ABSTRACT

Folic acid is a water soluble vitamin of the B-complex group used in

prevention of NTD (an acronym for neural tube defect)–a general term that describes

a variety of congenital anomalies resulting from abnormal neurulation during early

development of the central nervous system. Folic acid has an half life of 3.5 h and

therefore, the present investigation was concerned with the development of oral

gastroretentive floating tablets of folic acid, which after oral administration were

expected to prolong the gastric residence time and improve the bioavailability of the

drug as well as its half life. Drug-polymer compatibility studies by FTIR gave

conformation about their purity and showed no interaction between drug and selected

polymers. Various formulations were developed by using release rate controlling and

gel forming polymers like HPMC (K4M, K15M, K100M) and Carbopol 934 by direct

compression method with the incorporation of sodium bicarbonate as gas generating

agent. All the formulations had a floating lag time between 33 and 47 s and floated on

dissolution medium for more than 12 h. Swelling studies indicated significant water

uptake and contributed in drug release. From among all the developed formulations,

formulation F5 prolonged the drug release for longer period of time and it was

selected as the best formulation. F5 was found to be stable during stability studies

conducted according to ICH guidelines (30 ± 2 °C / 65 ± 5% RH and 40 ± 2 °C / 75 ±

5% RH) for two months. F5 satisfied physicochemical parameters, floating properties,

swelling index and in vitro drug release profile requirements for a floating drug

delivery system.

Key words: Folic acid; Gastroretentive; Neural Tube Defect (NTDs); Floating tablet;

Bioavailability.