Introduction
Urinary calculi commonly known as kidney stone has a long ancient history of incidence associated with pain in human. Scientists have found health evidence of kidney stone in an Egyptian mummy estimated to be more than 7000 years old. According to the US National Institute of Health, 1 person in 10 develop kidney stones during their life time and renal stone disease accounts for 7-10 of every 1000 hospital admissions in USA. It is also estimated by Hussain et al., (1996) that 3% of world population suffers from calculi in their life time. In several countries, kidney stones are a common problem (Morton et al., 2002), affecting one person in 1,000 annually, and the incidence is increasing in developing countries particularly the tropics (Robertson, 2003).

Kidney stones are most prevalent in patients between ages of 30 and 45 and the incidence declines after the age of 50. Men tend to be affected frequently than women and the ratio of incidence was 3:1 (Kassimi et al., 1986).

Precipitation of substances like calcium oxalate, calcium phosphate, magnesium ammonium phosphate (struvite), urate or cystine that normally dissolve in urine, causes calculi in humans which is referred as kidney stones. Although they may form any where in the urinary tract, they develop in the renal pelvis or calyces as microscopic particles and build up to stones, over time. Nature of occupation, fluid in take, diet, and self-medication are some of the causes increasing the frequency of kidney stone formation in human beings (Andrews et al., 1998). Certain foods, family history, urinary tract infection, kidney disorders (like cystic
kidney disease), and metabolic disorders (like hyperparathyroidism) are linked to stone formation. Renal tubular acidosis, cystinuria, hyperoxaluria, hypercalciuria, hyperuricosuria, gout, excess intake of vitamin-D, blockage of the urinary track, certain diuretics, and calcium based antacids may also increase the risk of formation of kidney stones. Chronic inflammation of the bowel, ostomy surgery, patients taking the protease inhibitor *Indinavir*, a drug used to treat HIV infection (AIDS) are at risk of developing kidney stones (Andrews *et al.*, 1998). The chemical composition of stones depends on the chemical imbalance in the urine.

The four most common types of stones are of calcium, uric acid, struvite, and cystine. Approximately 85% of stones are composed predominantly of calcium compounds, calcium oxalate, or calcium phosphate. Calcium oxalate is more common and occurs in patients with metabolic disorders. If the acid level in the urine is high or kidneys separate too much acid, the uric acid stone may form. Genetics may play a role in the development of uric acid stones. Struvite stones, also called as infection stones develop when a urinary tract infection (eg. cystitis) affects the chemical balance of the urine. Some people inhabit a rare, congenital condition that results in large amount of cystine in the urine that leads to cystine stones.

Surgical interventions are the only option for patients suffering from kidney stones that includes extra corporeal shock wave lithotripsy, percutaneous lithotripsy and ureteroscopic lithotripsy that have their individual repercussions (Katzberg, 1997 and Krambeck, 2006). Acceptance of plant medicine as a
potential alternative or complimentary is evident with the number of patients desiring such drugs over surgical procedures (Mathur and Ramamurthi, 2003). Concern about the adverse effects and skyrocketing cost of conventional health care are some of the other reasons for patients taking alternative / complementary medicine (Pal, 2002).

Ayurveda ‘the Science of Life” is one of the oldest system of health care originated in India during the pre-Vedic period, has the principles of positive health and therapeutic measures related to physical, mental, social and spiritual welfare of human beings. It deals with both the preventive and curative aspects of life in a most comprehensive way (Rawat and Uniyal, 2003).

Siddha system of medicine is attributed to the sage Agasthya and the therapeutics consists mainly of the use of metals and minerals. Another complementary system of medicine, Unani, is popular and practiced in Indian sub-continent and other parts of the world. In India, medicinal plants have made a good contribution to the development of ancient Indian Materia Medica. One of the earliest treatises on Indian medicine, the Charak Samhita (1000 BC) records the use of over 340 drugs of vegetable origin. According to World Health Organization (WHO), more than 80% of the world population relies on traditional systems of medicine, largely plant-based, for their primary health care needs (Rawat and Uniyal, 2003).
Though several formulations were described in ancient texts of Ayurveda and Siddha, significant number of formulations contains heavy metals or minerals. The presence of heavy metals in any formulation is of concern as it may lead to accumulation of metals in human tissues and organs (Hontz, 2004; Tait et al., 2002; Moore and Adler, 2000). The efficacies of these formulations against any specific type of stones have not been proved through scientific documentations. Despite the usage of medicinal plants from time immemorial for the treatment of several diseases that include kidney stones, information on the standardization, safety, quality, and authenticity of them is still not satisfactory (Tiwari, 2003).

Knowledge on traditional medicines if combined with modern tools of isolating active principles and carrying out pharmacological studies will aid high quality products in the treatment of several diseases. DCBT5678, a formulation developed by Dalmia Centre for Research and Development, comprised of five plant extracts was taken up for this study with respect to the efficacy of the formulation in the treatment of kidney stones. This formulation is a hydro-alcoholic extract of the following plants namely, leaf of Bryophyllum pinnatum (Lam.) Oken.Kurz, whole plant of Euphorbia microphylla Sprengel. flower of Butea monosperma (Lam.) Taub. flower of Bombax malabaricum DC. and fruits of Tribulus terrestris L. This formulation was arrived based on the extensive literature search and with an indicative toxicology study, conducted earlier. An open pilot efficacy study with DCBT5678 was also carried out previously on 10 patients having 1 or many stones of size between 5 and 10mm for a period of 10
months showed that 40% of the patients had complete dissolution of stones whereas 20% of them showed reduction in size and number of stones. The remaining 40% of the patients did not respond. The drug was tolerated well and did not have any side effects during the treatment period.

So, the present study was designed with the following objectives,

a) to validate the drug formulation, DCBT5678 against the kidney stone disorder with more number of patients using structured protocol and case records under expert biomedical supervision employing detailed laboratory investigations and ultra sonogram studies.

b) to establish phytochemical finger printing of the herbal ingredients of DCBT5678 to pave way for better quality control during the manufacture of the formulation.

c) to study the drug stability of the DCBT5678 formulation during storage at different periods and

d) to study the antimicrobial activity of the individual plant extract of DCBT5678 against the clinically relevant urinary tract microorganisms.