Traditional herbal medicines imply considerable historical use, and India has a rich tradition of herbal medicine as evident from Ayurveda that has been known for nearly 5000 years, which includes diet and herbal remedies, while emphasizing the body, mind, and spirit in disease prevention and treatment (Morgan, 2002). Herbal medicines have been used as efficient remedies for the prevention and treatment of multiple health conditions for centuries in every known culture. Traditional herbal medicines are also in immense demand in the developed world for primary health care because of their efficacy, safety, and lesser side effects and also recommended therapeutics for age-related disorders like memory loss, osteoporosis, immune disorders, etc. (Kamboj, 2000).

Herbal drugs comprise only those traditional medicines which mainly use medicinal plant preparation for therapy. The herbal medicines/traditional medicaments have been derived from the rich traditions of ancient civilizations and scientific heritage (Kamboj, 2000). The turnover of herbal medicines in India is about $ 1 billion, with a meager export of about $ 80 million as over-the-counter products, ethical, classical formulations and home remedies of Ayurveda, Unani and Siddha systems of medicine (Pal, 2003).

According to the World Health Organization (WHO), the use of herbal remedies has been increased throughout the world as compared to conventional drugs by two to three times (Evans, 1994) and the use of plants for healing purposes predate human history and form the origin of much modern medicine. Most of the effective drugs are plant based and many conventional drugs originated from plant sources: Aspirin

(willow bark), Digoxin (from foxglove), Quinine (from cinchona bark), and Morphine (from the opium poppy) (Vickers and Zollman, 1999).

Herbal medicine and conventional pharmacotherapy have two important differences:

Herbal Medicine- Herbalists generally utilize unpurified plant extracts containing several different constituents and claimed that these can work together synergistically so that the effect of whole herb is higher than the summed effects of its components. It is also claimed that toxicity of whole herb is reduced instead of isolated active ingredients ("buffering"). Although two samples of a particular herbal drug may contain constituents in different proportions and practitioners claim that this does not usually cause clinical problems.

Herb Combining- Several different herbs are used together and practitioners follow the principles of synergy and buffering which applies to combinations of plants and claim that combining the herbs improves efficacy and reduces the adverse effect. This statement contrasts with conventional practice, where polypharmacy is usually avoided whenever possible (Vickers and Zollman, 1999). To involve herbal product into the mainstream of the today's health care system; researchers, manufacturers and regulatory agencies are interested in rigorous scientific methodologies, pharmacognostical standardization and clinical trials to ensure the quality, efficacy and safety of the traditional herbal products.

Plants, parts of plants and their products have been used since time immemorial for the prevention and treatment of various health ailments. About 25% plant based drugs are prescribed worldwide in which 252 drugs are in WHO essential medicine list, 11% is exclusively of plant origin and 121 such active compounds are in use.

Approximately 80% of African and Asian population relies on traditional medicines for their primary healthcare. In India, nearly 80% of the rural population uses medicinal herbs or indigenous systems of medicine. About 960 plant species are used by the Indian herbal industry of which 178 are of high volume exceeding 100 metric tons a year (Sahoo *et al*., 2010).

Gastric ulcer

Ulcer is an open sore that develops on the inside lining of stomach (gastric ulcer) or small intestine (duodenal ulcer) and these two types of ulcers are known as Peptic Ulcer Disease (PUD) and characterized by high acidity ensuing in mucosal erosions causing extreme pain and uneasiness. PUD is the most predominant gastrointestinal diseases with a worldwide prevalence of about 40% in developed countries and 80% in developing countries (Adinortey *et al*., 2013). In India, peptic ulcer is more prevalent in Jammu and Kashmir, followed by Southern India, North India comes next, and East and North East have a comparatively lower prevalence (Das *et al*., 2008). Higher prevalence of peptic ulcer in southern India over northern India may be attributed to the fact that rice is the staple food in this region (Das *et al*., 2011a). Globally, the United States of America is the leading country for the development of PUD with 4 million individuals (new cases and recurrences) affected by this disease every year. Lifetime prevalence of PUD in the USA is approximately 12 % in men and 10% in women (Le and Fantry, 2008). PUD is most common in adults, but it can occur at any age, including infants and children's (Beer and Berkow, 2006). A person with middle age group (30–50 years) is more prone to develop peptic ulcer disease,

although patient over the age of 60 years accounts for 80% of deaths even though they only account for 15% of cases (Rutter, 2005).

Gastric ulcer is a widespread global problem in the modern era and it is predictable that around 14.5 million of the worldwide population is affected with a mortality rate of 4.08 million (Srikanta *et al*., 2007). The pervasiveness of gastric ulcer is due to behavioral and environmental factors such as; inadequate dietary habits, smoking, too much use of non-steroidal anti-inflammatory agents (NSAID), stress, hereditary predisposition and infection with *Helicobacter pylori* (Groenen *et al*., 2009). Mainly two factors such as infection with *H. pylori* and long-term use of NSAIDs may be responsible for the development of gastric ulcer (Kangwan *et al*., 2014).

Rheumatoid arthritis

Arthritis disease has been known to exist since great ancient times. The earliest detailed description of arthritis occurs in Atharvaveda which was composed about 1000 B.C. as evident from the following verse.

पादाभ्यां ते जानुभ्यां श्रोणिभ्यां परिमंसस: ।
अनुकादर्षणोरुष्णिहाम्य: शीर्ष्णो रोगमनोशम् ।।

Charak Samhita included the etiology, symptoms, diagnosis and treatment of arthritis, which was written in post Vedic period. Charak has prescribed both local and systemic medicaments for the treatment of arthritis (Sharma *et al*., 1973).

Rheumatoid arthritis (RA) is a common autoimmune disorder characterized by chronic inflammation, synovial membrane inflammation, and destruction of joints due to progressive attrition of articular cartilage in the synovial joint through

generations and infiltration of auto-antibodies. Rheumatoid arthritis occurs worldwide with a variable incidence and severity. Prevalence of arthritis is higher in Europe and North America other than in developing countries. The highest prevalence of this disease is observed in the age group of 25–29 years (Akhter *et al*., 2011). In Indian subcontinent regions around 0.4 -0.6 % population is affected with RA and the prevalence is 1% in adult population worldwide. RA is three times more common in women as compared to men (Madhu and Harindran, 2014).

Urolithiasis

Lithiasis (stone formation) is one of the most painful urologic disorders responsible for urolithiasis, acute and chronic renal failure and associated with morbidity and end-stage renal failure in India (Aggarwal *et al*., 2014). Approximately 12% of the global population is affected with lithiasis and its re-occurrence rate in males is 70-81% and 47-60% in female (Soundararajan *et al*., 2006). The prevalence and incidence of urolithiasis are reported to be increasing across the world and more common in children over the past few decades due to rapid variations in habits and increasing affluence (Lopez *et al*., 2010). Various factors like age, sex, geographic area, racial distribution, industrialization, socioeconomic status, diet, and environment, influences urolithiasis in terms of both the site and the physicochemical composition of the calculi (Moe, 2006). Recent epidemiology studies reveal that about 80% of stones are made up of calcium oxalate and calcium phosphate; 10% of struvite (magnesium ammonium phosphate formed during infection with bacteria that possess the enzyme urease), 9% of uric acid and the remaining 1% are composed of

cystine or ammonium acid urate is diagnosed as drug-related stones (Alok *et al*., 2013).

To the best of our knowledge, till date, no comprehensive report is available on anti-arthritic, anti-ulcer and anti-urolithic activity of *A. dichotoma*. Thus, the present investigation was aimed to explore such traditional system of medicines used in the treatment of arthritis, gastric ulcer and stone removal that may act as a contributing factor in achieving the goal of WHO in this regard. Hence, present investigation deals with pharmacognostical, phytochemical and pharmacological evaluation of *Aganosma dichotoma* for its anti-ulcer, analgesic, anti-inflammatory, anti-arthritic, and anti-urolithic properties, which are being used by the traditional healers for the treatment of following ailments.

Traditional, complementary and alternative medicines are commonly used to treat or prevent disease and chronic illness. Traditional medicine has also been used in the treatment and care of such life-threatening illnesses as well as age related disorder for which no modern medicine is available. Best known traditional medicine system includes Ayurveda, Siddha, Homeopathy and Unani. Evidence based assimilation of Indian traditional medicine in clinical practice will help to offer quality healthcare to all. Indian traditional medicine/medicinal plants are considered as a crucial source of new drug. Deforestation is the main cause for depletion of medicinal plant. Hence, protection strategies for both knowledge and resources at social, scientific and legislative levels are required urgently to save the traditional wisdom. Knowledge can endure and flourish only through the dissemination and sharing. Keeping this in mind, this research is focused on the evaluation of different ailments. Therefore, the main objective of the study is to explore the traditional use of *A. dichotoma*.

Vernacular name of *A. dichotoma* is Malati in Hindi, although there are some other plants which are also known as Malati in different languages, for example *Combretum indicum* (Combretaceae) known as malati in Hindi and *Jasminum grandiflorum* (Oleaceae) (Malati in Telugu). Due to same common name of the medicinal plants there are chances of misidentification resulting in ambiguity. Hence standardization will provide guideline for proper identification. In this context, the present study was undertaken for pharmacognostical standardization and evaluation of anti-ulcer, analgesic, anti-inflammatory, anti-arthritic and anti-urolithic potential of *A. dicotoma* root.

OBJECTIVE

1. **Pharmacognostical Evaluation**

- To investigate pharmacognostical, physicochemical and phytochemical analysis of *A. dichotoma* as per WHO guideline for quality control standardization.
- To carry out High performance thin layer chromatography (HPTLC) fingerprinting and quantification of identified phytoconstituents of the ethanolic extract and successive fraction(s) of the root.
- To isolate, and characterize the phytochemicals present in root using chromatographic techniques.
- To evaluate *in-vitro* antioxidant activity of the extract and fraction(s) of the selected root.

2. **Pharmacological Evaluation**

- To carry out acute oral toxicity and sub-acute toxicity study for dose fixation of the ethanolic root extract.
- To scientifically validate the anti-ulcer activity of the ethanolic root extract of *A. dichotoma* on experimental animals using both physical and chemical induced ulcerogens.
- The present study aims to scientifically validate the traditional claims of *A. dichotoma* as analgesic and anti inflammatory as well as to investigate its anti arthritis potential.
- To investigate anti-urolithic potential of *A. dichotoma* to scientifically validate the ethno-medicinal claims of root in treatment of urolithiasis.