acts as a binding or adhesion agent in tablet so as to hold the powder together or in granular form, but it should be added during the granulation process, not after the granulation. Depending on the concentration of alginate added, it acts as a disintegrant agent and helps in rapid release of the drug. Thus, the tablets prepared with alginate have more mechanical strength as compared to other tablets that are prepared from starch. From different types of alginate, sodium alginate was used to prepare a matrix tablet by direct compression method or wet granulation method [63]. Interaction of sodium alginate with calcium salts results in formation of water insoluble gels which allows encapsulation of variety of drugs in substantial amount. Upon coming in contact with water, an *in situ* gel is formed and the drug molecule diffuses slowly from this gel [64]. Thus, sodium alginate helps to provide a sustained and controlled release