The Journal of Phytopharmacology 2026; 15(2):181-191
Online at: www.phytopharmajournal.com

The Journal of Phytopharmacology
(Pharmacognosy and phytomedicine Research)

Review Article

ISSN 2320-480X
JPHYTO 2026; 15(2): 181-191
March- April
Received: 09-12-2025
Accepted: 21-03-2026
Published: 27-04-2026

doi: 10.31254/phyto.2026.15209

Calotropis procera: from ethnomedicine to modern therapeutics- phytochemistry, pharmacology, toxicity, and patent perspectives

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ABSTRACT

C. procera (Aiton) W.T. Aiton is a widely distributed xerophytic medicinal shrub inhabiting arid and semi-arid parts of Asia and Africa, and is widely used in indigenous systems of medicine to manage several pathological conditions. This review consolidates the available literature in relation to its ethnobotanical significance, phytochemistry and pharmacological activities in an endeavour to facilitate future scientific investigation. Ethnomedicinal reports describe its utilisation for the management of a vast array of conditions, including inflammation, diseases of the skin, respiratory tract and digestive system, as well as infestation by different kinds of parasites across diverse ethnic systems. Chromatographic analysis shows the presence of biologically active compounds like cardenolides (calotropin, uscharin, etc.), flavonoids, terpenoids, alkaloids, phenolic compounds, etc., which attribute its biological properties. Pharmacological activities evaluated so far, both *in vitro* and *in vivo*, have proved significant anti-inflammatory, antioxidant, antibacterial, antifungal, antitumor and antiparasitic as well as anti-diabetic and hepatoprotective actions which occur through different pathways such as inhibition of pro-inflammatory mediators, alleviation of oxidative stress and induction of apoptosis, etc. But toxic cardiac glycosides present in it make strict dose standardization a prerequisite. Clinical trials remain lacking, though enough pre-clinical evidence is available; therefore, further research work with standardised materials of *C. procera*, safety evaluation and clinical trials will be fruitful. It may prove to be an important source for drug discovery in phytomedicine.

Keywords: *C. procera*, Phytochemistry, Ethnopharmacology, Pharmacological Activities, Toxicity, Natural Products, Drug Discovery.

INTRODUCTION

The Genus *Calotropis* consists of several xerophytic shrubs occurring in vast areas of the tropics and subtropics of Asia and Africa. Among the various species, *C. procera* (Aiton) W. T. Aiton is a representative species of the Apocynaceae family, which has been extensively studied due to its medicinal and economic significance. This plant is commonly named as 'Madar', 'Aak, or 'Sodom apple' and grows very well in arid and semi-arid regions. The plant shows excellent adaptability to extreme climatic conditions [1,2] and various vernacular names from different regions are listed in Table 1. Traditionally, *C. procera* has played an indispensable role in different indigenous systems of medicine, such as Ayurveda, Unani, and the African traditional system of medicine. The leaves, roots, latex, and flowers of the plant have been utilized in the treatment of various diseases, such as inflammation, skin diseases, asthma, gastrointestinal infections, and worm infestations. *C. procera* latex has proven to be a highly potent biologically active constituent; however, it is also considered toxic at sufficiently large doses [3].

Pharmacognostic and Phytochemical characteristics of the plant exhibit distinct characteristics, including milky latex present in all plant parts and thick cuticular leaves with developed laticiferous tissue. It contains a variety of medicinally active compounds, such as cardiac glycosides (cardenolides), flavonoids, terpenoids, alkaloids, and phenolic compounds, which exhibit a wide range of activity. Cardenolides like calotropin and uscharin is consider as the major constituents responsible for activity as well as for their toxicity [4,5].

Pharmacological effects and current status in various *in vitro* and *in vivo* studies have been reported, showing the potential use of *C. procera*. Moreover, *C. procera* has anti-inflammatory, antioxidant, antimicrobial, anticancer, antidiabetic, and hepatoprotective activity [5]. These activities are believed to be due to more than one mechanism, such as the effect on the inflammatory pathway and free radicals and inhibition of enzymes. Although the plant exhibits a good pharmacological profile, there are some drawbacks, such as toxicity, which arises due to the presence of very potent cardiac glycosides. Therefore, the appropriate dose needs to be identified, along with the proper identification of the active and toxic constituents and proper formulations [4].

This review provides a clear and critical overview of the ethnobotanical importance of *C. procera*, its phytochemical status, potential biological effects, and current limitations, along with the scope for further research and development of this plant as a medicinal plant. Despite extensive preclinical evidence, translational and clinical research on *C. procera* remains limited, highlighting a critical gap between traditional knowledge and modern therapeutic application.

METHODOLGY

Ethnobotanical, phytochemical, and pharmacological data on *C. procera* were compiled and examined through a comprehensive literature review. Data were retrieved from major electronic databases, such as Google Scholar, ScienceDirect, and Scopus, from the scientific literature published up to May 2024 using the keywords "*C. procera*," "ethnobotany," "phytochemistry," "pharmacological activities," and "patents" [6].

The scientific nomenclature and taxonomic status of the plant were verified using the World Flora Online (WFO) database. The titles and abstracts of the selected articles were then reviewed to determine their relevance to the present study, and the eligible papers were evaluated at the full-text level. Research articles, reviews, theses, and dissertations describing biological activities and phytochemical constituents were included in the literature review.

The compiled data on ethnobotanical, phytochemical, and pharmacologically validated studies were organized and evaluated for consistency, methodological design, quality, and reproduction with proper citation. Duplicate and irrelevant studies were removed from the dataset for consistent results, and the final data were extracted for further analysis.

Ethnobotany & Traditional Uses

C. procera is widely employed in various traditional medicine practices, such as Ayurveda, Unani, and several indigenous systems of medicine in Asia and Africa. Various parts of the plant, such as leaves, roots, flowers, and latex, are used to cure a large number of diseases owing to their ethnopharmacological importance (4). Medicinally, it is used as an anti-inflammatory and anti-infective (skin disorders and respiratory system disorders, such as cough and asthma), for the treatment of gastrointestinal problems, parasite infections, etc. It is considered purgative, anthelmintic, expectorant, and appetizer. Various traditional systems apply latex of *C. procera* as a topical application in wound healing, skin infection and for its antiseptic properties, but to be used with great care as it is poisonous [7,8].

Ethnobotanical information regarding the usage of *C. procera* also indicated region-specific usage. For example, the tribal communities of Uttar Pradesh apply leaves for toothaches and scorpion stings, while latex is applied to the affected parts for the treatment of leprosy, rheumatism, and parasite infections in the Madhya Pradesh tribal population [5]. The root is also used to treat fever, asthma, and swelling, while the flower is used to treat gastrointestinal disturbances and cholera [9].

In Ayurvedic medicines, *C. procera* is considered to possess tikta rasa (bitter taste), ushna virya (hot potency) and katu vipaka (pungent metabolic effect). It is used as a purgative, vermifuge, and anti-inflammatory agent. It is an ingredient in a few classical preparations, such as Dhanvantara Ghrita and Chitrakadi Taila, and is employed for metabolic and inflammatory disorders [10]. Apart from medicinal uses, there are other non-therapeutic uses, such as fibers extracted from the stem used for making ropes, fishing nets, and clothes, and latex is also used for tanning and coloring leather [11].

Phytochemistry

C. procera has an abundance of diverse bioactive compounds distributed in different plant parts, such as leaves, roots, flowers, and latex. Phytochemical studies have shown the presence of various classes of secondary metabolites, including cardiac glycosides (cardenolides), flavonoids, terpenoids, alkaloids, phenolic compounds, sterols, and tannins, which have a vast spectrum of activities [5]. Of these, cardenolides are considered the most significant bioactive constituents. Compounds include calotropin, calactin, calotoxin, uscharin and voruscharin. Structures for the representative major bioactive compounds are shown in Figure 1.

The latter components are mainly present in the latex and are the source of the therapeutic effect, but are also toxic because of their actions on heart muscles [12]. Also found in the latex were proteolytic enzymes, calotropin, trypsin-like, and other bioactive enzymes with antibiotic properties [13].

The presence of different triterpenoids and sterols (-amyrin, Taraxasterol, Lupeol, -sitosterol) and Flavonoid glycoside quercetin-3-rutinoside has been confirmed from roots and root bark, which contribute to the antioxidant, anti-inflammatory and hepatoprotective effects [14]. The discovery of new compounds like Benzoyllineolone derivatives and Calotropursenyl acetate are also found in root extract [15]. The presence of Flavonoids, phenolic compounds and alkaloids (with predominant Mudrine) is found in leaves, whereas the presence of other constituents such as stigmasterol, Calotropagenin and terpenoids was reported, which give different physiological actions [16]. Steroids (Processerol), flavonoids and phenolic compounds, which give anti-oxidant and anti-cancer properties, were identified from flowers. With all these advancements, modern analysis methods like Nuclear magnetic resonance (NMR) and mass spectrometry have confirmed the complex structure diversity in its active components.

At last, the extensive number of bioactive components, especially Cardenolides, Flavonoids and Triterpenoids present in *C. procera*, account for its broad spectrum of activities; but the cardiac glycosides present are highly cardiotonic and therefore require cautious application with strict dose Standardization and toxicity study. Distribution of major secondary metabolites in different parts, along with the chemical structure, is given in Table 2.

Pharmacological Activities

C. procera demonstrates several potential biological activities that are backed by a large number of *in vitro* and *in vivo* studies. Most of the therapeutic benefits that these actions are thought to mediate are attributed to the diverse types of compounds found within the plant, such as cardenolides, flavonoids, terpenoids, and proteolytic enzymes. The major biological effects that have been associated with the activities and their suggested mechanisms of action are illustrated in Figure 2.

Anti-inflammatory and Analgesic Activity

One of the most thoroughly investigated activities of *C. procera* is its anti-inflammatory properties. Extracts (particularly from latex and roots) have displayed profound anti-inflammatory effects in carrageenan-induced paw oedema, formaldehyde-induced arthritis and cotton pellet granuloma models [21,22]. The effects may be attributed to inhibition of endogenous inflammatory mediators (histamine, bradykinin and prostaglandins) and cellular infiltration into the inflamed area. Dried latex extracts have also revealed effective analgesic activity in acetic acid-induced writhing and tail-flick tests, and it was found to be as effective as some conventional drugs like aspirin [23]. These effects appear to occur peripherally rather than opiotergically because naloxone could not reverse them. Figure 3 illustrates the anti-inflammatory and analgesic mechanisms of *C. procera*.

Antioxidant Activity

The antioxidant activity of *C. procera* seems mainly due to its phenolics and flavonoids. The extracts of the plant have been able to scavenge the free radicals effectively by the assays of DPPH and metal ions chelation. Besides, it also inhibits lipid peroxidation and increases antioxidant endogenous enzymes, including SOD, catalase, and GSH [24].

Antimicrobial Activity

Fractions of *C. procera*, particularly the flavonoid fractions, have displayed general anti-microbial activity against both gram-positive and gram-negative bacteria and fungi like Candida albicans. It is believed that the fractions act by damaging microbial membranes and inhibiting enzymatic functions or other mechanisms. Minimum inhibitory concentrations for crude flavonoid extracts were found to be low, and zones of inhibition were large [25]. Figure 4 illustrates the proposed mechanism of antimicrobial action of *C. procera* extracts involving ROS generation, membrane damage, protein inactivation, ion imbalance, mitochondrial dysfunction, and DNA damage.

Anticancer Activity

C. procera has already been reported for the anticancer properties against breast cancer (MCF-7), colon cancer (HT-29), lung cancer (A549) and prostate cancer cell lines. Mechanisms through which anticancer property occurs include induction of apoptosis, cell cycle arrest and altered oxidative stress pathways. calotropin, frugoside and certain flavonoids, i.e. Kaempferol and luteolin, possess cytotoxic effects. Moreover, alteration in the levels of autophagy markers LC3-II and Beclin-1 suggests the role of autophagy in the inhibition of cancer cells [26].

Antidiabetic Activity

The anti-diabetic efficacy of *C. procera* is exhibited in alloxan-induced diabetic models. Administration of dried latex extracts orally decreased the blood glucose and increased the storage of liver glycogen in the diabetic models. Improvement of activity of antioxidant enzymes and lipid peroxidation in the diabetic models reflects its role in reducing diabetes induced oxidative stress [27]. Figure 5 illustrates the Mechanism of action of *C. procera* against hyperglycemic activity

Hepatoprotective Activity

These hepatoprotective effects of *C. procera* have been observed to be dose-dependent and part-specific based on the nature of the extract applied. The latex extract of C procera is observed to be effective in terms of protecting from CCl_4 -induced hepatotoxicity by bringing serum enzyme levels (AST and ALT) towards the normal range and reduction in oxidation stress markers, though some authors observed increased toxicity with root extract, thus warranting judicious selection and standardisation of the extract [28].

Anticonvulsant Activity

The roots of *C. procera* have also exhibited remarkable anticonvulsant activity in MES and PTZ models. The decrease in seizure duration and latency in MES and PTZ-treated animals could indicate that some modulatory pathways involving neurotransmitters play a role in seizure activity [29].

Anthelmintic and Antiparasitic Activity

The Latex extracts have a good anthelmintic effect on *C. procera* and earthworms. They induce paralysis and death of the parasite in a dose-dependent manner by some proteolytic enzymes, organic compounds, etc., that affect the parasite's metabolism and morphology [30].

Wound Healing Activity

It has been reported that topical administration of latex enhanced the wound healing rate, indicated by the increases of collagen content, protein content and epithelialization, which justified its application as folk medicine in wound and skin diseases 1].

Immunomodulatory Activity

It was documented that application of latex to the skin promoted wound healing, evidenced by the increased levels of collagen content, protein content and epithelialization. It proved to be effective for the folk treatment of wounds and skin disease [32].

Other Pharmacological Activities

Further activities reported are: Anti-angiogenic, antipyretic, antidiarrhoeal, estrogenic, spasmolytic, insecticidal and cardiotonic. In particular, anti-angiogenic activity is significant in cancer treatment. The extracts have a capacity to inhibit neovascularisation. Cardiotonic activity of the extracts is thought to be related to the presence of cardiac glycosides, which can affect heart muscles and their contraction, though cardiotoxic at high doses [33]. Pharmacological activities of *C. procera* with the plant parts are summarised in Table 3.

Patents and Intellectual Property Landscape of *C. procera*

Recent advancements in research on *C. procera* have led to the development of several patents highlighting its diverse therapeutic and technological potential. These patents encompass applications in inflammatory, oncological, infectious, and metabolic disorders, along with innovations in extraction and formulation strategies aimed at improving the stability and bioavailability of its bioactive constituents. A summary of key patents related to *C. procera* is presented in Table 4.

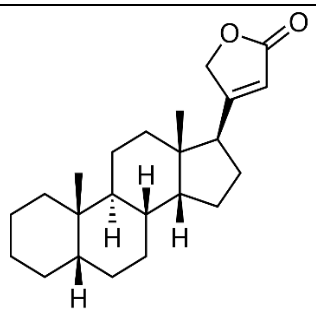
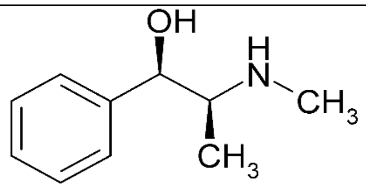
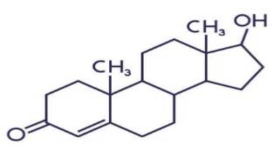
Toxicity And Safety Considerations

Despite its significant pharmacological potential, *C. procera* is associated with notable toxicity, primarily due to the presence of potent cardiac glycosides (cardenolides) such as calotropin and uscharin. These compounds exert digitalis-like effects by inhibiting Na^+/K^+-ATPase activity, which can lead to alterations in cardiac rhythm and potential cardiotoxicity at higher doses [45]. The latex of *C. procera* is particularly toxic and can cause severe irritation upon contact with skin and mucous membranes. Accidental exposure may result in dermatitis, conjunctivitis, and, in severe cases, corneal damage. Oral ingestion of plant parts has been reported to cause gastrointestinal disturbances, including nausea, vomiting, and diarrhoea, along with systemic toxicity [46]. Experimental studies have demonstrated that toxicity is dose-dependent and varies based on the plant part and type of extract used. While low doses of certain extracts exhibit therapeutic effects, higher concentrations may lead to hepatotoxicity, nephrotoxicity, and cardiotoxicity. Some studies have also reported embryotoxic and cytotoxic effects, indicating the need for caution in vulnerable populations [47]. Furthermore, contradictory findings regarding hepatoprotective versus hepatotoxic effects highlight the importance of extract standardisation and dose optimisation. These inconsistencies may arise due to variations in phytochemical composition influenced by geographical origin, extraction method, and plant maturity. Given these concerns, it is essential to establish safe dosage limits, conduct detailed toxicological evaluations, and perform clinical studies before therapeutic applications can be recommended. Formulation strategies such as targeted drug delivery systems and controlled release formulations may also help mitigate toxicity and enhance safety profiles.

Table 1: Vernacular names of *C. procera* Linn

Languages	Vernacular Names
Sanskrit	Shwetarka, Ravi, Arka
English	Madar tree
Hindi	Aak, Akavana, Madar
Marathi	Rui, Mandara
Gujarati	Akado
Punjabi	Ak
Kannada	Ekka, Ekkadagida
Telgu	Jilledu
Tamil	Vellerukku, Erukku
Urdu	Madar, Aak
Oria	Arakha
Kashmiri	Acka
Bengali	Akanda, Akone
Assami	Akand, Akan
Malayam	Erikku

Table 2: Presence of secondary metabolites in different parts of *C. procera* along with their representative chemical structures

Plant Part	Secondary metabolite	Chemical structure	References
Latex	Cardenolides		[17]
	Alkaloids		
	Steroids		

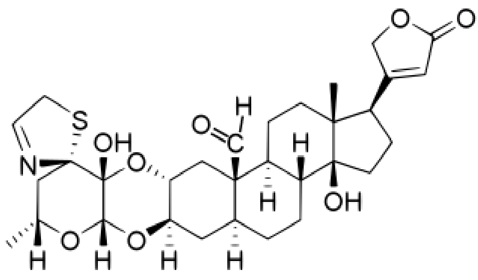
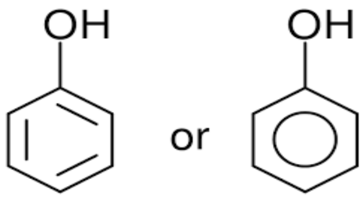
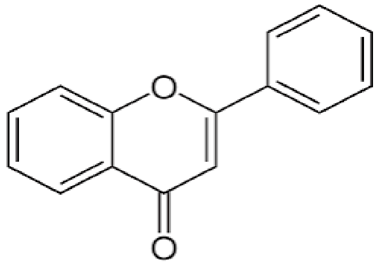
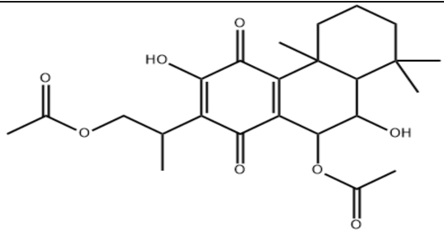
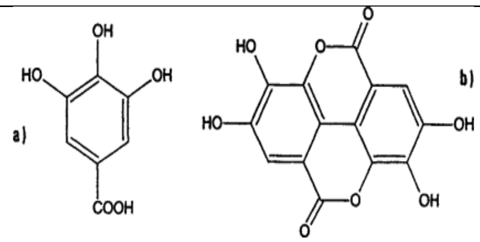
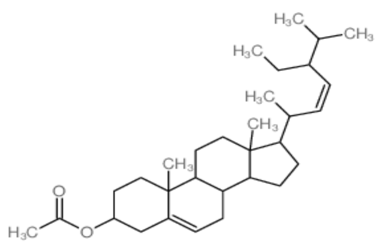
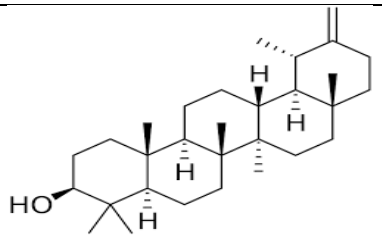
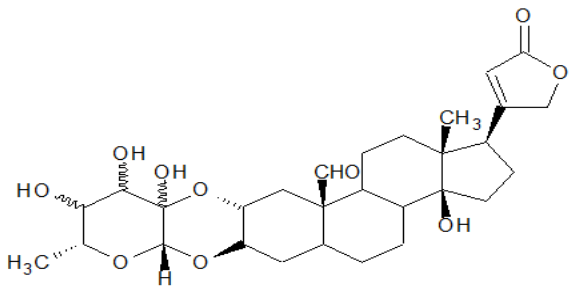
	Uscharin		[18]
Leaves	Phenols		[16],[19]
	Flavonoids		
	Terpenoids		
	Tannins		
	Stigmasta-5,22-dien-3-ol		
Roots	Taraxasterol		[20]

Table 3: Pharmacological activities of *C. procera* with reference to the plant part used

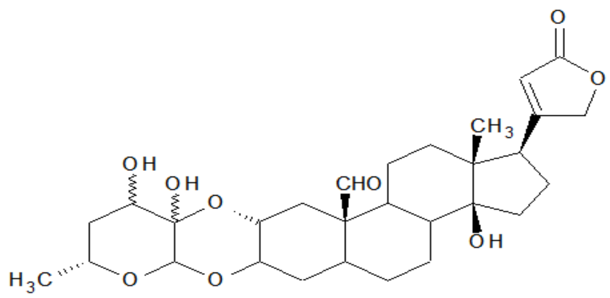
Part used	Extract / Formulation	Pharmacological activity	References
Roots	methanolic, n-hexane, ethyl acetate and water extracts	Anti-angiogenic effect	[34]
Dry latex	Aqueous extract	Anti-diabetic activity	[35]
Dry latex	Ethanolic extract	Analgesic activity	[36]
Leaf	chloroform extract & aqueous extract	Anticonvulsant activity	[37]
Leaf & Latex	Methanol extract	Antimicrobial activity	[38]
Stem, latex and flowers	Aqueous extract	Antipyretic activity	[39]
Roots and dry latex	Chloroform extract, aqueous extract	Anti-inflammatory activity	[40]
Roots	Alcoholic and aqueous extract	Anti-oxidant activity	[24]
Stem, flowers and Roots	Ethanolic extract	Hepatoprotective activity	[41]
Latex	Alcoholic and aqueous extract	Cytotoxic activity	[42]
Latex	Pure solution	Wound healing activity	[43]
Roots & Latex	Ethanolic extract	Hepatoprotective activity	[44]

Table 4: Selected patents on *C. procera,* highlighting therapeutic and technological applications

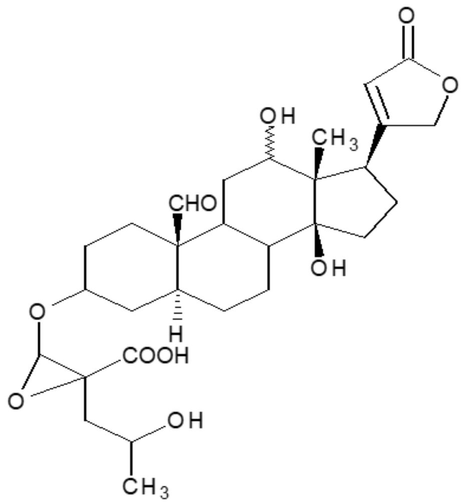
Sr No.	Title	Inventors	Patent No.	Year	Application	Invention Description
1	Extract of *C. procera* for the treatment of congenital syphilis	Mrak	EP0514508	1992	Anti-infective (congenital syphilis)	Describes ethanol-based extraction of plant parts for the treatment of congenital syphilis and related infections.
2	Extracts of latex of *C. procera* and the method of preparation	Vijay *et al.*	EP1755627A1; US20080280995A1	2007	Anticancer (HCC, cytotoxic activity)	Reports latex-derived extracts with significant anticancer activity in experimental models.
3	*C. procera* extracts as anti-ulcerative colitis agents	Awaad *et al.*	US9533019B1	2017	Anti-inflammatory (ulcerative colitis)	Describes the preparation of alcoholic extracts for the therapeutic management of ulcerative colitis.
4	Novel formulation of *C. procera* for the management of diabetes mellitus	Vyas *et al.*	IN201911004442	2019	Antidiabetic (enhanced delivery)	Describes SNEDDS-based formulation to improve bioavailability and therapeutic efficacy in diabetes.
5	Novel method for the preparation of latex powder of *C. procera* and its applications	Sonawane *et al.*	IN201921040493	2020	Antioxidant, hemostatic applications	Describes the preparation of dried latex powder exhibiting antioxidant and blood-clotting activity.
6	Method for the extraction of latex from *C. procera* and the product thereof	Khanna *et al.*	IN202211073273	2022	Standardised latex extraction	Describes a centrifugation and lyophilisation-based method for obtaining stable bioactive latex products.



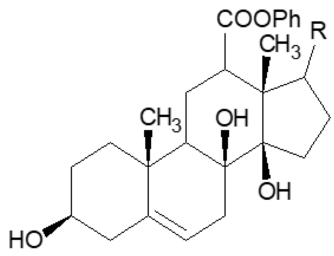
Calotoxin



Calotropin



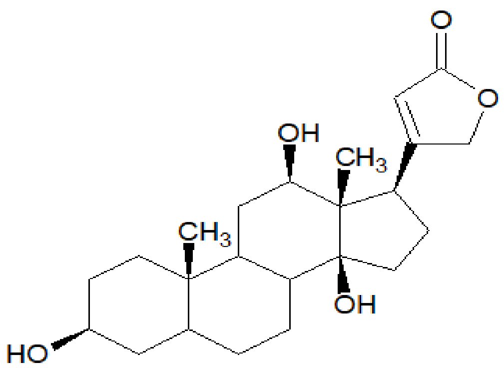
Calactinic Acid



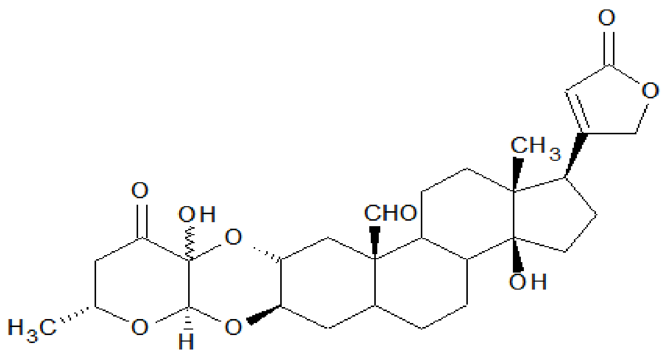
Benzoyllineolone

R = -Ac

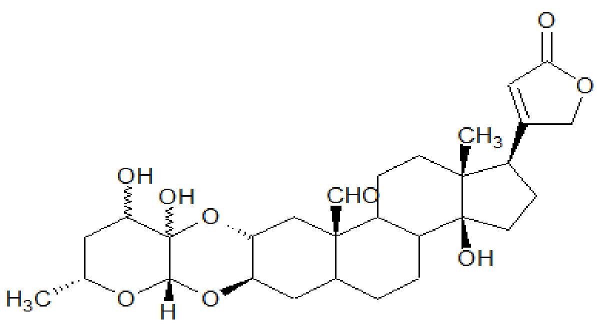
Benzoylisolineolone



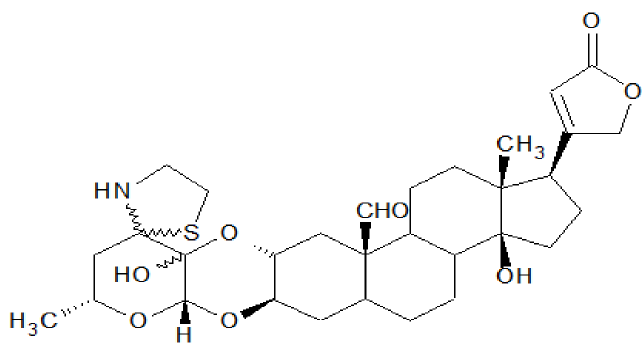
Syriogenin



Uscharidin



Proceroside



Voruscharin

Figure 1: Chemical structures of major bioactive compounds of *C. procera*

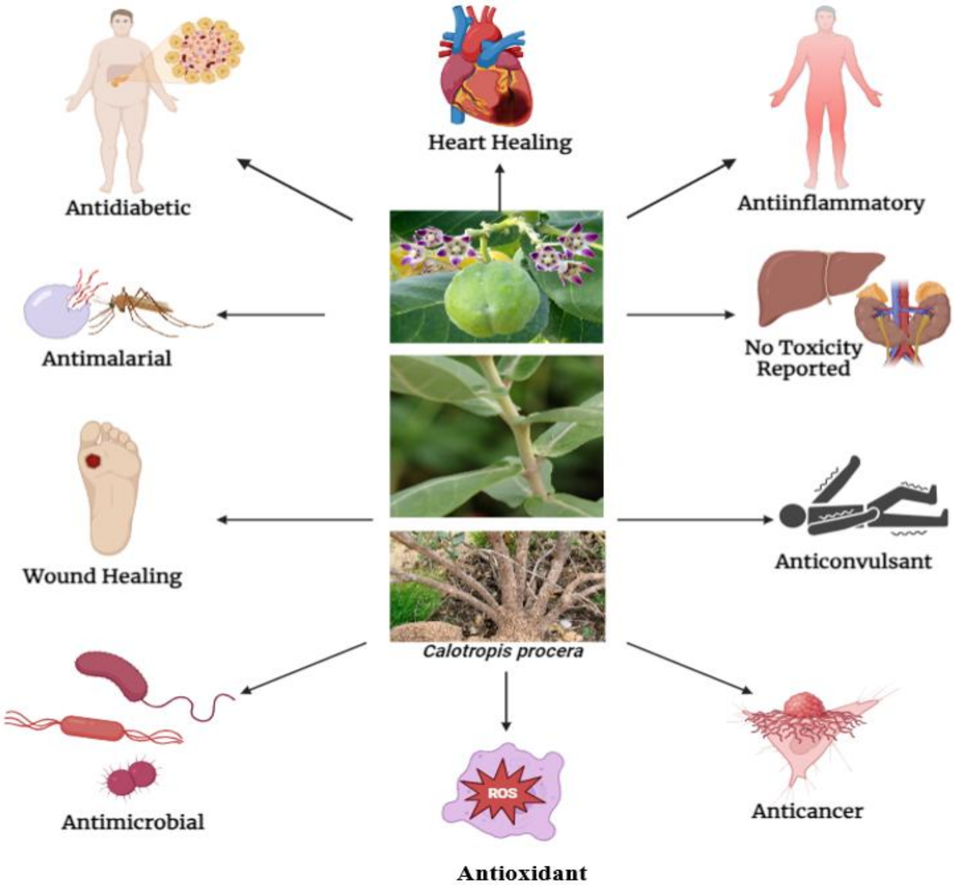


Figure 2: Pharmacological activities of *C. procera* [48]

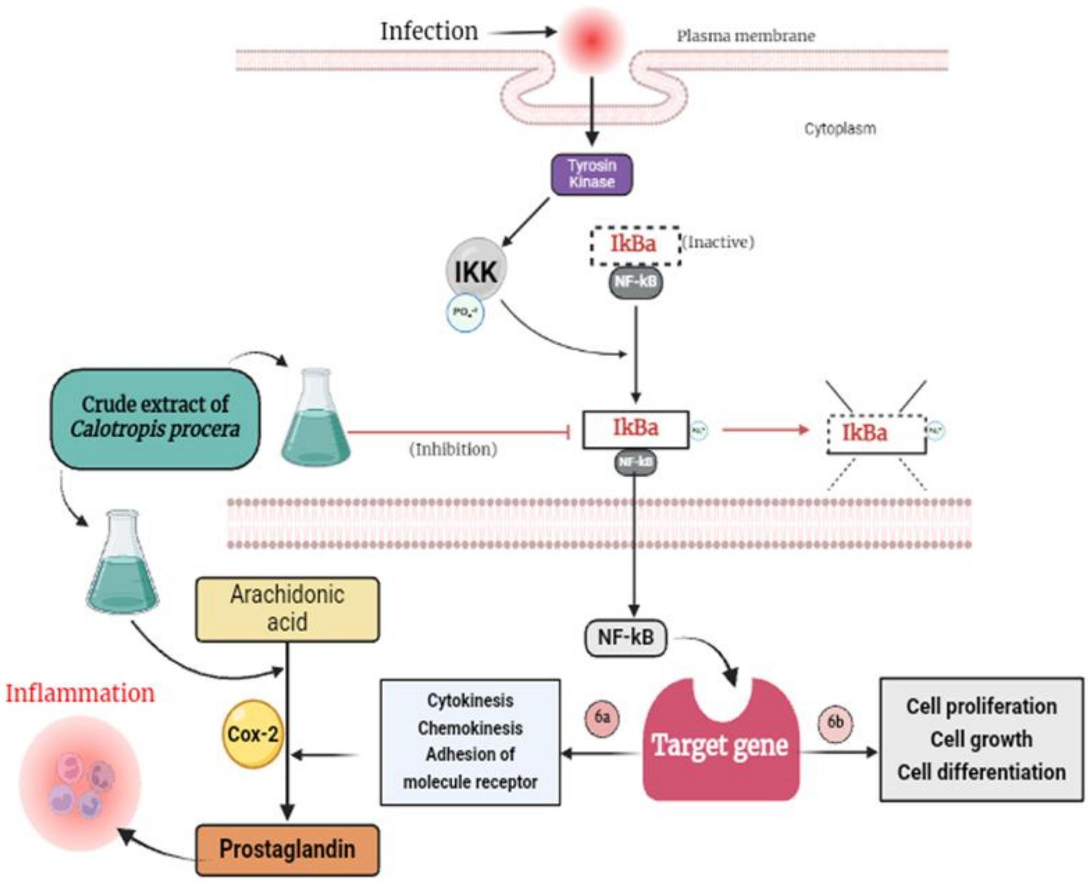


Figure 3: Mechanism of action of *C. procera* part nanoparticles on bacteria: anti-inflammatory effects of crude extract or pure components [48]

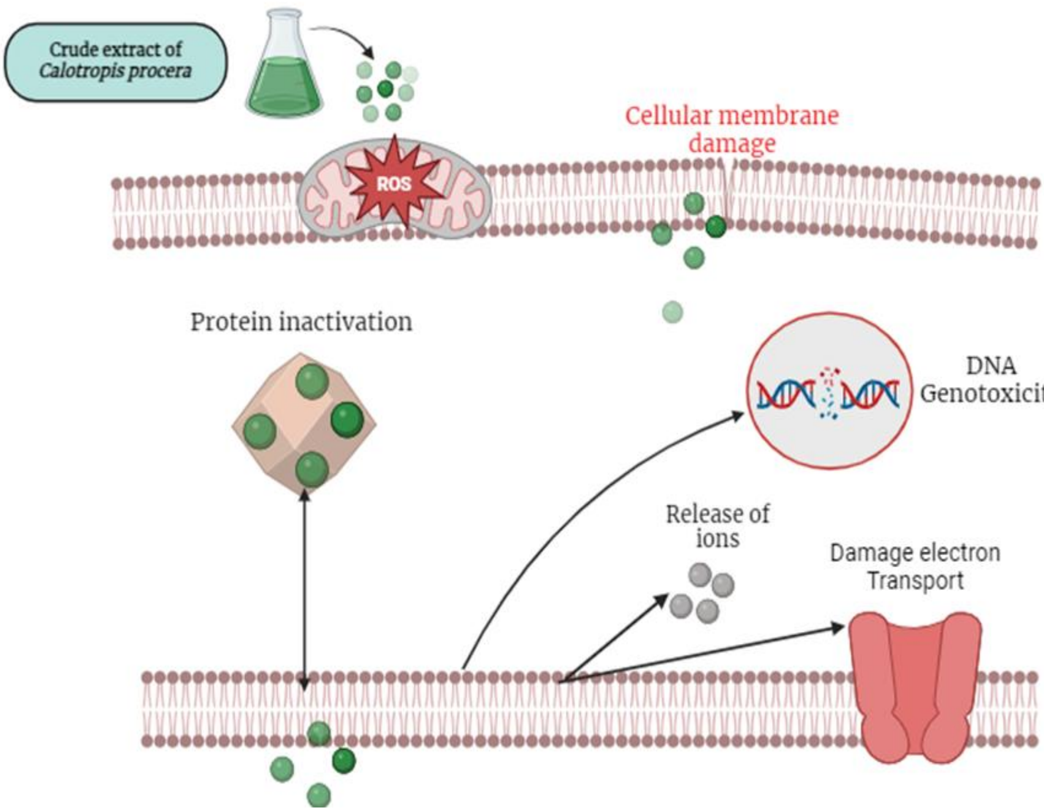


Figure 4: Proposed mechanism of action of *C. procera* extracts illustrating induction of reactive oxygen species (ROS), cellular membrane damage, protein inactivation, ion imbalance, mitochondrial dysfunction, and DNA genotoxicity [48]

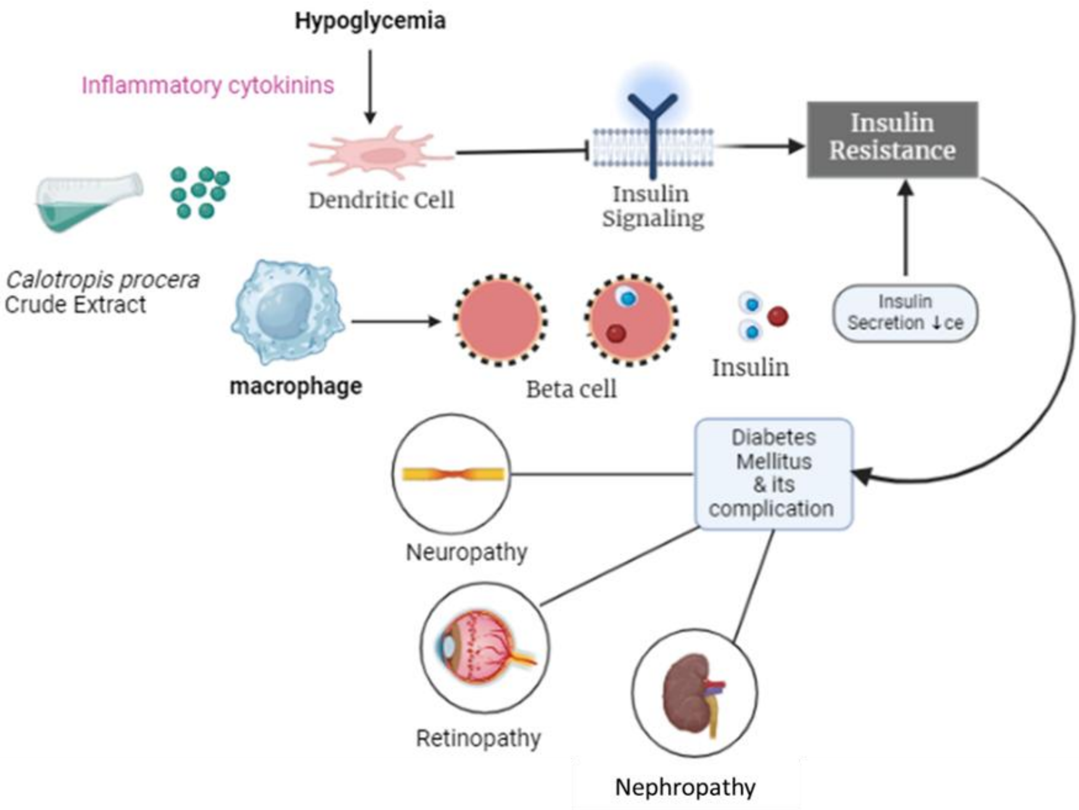


Figure 5: Mechanism of action of *C. procera* against hyperglycemic activity [48]

Industrial And Novel Applications

Beyond its medicinal significance, *C. procera* has attracted attention for various industrial and biotechnological applications. The plant's fibres, obtained from the stem bark, are strong, lightweight, and resistant to moisture, making them suitable for manufacturing ropes, carpets, fishing nets, and eco-friendly textiles [5]. The latex of *C. procera* contains rubber-like compounds and proteolytic enzymes, which have been explored for applications in biodegradable materials, bio adhesives, and enzyme-based industries. Additionally, its proteases have shown potential in leather processing and waste management due to their ability to degrade proteins efficiently [49].

Recent studies have also highlighted the plant's role in green synthesis of nanoparticles, where extracts are used as reducing and stabilising agents for the synthesis of metal nanoparticles such as silver and gold. These nanoparticles exhibit enhanced antimicrobial and anticancer activities, indicating promising applications in nanomedicine and drug delivery systems [50].

Furthermore, *C. procera* has been investigated for its potential in biofuel production due to its ability to grow in arid environments with minimal agricultural input. Its adaptability and high biomass yield make it a potential candidate for sustainable energy production.

FUTURE PERSPECTIVES

Future research should focus on the isolation and characterisation of specific bioactive compounds, along with detailed mechanistic studies to understand their molecular targets. Additionally, the development of advanced drug delivery systems, such as nano formulations and targeted delivery approaches, may help enhance therapeutic efficacy while minimising toxicity. Clinical trials are essential to validate the safety and efficacy of *C. procera*-based formulations in humans. Furthermore, integration of traditional knowledge with modern scientific approaches can facilitate the development of evidence-based phytotherapeutics. In conclusion, *C. procera* holds considerable promise as a source of bioactive compounds for pharmaceutical and industrial applications. With appropriate scientific validation and safety evaluation, it has the potential to contribute significantly to the development of novel therapeutic agents.

CONCLUSION

C. procera represents a pharmacologically versatile medicinal plant with significant ethnobotanical relevance and diverse therapeutic potential. The presence of bioactive compounds such as cardenolides, flavonoids, and terpenoids underpins its wide range of biological activities, including anti-inflammatory, antioxidant, antimicrobial, anticancer, and antidiabetic effects. These findings validate many of its traditional uses and highlight its importance as a potential source for novel drug discovery. However, despite extensive preclinical evidence, the translation of these findings into clinical applications remains limited. One of the major challenges associated with *C. procera* is its toxicity, primarily due to cardiac glycosides present in the latex and other plant parts. This necessitates careful standardisation, dose optimisation, and comprehensive toxicological evaluation before therapeutic use can be considered safe.

Conflict of interest

The authors declared no conflict of interest.

Financial Support

None declared.

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HOW TO CITE THIS ARTICLE

Mali RG, Yeole K, Pardeshi C, Wadekar R. *Calotropis procera*: from ethnomedicine to modern therapeutics- phytochemistry, pharmacology, toxicity, and patent perspectives. J Phytopharmacol 2026; 15(2):181-191. doi: 10.31254/phyto.2026.15209