

# FORMULATION AND EVALUATION OF ASHWAGANDHA OINTMENT FOR RHEUMATOID ARTHRITIS

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**Abstract-** Rheumatoid arthritis (RA) is a chronic, inflammatory and debilitating disease. Rheumatoid arthritis is one of the most common autoimmune diseases. It is an inflammatory disease that affects approximately 1.3% of adults worldwide. Arthritis, generally inflammation of the joints, is one of the most well-known diseases and occurs at all ages. In India, more than 20% of the total population suffers from arthritis. The inability to treat and adverse effects of allopathic medicine have led to extensive research on natural products with antirheumatic activity. Ayurveda is a traditional system of medicine widely used in India. Studies show that *Withania somnifera* (Ashwagandha) is an effective and effective anti-inflammatory drug with fewer side effects compared to synthetic drugs used to treat rheumatoid arthritis. Considering the above reasons, try to develop and develop anti-rheumatic drugs. Thanks to this study, the sample shows the best parameters such as pH, viscosity, consistency, diffusion (diffusion coefficient), drug content, swelling index and research extrudability.

**Keywords:** Herbal; Rheumatoid arthritis, Ashwagandha, joint pain, inflammation.

## 01.INTRODUCTION

A prevalent health issue that impacts a large number of individuals in the United States is arthritis (1). When the body's immune system malfunctions, it can lead to long-lasting discomfort in various areas of the body. The illness and its therapies can lead to severe health problems [2]. According to a study, about The main objectives of RA treatment are to alleviate discomfort and swelling, slow down the disease progression, minimize impairment, and enhance the well-being of the patients (4). Individuals with arthritis frequently experience intense discomfort, and nearly half of all adults with arthritis suffer from persistent pain (5). There are over 100 different forms of arthritis (6). Rheumatoid arthritis (RA) is a condition that causes swelling and pain in many joints (7). This is a long-term condition that can impact any joint in the body, but it is most often seen in the hands, wrists, and knees. Inflammation of the joint occurs when the immune system, which is supposed to protect the body from foreign invaders, attacks the synovium, the thin layer that covers the joint, by mistake joint lining. The pain then spreads to surrounding tissues, eventually causing damage to cartilage and bone. In addition to genetic (changeable) factors and the environment, there are also hormonal factors (8,9,10,11). The main cause of RA is a mutation in human leukocyte antigens (HLA), specifically the HLA-DRB1 gene. HLAs synthesize amino acids that help the immune system distinguish its own amino acids from foreign amino acids in bacteria and viruses (12,13).

### Symptoms:

Symptoms include joint pain, aching, joint stiffness in the morning, insomnia, drowsiness, weight loss, and flu-like symptoms.

### DIAGNOSIS:

Rheumatoid arthritis is diagnosed by rheumatoid factor, these are abnormal antibodies (IgG) which are present in blood. These are reacted with antigen and form antigen-antibody complex that leads to pain and inflammation of synovial membrane. The American College of Rheumatology requires at least four of the following seven criteria to confirm the diagnosis [14, 15].

- Morning stiffness around the joint that lasts at least 1 hour
- Arthritis of three or more joints for at least 6 weeks
- Arthritis of hand joints for at least 6 weeks
- Arthritis on both sides of the body for at least 6 weeks
- Rheumatoid nodules under the skin
- Rheumatoid factor present in blood testing
- Evidence of rheumatoid arthritis on X-rays.

Before the discovery of synthetic drugs man was completely depends on the medicinal plants for the treatment of disease There are many synthetic drugs that are being used as standard treatment for rheumatoid arthritis but they have adverse effect that can compromise the therapeutic treatment so these adverse effects increase the chances for the use of herbal plants for the rheumatoid arthritis treatment. The present review is dedicated to the medicinal plants that are used in the treatment of rheumatoid arthritis.

**Risk Factors and Complications:**

The CDC suggests that patients at higher risk of developing RA may include people aged 60 and over, women, obesity, obesity, and smoking (16, 17).

**STAGES OF RHEUMATOID ARTHRITIS:**

The stages of RA by the condition of cartilage, ligament, and joints are as follows.

**Stage I:** early RA: Negative effect on X-ray, whereas symptoms of joint thinning may be present.

**Stage II:** moderate progressive: X-ray confirmation of joint thinning surrounding a bone with or devoid of little joint erosion. 1. little cartilage destruction is probable. 2. Joint movement is restricted; the absence of bone deformities are seen. 3. Atrophy of surrounding soft tissue. 4. Damage of muscle adjacent to joints.

**Stage III:** severe progression: 1. X-ray examination of joints shows erosion. 2. Joints deformities with reversible stiffness joints. 3. Widespread soft tissue atrophy.

**Stage IV:** terminal progression: 1. X-ray observation of joint damage and osteoporosis surrounding the joints. 2. Joint deformities with irreversible stiffness of the joints (ankylosis). 3. Widespread soft tissue atrophy and abnormalities.

**02. LITERATURE REVIEW :****1) K. Suria prabha et al. (18)**

Diclofenac sodium, a non-steroidal anti-inflammatory drug, is widely used in the treatment of chronic rheumatoid arthritis and osteoarthritis. and arthritis spondylitis. This drug causes the first reaction, only 50% of the drug is present.

**2) Dheeraj T Baviskar (19)**

et al. Purpose: To produce diclofenac sodium gel (HPMC) and Carbopol 934P using high molecular weight hydroxypropyl methylcellulose for local and distribution purposes. Method: HPMC K100M and Carbopol 934P were used as gelling agents to prepare diclofenac sodium gel. Check the formulation for pH, spread, consistency, viscosity, uniformity, chemical content and stability.

**3) Pallab Dasgupta and Amartya . (20)**

Ashwagandha is a famous herb mentioned in the scientific texts of Ayurveda for the treatment of anxiety, hypertension, sleep and recovery. This study involves comparing samples of two commercially available ashwagandha churna formulations from Dabur and Dhaka Oushodhalay.

**4) Agatha Betsy . (21)**

and health and disease prevention. contents.

**5) Rane Rajashree et al] ( 22 )** examined three types of herbs namely Amla, Ashwagandha and Shatavari capsules at various stages of production for general measurements and some poor nutritional assessments.

**6) KS Anand et al. (23)**

Use of nonsteroidal anti-inflammatory drugs in the treatment of osteoarthritis, rheumatoid arthritis, lupus erythematosus arthritis, psoriasis and other seronegative diseases. Spinal arthropathy is common. 03. Aims and Objectives Aims: - Development and evaluation of ointments for the treatment of RA.

**03. AIM & OBJECTIVE**

Development and evaluation of ointments for the treatment of rheumatoid arthritis Aims: -Preparation and evaluation of cosmetics containing herbal extracts. Evaluation of anti-inflammatory properties of cosmetics.

**04. PLAN OF WORK**

- Literature review: formulation and evaluation of ointment
- Check availability of required chemicals and equipment.
- Formulation of ointment using herbal extract
- Evaluate parameters of prepared ointment
- Determination of colour and odour
- Determination of consistency
- Determination of pH
- Determination of spread ability
- Determination of extrudability
- Determination of diffusion study
- Determination of LOD
- Determination of solubility
- Determination of washability
- Non irritancy test

## ➤ Stability study

**5.METHOD**

The ointment was prepared by using the ointment base that is hard paraffin along with other excipients such as wool fat, Ceto stearyl alcohol, soft paraffin, methyl paraben, oil, glycerine etc. the ointment is prepared by mixing all the excipients along with herbal extract that are Ashwagandha extract.

Sr. No.	Ingredients	Roleof ingredients
1.	Wool fat	Emollient
2.	Petroleum jelly	Ointment Base
3.	Cetostearyl alcohol	Surfactant (Used to reduction of surface tension)
4.	Stearic acid	Ointment Base
5.	Rose oil	Fragrance
6.	Methyl parabene	Preservative
7.	Glycerine	Humectant
8.	Ashwagandha	Anti inflammatory

**06.FORMULATION****Procedure: -**

- a. Preparation of ointment base-
  - i.Initially ointment base was prepared by weighing accurately grated petroleum jelly which was placed in evaporating dish on water bath.
  - ii.After melting of soft paraffin remaining ingredients (wool fat, Ceto stearyl alcohol, sodium nitrate, etc.) were added
  - iii.Stir the preparation gently to aid melting and mixing homogenously
  - iv.Cool the preparation to obtain ointment base.

Sr. No.	Name of Ingredient	Quantity
1.	Wool fat	0.5 gm
2.	Ceto stearyl alcohol	0.5 gm
3.	Stearic acid	2 gm
4.	Petroleum jelly	8.0 gm
5.	Rose oil	3 drops
6.	Methyl paraben	1gm
7.	Glycerine	6 gm

8.	Sodium nitrate	1 gm
9.	Ashwagandha extract	gm

- b. Accurately weighed (Ashwagandha extract ) were added to the ointment base.  
 c. Add the base (if needed) until to form homogenous ointment, finally transferred in a suitable container.

## 07.EVALUATION PARAMETERS

### 7.1 Appearance-

The appearance of the cream was found by observing its color, opacity, etc



### 7.2 Physical Evaluation-

In this test colour, odour, texture and state of the formulations were checked by visual examination.



### 7.3 Irritancy-

Irritancy test:- The ointment was applied on left hand dorsal side surface of 1sq.cm and observed in equal intervals upto 24 hrs for irritancy, redness and edema.

### 7.4 Homogeneity:-

The test was done by physical touch with hands .

**7.5 Washability:-** The washability of the ointment applied on skin was done by washing under tap water with minimal force to remove the cream .



### 7.6 Determination of pH-

By using buffer solution, the pH meter was calibrated. The 0.5gm of ointment was dissolved in 50 ml of distilled water after that pH is measured.

### 7.7 Spreadability-

Spreadability Test:- 500mg of the cream was sandwiched between 2 slides. A weight of 100gm was placed on upper slide. The weight was removed and extra formulation was scrapped off. The lower slide was fixed on board of apparatus and upper slide was fixed with non flexible string on which 20g load was applied. Time taken by upper slide to slip off was noted down.



### 7.8 Extrudability

Collapsible tube container was filled with formulation the extrudability is said to be in terms of weight of ointment required to extrude 0.5 cm of ribbon of ointment in 10 seconds.

### 7.11 Solubility

It gets soluble in boiling water and it is miscible with alcohol, ether and chloroform.

### 7.12 Stability study

Stability studies were performed on all the formulations by maintaining at room temperature for 20 days with constant time interval. During the stability studies the parameters like homogeneity, viscosity, physical changes, pH and type of smear were studied.

## 08.RESULT & DISCUSSION

The present study was carried out to formulate and evaluate the ointment to treat rheumatoid arthritis. For this Ashwagandha extract are used.

The physiological properties were studied which shows the satisfactory results for spreadability, extrudability, washability, solubility, loss on drying and others.

**Homogeneity :-** It was found that the cream was homogeneous and smooth and consistent in nature.

**Type. of smear :-** It was found that the cream produced non-greasy film on the skin surface.

### 7.3 Irritancy-

The ointment was applied on left hand dorsal side surface of 1sq.cm and observed in equal intervals upto 24 hrs for irritancy, redness and edema.



Table :

Sr. No.	Evaluation Parameters	F1	F2	F3	Standard values
1.	Colour	pink	pink	Pink	pink
2.	Odour	pleasant	pleasant	pleasant	pleasant
3.	Appearance	pink	pink	pink	
4.	Determination of pH	5.6	5.6	5.6	5.6
5.	Spreadability	Good	Good	Good	Good
8.	Extrudability	Good	Good	Good	Good
9.	Washability	Good	Good	Good	Good
10.	Consistency	Smooth	Smooth	Smooth	Smooth
11.	Solubility	Soluble in Boiling water	Soluble in Boiling water	Soluble in Boiling water	Soluble in Boiling water
12.	Irritancy	Non-Irritant	Non-Irritant	Non-Irritant	Should be non-irritant
13.	Stability study	2 <sup>o</sup> C Stable	25 <sup>o</sup> C Stable	37 <sup>o</sup> C Stable	Should be stable in given temp.

Also, after preparation the prepared formulation also placed for a stability study in different temp. conditions like 2<sup>o</sup>C,25<sup>o</sup>C,37<sup>o</sup>C within four weeks. There is no change found in spreadability, diffusion and in irritancy.

#### 10.CONCLUSION:

In this Iproject work of formulation and evaluation of ointment which are used for treatment of rheumatoid arthritis. From the above result it is concluded that the formulated ointment shows good physical properties ( colour, odour& texture ), spreadability, pH, homogeneity, emolliency, washability, and it does not shows any irritation . From the above

studies it is concluded that the ointment is safe to use . It does not shows any side effects like irritation, roughness, and drying to skin because it contains herbal ingredients. The formulated ointment is safe for use.

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