Numerous medicines of plant, animal, mineral origin have been cited for the treatment of kidney stones. However, literature from Ayurveda, Siddha, Unani and Homoeopathy, the oldest systems, do not have validated studies to substantiate the observations. In addition, a number of formulations contain minerals and metals. This poses practical difficulty for physicians of biomedicine to prescribe these drugs to the patients. To overcome this major limitation, a plant-only formulation, that is, a hydro-alcoholic extract of 5 plants was formulated. The formulation coded as DCBT5678 was standardized based on the guidelines given by World Health Organization and many finger print profiles for each of the plant material used in the formulation were deciphered using HPTLC. The phytochemical profiles of each plant material in different photoperiods were carried out and the best period of collection of raw material was identified. The stability of the drug formulated were determined through HPTLC over a period of 3 years and found that the phytochemical markers were stable and no deterioration of any compound was noticed. The quantified (peak area) markers in each of plant material in the formulation was found to be flavonoids. The formulation was validated for its safety and efficacy through clinical studies. DCBT5678 was dispensed orally to 55 patients in two open studies. The first study had 45 patients enrolled, of which 9 dropped out and 36 completed then 10-month trial period. DCBT5678 proved efficacious in dissolving/reducing/decreasing the size/number of stones in 58.3% of the patients. 11.1% of the patients had complete dissolution of stones within the first
month of medication. The mean urea and uric acid concentration in the blood and serum respectively showed significant reduction at the end of the trial period. In the second study, on 10 potential uric acid stone bearers, of which 5 had uric acid stone(s) alone and 3 patients had mixed stone(s) with the remaining 2 having calcium oxalate stones. Two patients dropped themselves out from the trial without assigning any reason. Five out of eight patients (62.5%) had complete dissolution of stones at the end of the trial period. The reduction in the mean number and the size of the stones in the kidneys of the patients between the baseline and at the end of the trial were found to be gradual. None of the patients showed any adverse symptoms in both the trials. Three of the five plant extracts showed distinct anti-microbial activity against urinary tract-infective organisms, Proteus spp and Escherichia coli. The plant formulation, DCBT5678 was safe and efficacious in treating uric acid stones in kidneys.