

Pharmacological and Toxicological Evaluation of Divya Swasari Coronil Kit

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Abstract- In the present investigation an attempt has been made to assess the pharmacological potential of Divya-Coronil-Kit comprising of Coronil tablet, Swasari Vati and Anu Taila for management and control of Covid-19 infections. On evaluation, it was found that DCK containing Coronil Tablet, Swasari Vati and Anu Taila. Coronil Tablet contains 25 SPMs from 03 Medicinal Plants. Divya Swasari Ras Vati contains 89 SPMs from 09 Drugs whereas Anu Taila contains 204 phytoconstituents / SPMs from 27 Herbal Drugs. Coronil Tablet acts as immunity Booster. Divya Swasari Ras Vati is useful in cold, cough, and other viral diseases). Divya Anu Taila act internally for cooling brain and nerves; Improves sensory organs functions). Coronil Tablet, Swasari Vati and Anu Taila indicated the presence of alkaloids, glycosides, resins, terpenes, flavonoids, phytosterols, tannins, saponins, reducing sugars, anthraquinones, steroids, proteins, amino-acids. High amount of total phenolic content (TPC) and total flavonoid content (TFC) were found in the Coronil Tablet and Swasari Vati. A high amount of TFC was found in the Coronil Tablet but less than Divya Swasari Ras Vati. Coronil Tablet extract has also induced significant NO scavenging activity and antioxidant activity of Coronil Tablet was significant. Acute Toxicity studies clearly indicated that there was no mortality in rats upto 2000 mg/kg/b.wt. Coronil tablet and Swasari Vati induced a very wide safety margin and classified as Non-Toxic. Both Coronil Tablet and Swasari Vati increased swimming endurance and produced significant decrease in edema (significant anti-inflammatory effects) but effects were comparatively less significant than standard reference drug i.e. Indomethacin.

Keywords: Adaptogenic, anti-inflammatory, antioxidant, acute toxicity, Coronil tablet, sub-acute toxicity, Swasari Ras Vati, swimming test, free radical scavenging activity, total phenolic content, total flavonoid content.

1. Introduction

Coronavirus (COVID-19)

Coronavirus term is derived from the Latin “corona” and the Greek “κορώνη” (koronē, “garland, wreath”), meaning crown or halo. Any member of the genus *Coronavirus* of enveloped, single-stranded RNA viruses which have prominent projections from the envelope and are pathogens of humans, other mammals, and birds, typically causing gastrointestinal, respiratory, or neurological disease (Sexton *et al.*, 2016).

Marra *et al.*, 2003, Novel coronavirus, also known as 2019-nCoV, is a type of virus that causes respiratory illness. Most of these viruses only affect animals, but sometimes these viruses can change and infect people. COVID-19 (coronavirus disease 2019) is a respiratory tract infection with a newly recognized corona-virus thought to have originated as a zoonotic virus that has mutated or otherwise adapted in ways that allow human pathogenicity (Geller *et al.*, 2012; Christou, 2011).

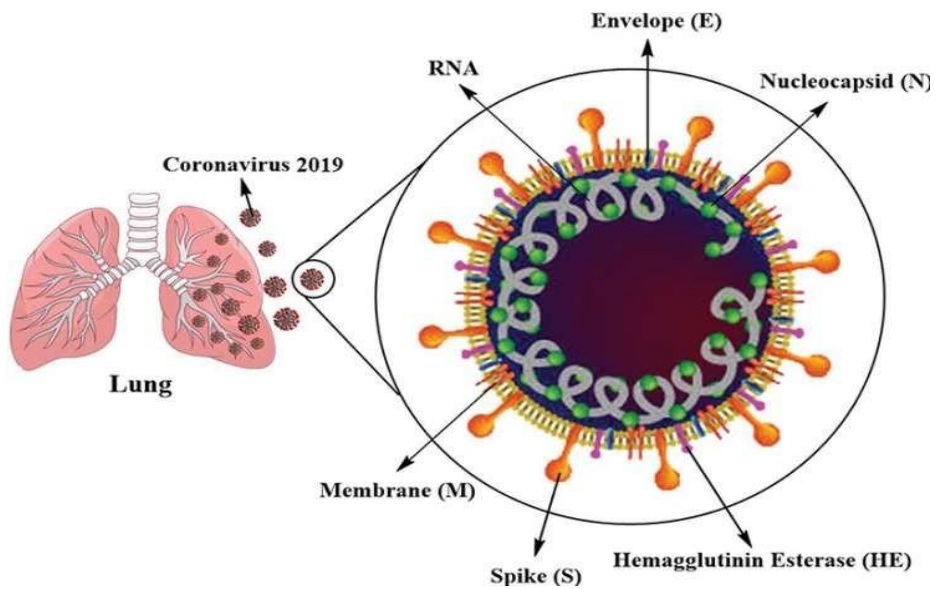


Figure 1: Structure of Corona Virus.

	Origin	Animal reservoir	Receptor	Intermediate host	year
SARS-CoV-2	Wuhan, China	Bats	Angiotensin converting enzyme 2 (ACE2)	Unknown	2019
MERS-CoV	Saudi Arabia	Bats	Dipeptidyl peptidase 4 (DPP4)	Camel, dromedary	2012
SARS-CoV	Guangdong, China	Bats	Angiotensin converting enzyme 2 (ACE2)	Palm civet	2002

Figure 2 : History of Corona viruses.

Classification of Coronavirus

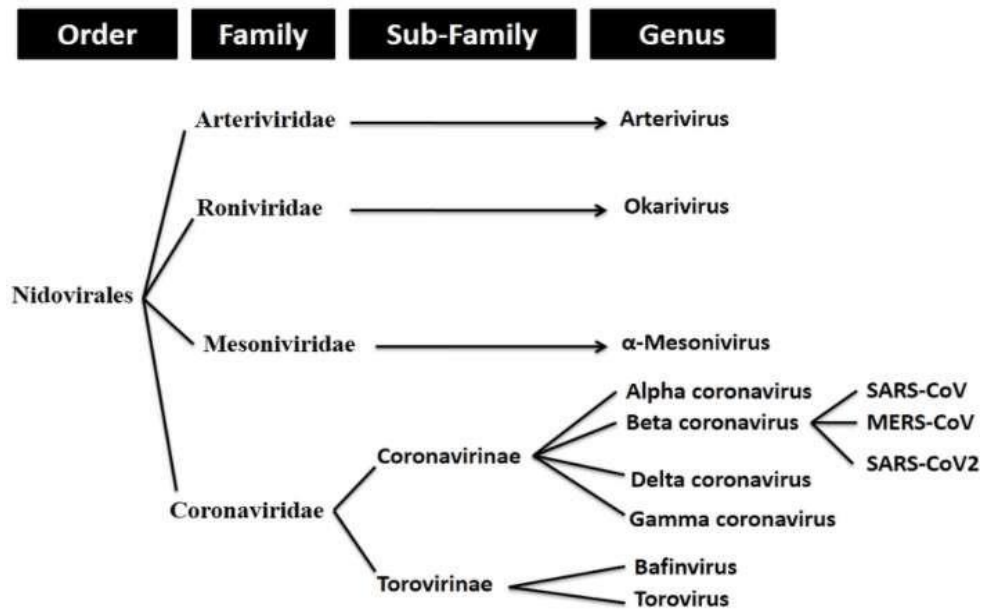


Figure 3: Classification of Coronavirus.

Causes and Risk Factors: Infection due to SARS-CoV-2 (2019 novel coronavirus)

This illness is caused by a virus through anyone of the following mode:

- Breathing in droplets from an infected person's cough or sneeze.
- Touching something, like a table or a doorknob, that was exposed to the virus (*contaminated*) and then touching your mouth, nose, or eyes.
- Being around animals that carry the virus, or eating uncooked or undercooked meat or animal products that contain the virus.

What increases the risk of Corona Virus Infection?

- Live in or travel to an area with a novel coronavirus outbreak.
- Come in contact with a sick person who recently traveled to an area of the novel coronavirus outbreak.
- Provide care for or live with a person who is infected with the novel coronavirus.

What are the signs or symptoms of novel corona-virus infection?

The novel corona-virus causes respiratory illness that can lead to pneumonia. Symptoms of pneumonia may include:

- Fever.
- Cough.
- Difficulty in breathing.

Table 1: Symptoms of Covid-19.

Most Common Symptoms	Less Common Symptoms	Serious Symptoms
<ul style="list-style-type: none"> • Fever. • Cough. • Tiredness. • Loss of taste or smell. 	<ul style="list-style-type: none"> • Sore throat. • Headache. • Aches and pains. • Diarrhea. • Rash on skin, or discoloration of fingers or toes. • Red or irritated eyes. 	<ul style="list-style-type: none"> • Difficulty breathing or shortness of breath. • Loss of speech or mobility, or confusion. • Chest pain.

On average it takes 5–6 days from when someone is infected with the virus for symptoms to show, however it can take up to 14 days.

Diagnosis: Clinical Presentation

Patient History

- Patients with moderate to severe disease complain of dyspnea.
- Hemoptysis has been reported in a small percentage of patients.
- Pleuritic chest pain has been reported.
- Upper respiratory tract symptoms (eg, rhinorrhea, sneezing, sore throat) are unusual.
- Headache and gastrointestinal symptoms (eg, nausea, vomiting, diarrhea) are uncommon but may occur.

Patients may report close contact with an infected person; outside of an identified outbreak area, a history of recent travel (within 14 days) to an area with widespread infection is relevant, although cases with no identifiable risk factor are being reported.

Patient Physical Examination

Reported case series have not detailed physical findings, but clinicians should be particularly attuned to pulmonary and hemodynamic indicators of severe disease. Patients with severe disease may appear quite ill, with tachypnea and labored respirations. Fever is usual, often exceeding 39 °C. Patients in the extremes of age or with immunodeficiency may not develop fever. Hypotension, tachycardia, and cool/clammy extremities suggest shock. In children, hypotension plus 2 or 3 of the following criteria:

- Altered mental status
- Tachycardia (heart rate more than 160 beats per minute in infants or 150 in older children) or bradycardia (heart rate less than 90 in infants or 70 in older children)
- Prolonged capillary refill or warm vasodilation and bounding pulses
- Tachypnea
- Mottled skin, petechiae, or purpura
- Oliguria
- Hyperthermia or hypothermia

Clinical diagnostic tools for novel coronavirus:

Lab tests, which may include:

- Physical examination.
- A nasal swab to take a sample of fluid from your nose.
- A throat swab to take a sample of fluid from your throat.
- A sample of mucus from your lungs (*sputum*).
- Blood tests.

Prevention of Corona-virus Infection

To prevent infection and to slow transmission of COVID-19, the following are needed :

- Get vaccinated.
- Stay at least 1 meter apart from others, even if they don't appear to be sick.
- Wear a properly fitted mask when physical distancing is not possible or when in poorly ventilated settings.
- Choose open, well-ventilated spaces over closed ones. Open a window if indoors.
- Wash hands regularly with soap and water or clean them with alcohol-based hand rub.
- Cover mouth and nose when coughing or sneezing.
- If feeling unwell, stay home and self-isolate until recovery.

Inflammation

Dewanjee *et al.*, 2013 illustrated that inflammatory diseases (acute as well as chronic debilitating diseases) are globally identified as the major cause of morbidity in today's era of modern lifestyle across the population.

Roomme *et al.*, 2007, word inflammation is derived from the Latin word - "inflammers" / "inflammatio" (to burn) is part of the complex biological response / defense of an organism against local injury, infections and acute / chronic inflammation (rheumatoid arthritis, asthma, colitis, hepatitis, cancer, cardiovascular and neurodegenerative disorders) / biological response to harmful stimuli (Parhnam *et al.*, 2008).

Libby *et al.*, 2003 illustrated that inflammatory diseases including different types of rheumatic diseases are very common throughout the world.

Causes

- Living organisms: ex. bacteria, viruses, fungi, protozoa & metazoa
- Chemicals: ex. Turpentine
- Mechanical & Thermal injuries: ex. burns, electricity, radiations
- Immune reaction: causes inflammation due to Ag-Ab reaction

Anti-Inflammatory Agents

Non-steroidal anti-inflammatory drugs

The NSAIDs, sometimes called the aspirin-like drugs, are among the most widely used of all drugs. The NSAIDs reduce mainly those components of the inflammatory and immune response in which prostaglandins, mainly derived from COX-2, play a significant part.

Medicinal Plants As Anti-inflammatory Agents

Prasad *et al.*, 2002, herbal medicine always played an important role in meeting the global health care needs particularly in developing countries. In recent times there has been a shift in worldwide trend from synthetic to herbal medicine, while we can say “Return to Nature” and are available as “traditional herbal medicines” and in Indian culture are known as “Indian System of Medicine” (Newman *et al.*, 2000).

Butler (2004) found that medicinal plants have been known for ages and are highly valued all over the world as a rich source of therapeutic agents. Nature has blessed India with an enormous wealth of medicinal plants due to different climate in its different parts and therefore India is considered as the “Medicinal Garden of the Globe”. India has six recognized systems of medicine like Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy. These systems are part of “Alternative System of Medicine”.

Iwalewa *et al.*, 2007, diseases with inflammatory etiology or pathology are having an increase in incidence around the globe (Burke *et al.*, 2005). Tiwari (2008), for prevention as well as treatment of diseases (including inflammatory diseases) there have been uses of herbal medicines for a prolonged period. Gessner *et al.*, 2017, Anti-inflammatory agents are the chemical entities that can prevent inflammation. They can be synthetic or natural, former being steroidal and non-steroidal with many side effects and latter of plant and/or microbe origin with less or no side effects (Lima, 2018; Corlett, 2016; Ghasemian *et al.*, 2015).

Madhuri & Pandey (2009), mechanisms of action include modulation of detoxification enzymes, scavenging of oxidative agents, stimulation of the immune system, regulation of gene expression in cell proliferation and apoptosis, hormone metabolism, antibacterial and antiviral effects.

Oxidative Stress (OS)

Vishal *et al.*, 2005, it is defined as a disturbance between free radical, Reactive Oxygen Species and endogenous anti-oxidant defense mechanism. Ueda *et al.*, 2010, summarised that ROS cause inflammations, degeneration of cells, tissues and organs, in cancer development and even in disease progression (Amaral *et al.*, 2013).

Schwager *et al.*, 2008 found that Oxidative stress is involved in various physiological and pathological processes including DNA damage, proliferation, cell adhesion, and survival / pathological state including carcinogenesis (Valco *et al.*, 2006). Sdayria *et al.*, 2018, established that all these collectively lead to carcinogenesis (complex interaction between ROS generation, ROS signalling, ROS –induced damage and carcinogenesis) (Vilar *et al.*, 2016).

Antioxidants

To counteract oxidative stress, body produces an armoury of antioxidants (neutralise or “mop up” free radicals) to defend itself. Thioredoxin and glutathione (vitamin C is involved in its biosynthesis) are the examples of antioxidants (useful in oxidative stress by scavenging oxygen free radicals). Examples are Epigallo catechin gallate (EGCG; as ester of gallic acid and epigallocatechin; richest source is green tea / black tea), Vitamin C (richest source is Amla fruits), Vitamin E, carotene, curcumin, reveratrol and Quecetin.

Plants with Anti-oxidant Activity

Newman *et al.*, 2016, illustrated that most of the herbal medicines have been used to treat many diseases in most developing countries. Callegari *et al.*, 2016, Polyphenols, flavonoids, and steroids are some of the phytochemicals that have been extensively studied as anti-oxidant agents (Vajja *et al.*, 2004).

Coronil Kit (Patanjali; "Immuno booster")

Patanjali Divya Coronil Kit (Immunity Booster designed with powerful herbs to boost human immunity) is a collection of three ayurvedic medicines / formulations which provide relief during common cold and viral infections / respiratory pathogenic infections (multifarious benefits; COVID-19 pandemic). The correct dosage of Divya Coronil Kit depends on the patient's age, gender, and medical history. So far, no side effects of Patanjali Coronil Kit have been reported in the medical literature.

Patanjali Research Institute has established it as "first evidence-based medicine for COVID-19" which works against asymptomatic, symptomatic and severe (cases) also for treatment, prevention, cure of COVID-19 and also help to control the health hazardous ill after-effects. Patanjali Research Institute has stated it was developed and formulated by the combined efforts of Patanjali Research Centre and National Institute of Medical Sciences (NIMS), a private medical college in Jaipur, Rajasthan. Patanjali claimed that medicine had fully cured (69% recovered within 03 days and 100% recovery was observed in next 07 days)(Balkrishna *et al.*, 2020; Balkrishna *et al.*, 2021).

Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) Ministry has approved Patanjali Divya Coronil Kit only as an 'Immuno Booster Product'. Conclusively, World Health Organization (WHO South-East Asia Wing) illustrated bad science and poor ethics of Patanjali (false and fabricated and unscientific). WHO has not reviewed or certified the effectiveness of any traditional medicine for the treatment of COVID-19 as there was severe criticism as the Divya Coronil Kit lacked scientific evidence regarding its efficacy.

Indian Medical Association (IMA) had made the statement that Patanjali's claims amounted to "blatant deceiving of the people of the country." Subsequently, IMA has questioned the said 'clinical trials' of Coronil & WHO refuted the false claim made by Patanjali Ayurveda for giving any certificate regarding its effectiveness for Covid-19 treatment. The product Divya Coronil Kit has been exported to 158 countries and earned a more than two thousand crores turnover. Coronil received the Certificate of Pharmaceutical Product (CoPP) from the Ayush as per the WHO certification scheme. CoPP certificate to Coronil Kit was issued by DCGI, Government of India.



Figure 4 : Coronil Kit (Patanjali).

Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) Ministry has approved Patanjali Divya Coronil Kit only as an 'Immuno Booster Product'. Pharmacologically, coronil Tablet acts as immunity Booster (Antioxidant, Relieve cough; Inhibit microbial growth; Cure inflammation; Malaria; Secretion of phlegm).

To curb the rising cases of COVID-19, doctors, medical institutes, hospitals recommended various therapeutic strategies that include medicines like Fabiflu tablets, Limcee tablets, etc. However, there are a very few researches and factual backing behind this product. Patanjali being a huge brand, it makes consumers more vulnerable to their marketing strategies. There was a need of thorough examination and study of the ingredients and the formulation so present work was undertaken with following aim and objectives:

- Composition of ingredients present in Coronil tablet, Swasari Vati, Anu Taila.
- Effect of Coronil tablet and Swasari Vati on blood parameters, LFTs, KFTs, triglycerides, cholesterol for acute and sub-acute toxicity studies.
- Adaptogenic and anti-inflammatory activity of Coronil tablet and Swasari Vati.

Methodologies

- Compilation of pharmacognostical and pharmacological data of Coronil tablet, Swasari Vati and Anu Taila (Patanjali).
- Compilation of clinical behavioral observations and biochemical profiles (blood parameters, LFT, KFT,

triglycerides, cholesterol) and body weight analysis.

- Adaptogenic activity of Coronil tablet and Swasari Vati
- Anti-inflammatory activity of Coronil tablet and Swasari Vati

Pharmacognostical and Pharmacological Assessment

The formulation of Swasari Coronil Kit includes Coronil Tablet, Swasari Vati and Anu Taila which are derived from various medicinal plants. Swasari Coronil Kit contains Coronil Tablet (640 mg Tablet) with more than 30 phytotherapeutic constituents / secondary plant metabolites (SPMs) derived from 03 medicinal plants (Table 2). Divya Swasari Ras Vati (540 mg Tablet) contains more than 100 SPMs from 08 medicinal plants with various types of Bhasmas (Table 3). Anu Taila contains almost 28 medicinal herbal drugs having more than 200 phytoconstituents. (Table 4)

Table 2: Composition of Coronil Tablet (640 mg each tablet)

S. No.	Constituents	Concentration
1	Extract of Giloy (<i>Tinospora cordifolia</i>)	300 mg
2	Extract of Ashwagandha <i>Withania somnifera</i>	250 mg
3	Extract of Tulsi (<i>Ocimum basilicum</i>)	50 mg
4	Gum Acacia	25 mg
5	Talcum	7.5mg
6	Aerosil	6.5 mg
7	Magnesium stearate	1.0 mg
Total Weight (each tablet)		640 mg

Table 3: Composition of Divya Swasari Ras Vati (540 mg Tablet)

S. No.	Constituents	Concentration (mg)
1.	Powder of Mulethi (<i>Glycyrrhiza glabra</i>)	64
2.	Powder of Kakdasinghi (<i>Pistacia integerrima</i>)	63
3.	Rudanti / Rudravanti (<i>Cressa cretica</i>)	63
4.	Sounth (Adrak; <i>Zingiber officinale</i>)	42
5.	Marich (<i>Piper nigrum</i>)	42
6.	Choti Pipal (<i>Piper longum</i>)	42
7.	Dalchini (<i>Cinnamomum zeylanicum</i>)	32
8.	Lavang (<i>Syzygium aromaticum</i>)	32
9.	Akarkara (<i>Anacyclus pyrethrum</i>)	32
10.	Abhrak Bhasma	12.571
11.	Mukta Shukti Bhasma	12.571
12.	Godanti Bhasma	12.571
13.	Kapardak Bhasma	12.571
14.	Praval Pisthi	12.571
15.	Sphatika Bhasma	12.571
16.	Tankan Bhasma	12.571
17.	Gum Acacia	25
18.	Talcum	7.5
19.	Aerosil	7.5
Total Weight (each tablet)		540 mg

Table 4: Composition of Anu Taila (20 ml)

S. No.	Constituents	Concentration
Each 100 ml prepared from the following:		
1.	Mahendra Jal	10 ml
2.	Goat Milk	100 ml
3.	Kalka of Safed Chandan - <i>Santalum album</i>	3.846 mg
4.	Agar (<i>Aquiteria agalocha</i>)	3.846 mg
5.	Tejpat (<i>Cinnamomum tamala</i>)	3.846 mg
6.	Daruhaldi / Daruharidra (<i>Berberis aristata</i>)	3.846 mg
7.	Mulethi (<i>Glycyrrhiza glabra</i>)	3.846 mg
8.	Bala (<i>Sida Cordifolia</i>)	3.846 mg
9.	Pundarika (<i>Nelumbo nucifera</i>)	3.846 mg
10.	Chhoti Elaichi (<i>Eletaria cardamomum</i>)	3.846 mg
11.	Vayavidanga (<i>Embelia ribes</i>)	3.846 mg
12.	Bel (<i>Aegle Marmelos</i>)	3.846 mg
13.	Kamal (<i>Nelumbo nucifera</i>)	3.846 mg
14.	Netrabala (<i>Pavanir odorata</i>)	3.846 mg
15.	Khas (<i>Vetveria zizanioides</i>)	3.846 mg
16.	Kevatimotha (<i>Cupenus rotundus</i>)	3.846 mg
17.	Dalchini (<i>Cinnamomum zeylanicum</i>)	3.846 mg
18.	Nagarmotha (<i>Cyperus scaniosus</i>)	3.846 mg
19.	Anantmool (<i>Hemidesmus indicus</i>)	3.846 mg
20.	Salaparni (<i>Desmodium gengeticum</i>)	3.846 mg
21.	Jivanti (<i>Leptadenia reticulata</i>)	3.846 mg
22.	Prasnipami (<i>Uravia picta</i>)	3.846 mg
23.	Devadaru (<i>Cedrus deodara</i>)	3.846 mg
24.	Satavar (<i>Asparagus racemosus</i>)	3.846 mg
25.	Renuka (<i>Vitex negundo</i>)	3.846 mg
26.	Chhotikateri (<i>Solanum xanthocarpum</i>)	3.846 mg
27.	Surabhi (<i>Boswellia sarrata</i>)	3.846 mg
28.	Kamalkeshar (<i>Nelumbo nucifera</i>)	3.846 mg
29.	Taila of : Til (<i>Sesumum indicum</i>)	100 ml

Table 5: Pharmacognostical and Pharmacological Assessment of Coronil Kit.

Parameter	Coronil Tablet	Swasari Vati	Anu Taila
Constituents	25 SPMs from 03 Medicinal Plants	89 SPMs from 09 Drugs	204 Phytoconstituents from 27 Herbal Drugs
Constituents Plants	Medicinal Plants:	Medicinal Plants:	Medicinal Plants:
	(i) <i>Tinospora cordifolia</i>	(i) <i>Glycyrrhiza glabra</i>	(i) <i>Santalum album</i>
			(ii) <i>Aquiteria agalocha</i>
		(ii) <i>Pistacia integerrima</i>	(iii) <i>Cinnamomum tamala</i>
	(ii) <i>Withania somnifera</i>		(iv) <i>Berberis aristata</i>
		(iii) <i>Cressa cretica</i>	(v) <i>Glycyrrhiza glabra</i>
	(iii) <i>Ocimum basilicum</i>	(iv) <i>Zingiber officinale</i>	(vi) <i>Sida Cordifolia</i>
			(vii) <i>Nelumbo nucifera</i>
		(v) <i>Piper nigrum</i>	(viii) <i>Eletaria cardamomum</i>
		(vi) <i>Piper longum</i>	(ix) <i>Embelia ribes</i>
		(vii) <i>Cinnamomum</i>	(x) <i>Aegle Marmelos</i>

		<i>zeylanicum</i>	(xi) <i>Nelumbo nucifera</i>
		(viii) <i>Syzygium aromaticum</i>	(xii) <i>Pavanir odorata</i>
			(xii) <i>Vetveria zizanioides</i>
		(ix) <i>Anacyclus pyrethrum</i>	(xiv) <i>Cinnamomumzeylanicum</i>
			(xv) <i>Cyperus scaniosus</i>
			(xvi) <i>Hemidesmus indicus</i>
			(xvii) <i>Desmodium gengeticum</i>
			(xviii) <i>Leptadenia reticulata</i>
			(xix) <i>Uravia picta</i>
			(xx) <i>Cupenus rotundus</i>
			(xxi) <i>Cedrus deodara</i>
			(xxii) <i>Asparagus racemosus</i>
			(xxiii) <i>Vitex negundo</i>
			(xxiv) <i>Solanum xanthocarpum</i>
			(xxv) <i>Boswellia sarrata</i>
			(xxvi) <i>Nelumbo nucifera</i>
			(xxvii) <i>Sesumum indicum</i>
Pharmacological / Medicinal Uses	Immunity Booster (Antioxidant, Relieve cough; Anti-microbial Malaria)	In cold, cough, and other viral diseases; Anti-inflammatory, anti-viral, Antibacterial, antifungal.	Act internally for cooling brain and nerves; Improves sensory organs functions; Relieves ailments in Head, neck, shoulders, eyes, nose, ears, skin, throat;
Dose	2 Tablet (BID; Before meal)	2-2 Tablet (BID; Before meal)	4-4 drops in each nostril daily before breakfast
Toxicity Profile	Safe dose: 3000 mg/kg bw Toxicity absent.	Safe dose: 2000 mg/kg bw ▪ Toxicity absent.	Not Applicable
Side Effects	Coronil Tablet is absolutely safe and no side effects.	No side effects of Divya Swasari Ras Vati.	No side effects of AnuTaila.

Divya Swasari Coronil Kit containing Coronil Tablet, Swasari Vati and Anu Taila. Coronil Tablet contains 25 SPMs from 03 Medicinal Plants. Divya Swasari Ras Vati contains 89 SPMs from 09 Drugs whereas Anu Taila contains 204 phytoconstituents / SPMs from 27 Herbal Drugs (Table 4.5). Coronil Tablet acts as immunity Booster (Antioxidant, Relieve cough; Inhibit microbial growth; Cure inflammation; Malaria; Secretion of phlegm). Divya Swasari Ras Vati is useful in cold, cough, and other viral diseases; Anti-inflammatory, anti-viral, Antibacterial, antifungal. Divya Anu Taila act internally for cooling brain and nerves; Improves sensory organs functions; relieves ailments in head, neck, shoulders, eyes, nose, ears, skin, throat; (Table 5).

Preliminary Qualitative Analysis of Divya Swasari Coronil Kit.

Swasari Coronil Kit containing Coronil Tablet, Swasari Vati and Anu Taila were used for phytochemical investigations were undertaken using different polar and non-polar solvent extracts. Preliminary phytochemical screening for the detection of various was carried out by using standard procedures described by Harborne, Khandelwal and Practical Pharmacognosy by Kokate.

Safety & Toxicity Evaluation of Coronil Tablet and Swasari Vati

Acute Toxicity Study

Actual oral toxicity of Coronil tablet and Swasari Vati extracts were evaluated in Albino Wistar Rats (150g) as per CCSEA / IAEC guidelines. Coronil tablet and Swasari Vati extracts were administered and physiological and behavioral changes were observed for salivation, tremors, convulsions, diarrheal, hyperactivity, ataxia, lethargy, sleep and coma.

Sub-Acute Toxicity Study

Group I rats served as normal control while Group-II and III received Coronil tablet extract (320 and 640 mg/kg respectively) while Group-IV and V received Swasari Vati extracts (270 and 540 mg/kg respectively) and physiological and behavioral changes were observed. The parameters assessed / analysed were red blood cell (RBC) count (Dacie and Lewis, 2001), hemoglobin (Hb), hematocrit (Ht), meancorpuscular volume (MCV), mean corpuscular haemoglobin (MCH), platelets (PLT) count, leukocyte (WBC) count. For biochemical analysis diagnostic kits were used (Figure 5 to Figure 8).

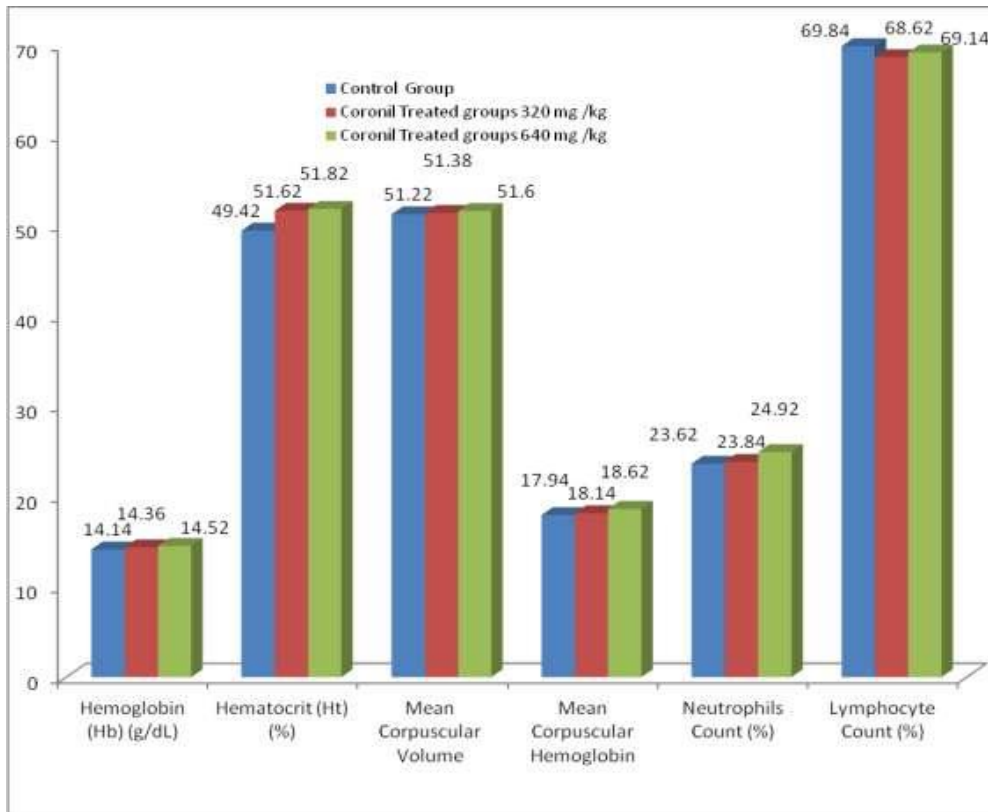


Figure 5 : Effects of Coronil tablet on blood parameters.

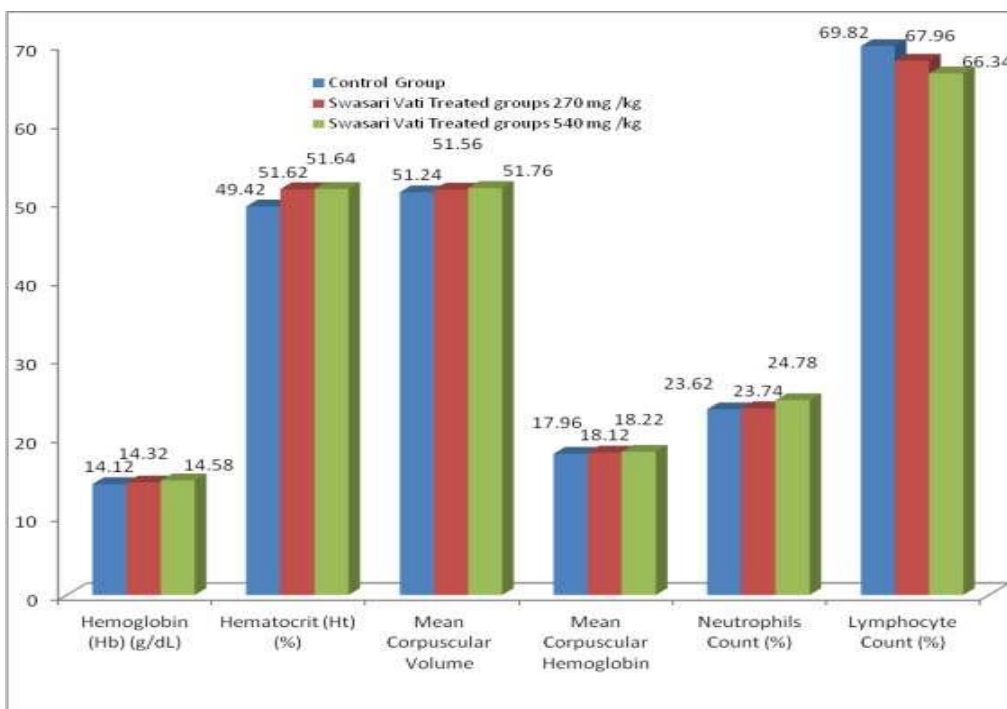


Figure 6: Effects of Divya Swasari Vati on blood parameters.

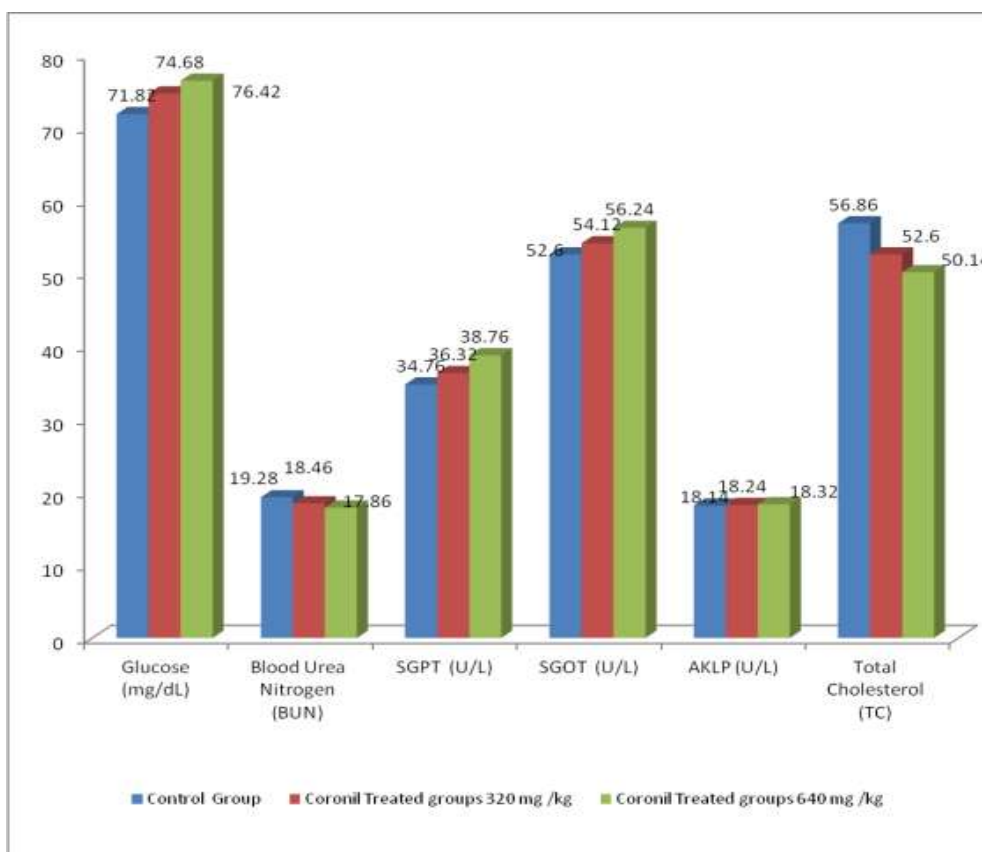


Figure 7: Effect of Coronil tablet on blood chemistry and LFT.

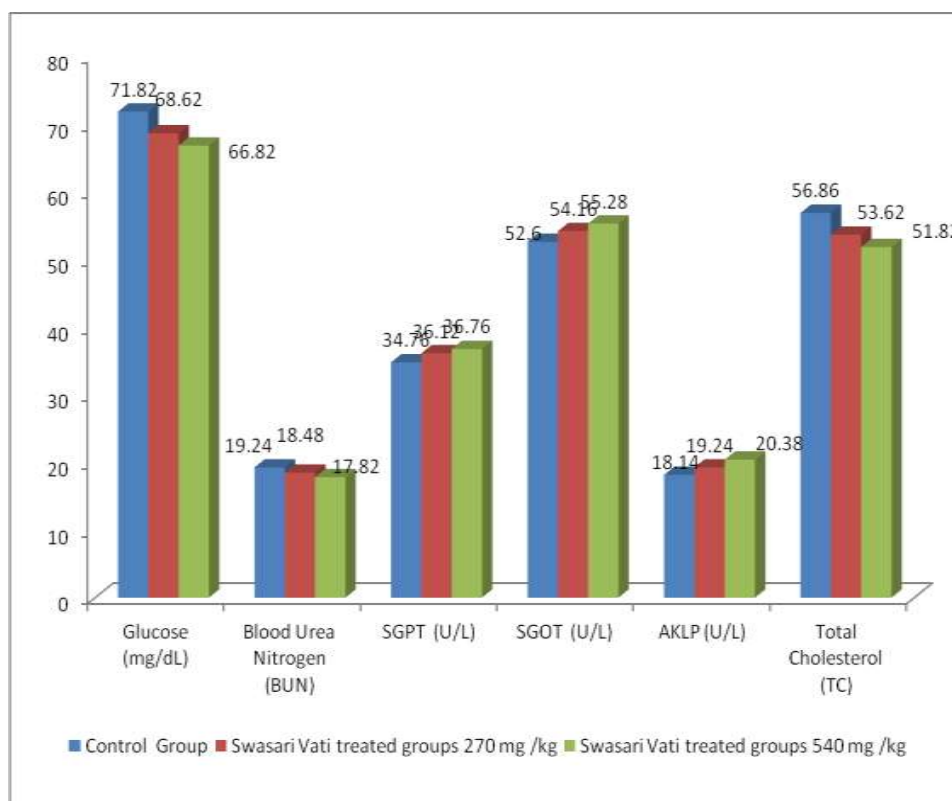


Figure 8: Effect of Divya Swasari Ras Vati on blood chemistry and LFT.

Adaptogenic Activity of Coronil Tablet and Swasari Vati.

(i) Forced swimming endurance test (Shakti *et al.*, 2011)

Table 6: Grouping of Animals.

Groups	Treatment/Dose	Animals
Group-I	Normal saline	6
Group-II	Standard (<i>W.somnifera</i>)	6
Group-III	Coronil tablet (400 mg/kg, p.o.) for 07 days	6
Group-IV	Swasari Vati (100 mg/kg, p.o.) for 07 days	6
Animals were subjected to swimming stress test on the 8th day and swimming time (mean) calculated. Rats were allowed to swim till get completely exhausted (animal started drowning at end point).		

(ii) Chronic Cold Restraint Stress Test (Shakti *et al.*, 2011)

Table 7: Grouping of Animals.

Groups	Treatment/Dose	Animals
Group-I	Normal saline	6
Group-II	Standard	6
Group-III	Coronil (640 mg/kg, p.o.) for 07 days	6
Group-IV	Swasari (540 mg/kg, p.o.) for 07 days	6
❖ Chronic Cold Stress was induced by exposing animals to 4°C for 2 hrs.		

Swimming time was found to be 27.33 (I), 44.83 (II), 37.66 (III), 40.66 (IV) mins. Swimming time of group I was significant ($P < 0.01$) when compared with group II, III, IV. (Table 8; Figure 9). In cold restraint stress model pretreatment with standard, Coronil Tablet and Swasari Vati reduced blood cell counts significantly.

Table 8: Mean swimming time.

Groups	Treatment/Dose	Swimming Time (Mean; in min)
Group-I	Normal saline	27.33 ± 2.883
Group-II	Standard	44.83 ± 1.014**
Group-III	Coronil tablet for 07 days	37.66 ± 1.333**
Group-IV	Swasari Vati for 07 days	40.66 ± 0.760**

Values are Mean ± SEM (6 animals) One-way ANOVA. ** $P < 0.01$.

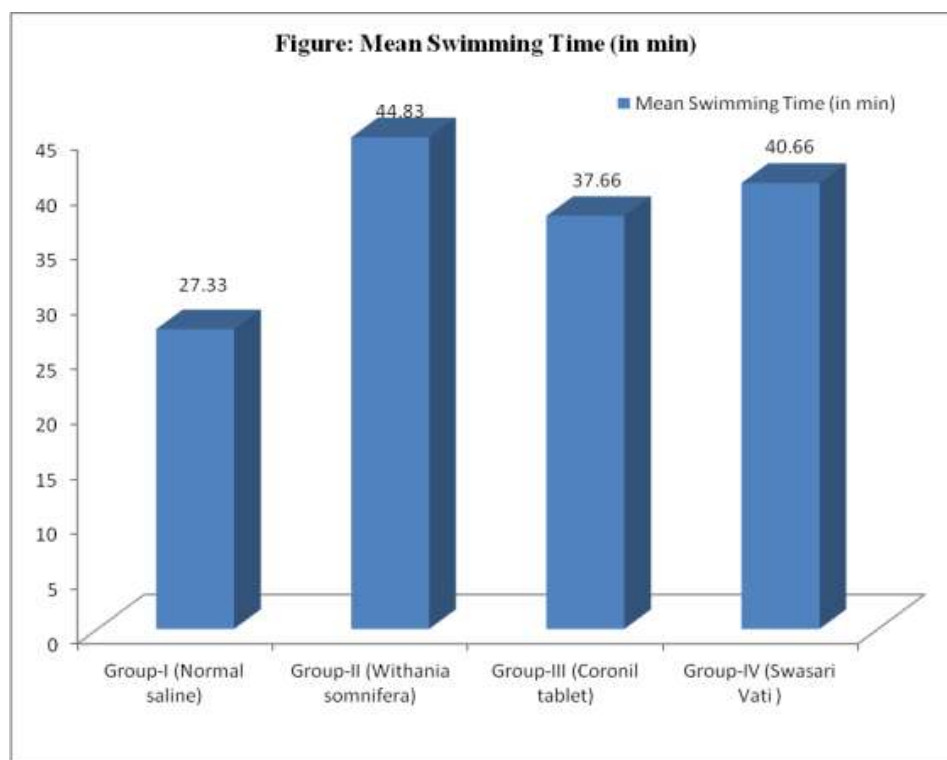


Figure 9: Swimming time (mean).

***In-Vivo* Anti-inflammatory Activities of Coronil Tablet and DivyaSwasari Ras Vati . Carrageenan Induced Rat Paw Edema in Albino Wistar Rats**

Group-I (Normal) : Normal saline and water *ad libitum*.

Group-II (Toxic Control) : Animals were injected with 1% Carrageenan

Group-III & Group IV (Drug / Coronil Tablet and Swasari Vati Treated): Inflammation was induced by injection of 1% Carrageenan. Successively, Coronil Tablet (640mg/kg/bw) and Swasari Vati (540mg/kg/bw) were administered through oral route respectively in Group III and Group IV.

Group-V (Standard) : Indomethacin (10mg/kg/bw) administered through oral cavity and paw edema inhibition was evaluated.

At 5th hour observation, it was observed that edema inhibition was better in rat treated with standard drug (35.97%) followed by Swasari Vati (540mg/kg/bw) (31.21%) and Coronil Tablet (640mg/kg/bw) (25.92%) (Table 9-10; Figure 10-11).

Table 9: Effect of Coronil Tablet and Swasari Vati on paw edema in albino rats.

Group	Paw edema (ml) volume				
	1 Hr	2 Hr	3 Hr	4 Hr	5 Hr
I : (Normal Control)	--	--	--	--	--
II : (Toxic Control / Carrageenan)	1.78±0.04	1.80±0.08	1.86±0.082	1.90±0.054	1.88±0.071
III : (Coronil Tablet ; 640mg/kg/bw)	1.54*±0.06	1.40*±0.05	1.52*±0.07	1.44*±0.07	1.30*±0.10
IV : (Swasari Vati; 540mg/kg/bw)	1.68±0.05	1.46*±0.06	1.52*±0.06	1.44*±0.18	1.40*±0.02
V : (Standard; 10mg/kg/bw)	1.50*±0.09	1.40*±0.04	1.44*±0.066	1.34*±0.22	1.28*±0.12

Note: *Values are significant at P<0.05 over control.

Figure 10 : Effect of Coronil Tablet and Swasari Vati on paw edema in rats.

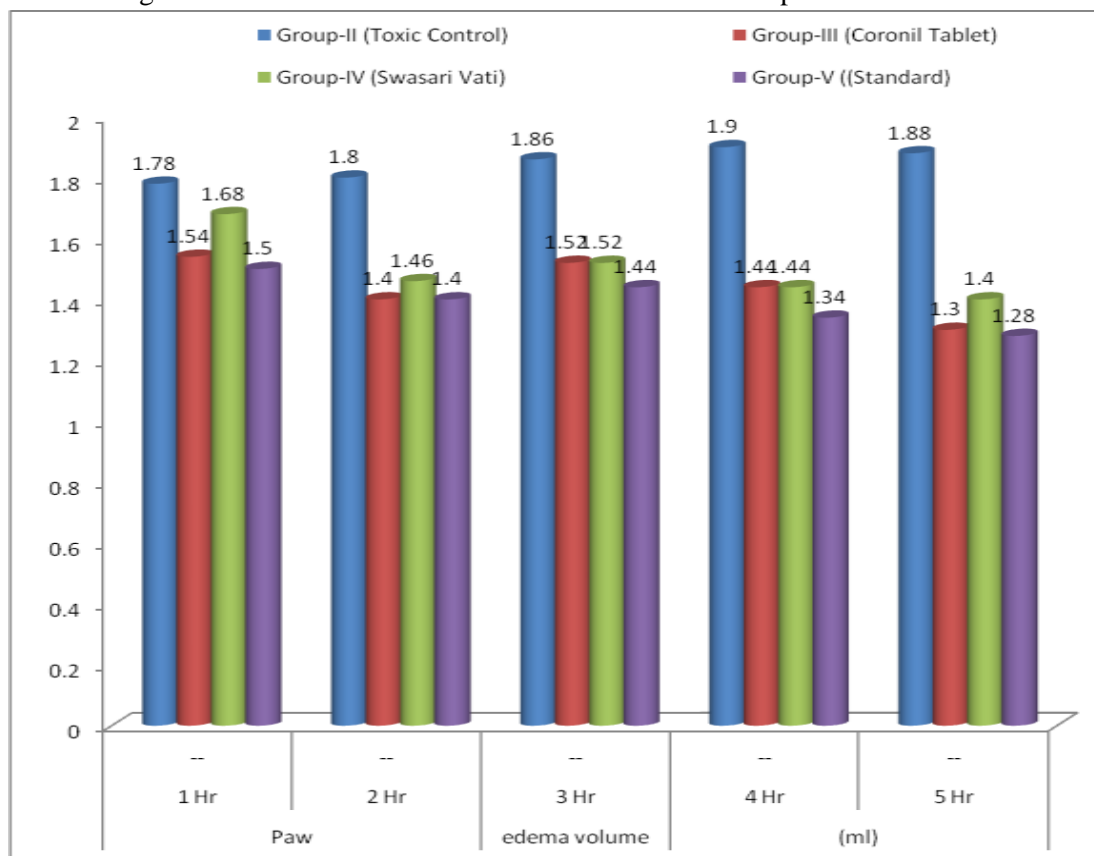


Table 10 : Inhibition of paw edema in Coronil Tablet and Swasari Vati.

Group	% of Inhibition of paw edema				
	1 Hr	2 Hr	3 Hr	4 Hr	5 Hr
I : (NormalControl)	--	--	--	--	--
II : (Toxic Control / (Carrageenan)	--	--	--	--	--
III : (Coronil Tablet ; 640 mg/kg/bw)	5.74	18.99	16.48	22.58	25.92
IV : (Swasari Vati; 540 mg/kg/bw)	10.34	20.6	15.93	21.5	31.21
V : (Indomethacin (10 mg/kg/bw)	13.21	21.22	19.23	26.34	35.97

Note: Values are % of inhibition over control (Group-II / Toxic Control).

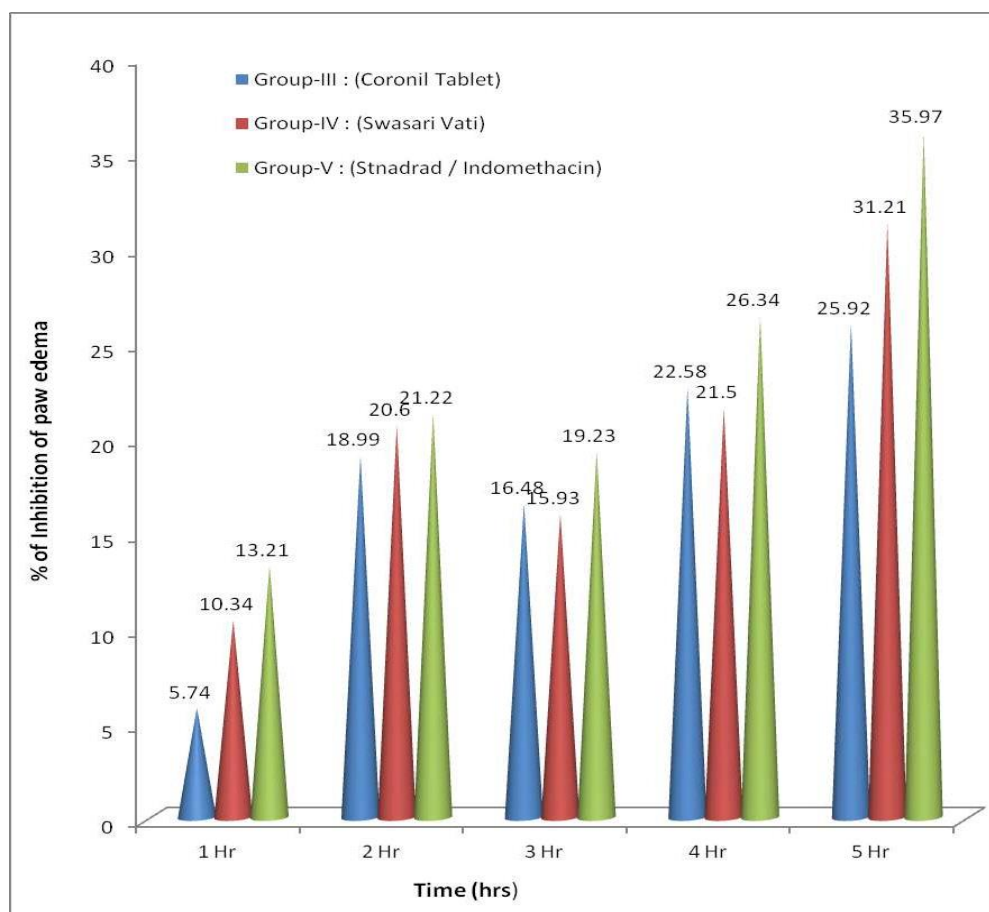


Figure 11: Inhibition of paw edema in Coronil Tablet & Swasari Vati.

Results and Discussions

It was found that Divya Swasari Coronil Kit containing Coronil Tablet, Swasari Vati and Anu Taila. Coronil Tablet contains 25 SPMs from 03 Medicinal Plants. Divya Swasari Ras Vati contains 89 SPMs from 09 Drugs whereas Anu Taila contains 204 phytoconstituents / SPMs from 27 Herbal Drugs (Table 2-4). Phytochemical chemical test analysis / Qualitative analysis of Coronil Tablet, Swasari Vati and Anu Taila indicated the presence of alkaloids, glycosides, resins, terpenes, flavonoids, phytosterols, tannins, saponins, reducing sugars, anthraquinones, steroids, proteins, amino-acids etc.

Acute Toxicity studies clearly indicated that there was no mortality in rats upto 2000 mg/kg/b.wt. Some behavioral shifts such as decreased engine function, ataxia etc. were observed which include slight abnormal behaviour; significant alterations in hematological parameters, disturbance in renal function. Coronil tablet and Swasari Vati extract caused significant change blood RBC, Hb, Ht, MCV, MCH, PLT count, WBC count, glucose, creatinine and BUN. However, liver enzymes SGPT, SGOT, T-Prot, and AKLP were not significantly altered. The Coronil tablet and Swasari Vati induced a very wide safety margin / classified as Non-Toxic (Figure 5 to Figure 8). Swimming time was found to be 27.33 (I), 44.83 (II), 37.66 (III), 40.66 (IV) mins. Swimming time of group I was significant ($P < 0.01$) when compared with group II, III, IV. (Table 8). In cold restraint stress model pretreatment with standard, Coronil Tablet and Swasari Vati reduced blood cell counts slightly. In *in-vivo* anti-inflammatory activity, Swasari Vati showed promising results, then Coronil Tablet. After 5th hour observation, it was observed that edema inhibition was better in rats treated with standard drug (35.97%) followed by Swasari Vati (31.21%) and Coronil Tablet (25.92%) Coronil Tablet & Swasari Vati produced significant anti-inflammatory effects (significant decrease in edema; Table 9-10; Figure 10-11).

Conclusions

On assessment, it was found that Coronil Tablet contains 25 SPMs of 03 Medicinal Plants. Divya Swasari Ras Vati contains 89 SPMs from 09 Drugs whereas Anu Taila contains 204 phytoconstituents / SPMs from 27 Herbal Drugs. The Coronil tablet and Swasari Vati possess very wide safety margin and classified as Non-Toxic. Both Coronil Tablet and Swasari Vati increased swimming endurance and also produced significant anti-inflammatory effects (significant decrease in edema) but less comparatively significant than standard drug i.e. Indomethacin.

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