

### 1.3 Product Information

#### 1.3.1 Summary of Product Characteristics (SmPC)

##### a. Product Details:

###### PIROXICAM CAPSULE

Each capsule contains:

Piroxicam.....20mg

Excipient.....Q.S.

**Dosage form:** Capsule

##### **Strength(s):**

Piroxicam.....20mg

**Route of administration:** oral

##### **Pharmacopoeial Status API:**

Piroxicam BP

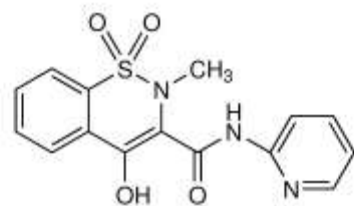
**Pharmacopoeial status FP:** BP2010

#### P.2.2 Component of the drug product

##### **Active Ingredients**

**NASACAM** is a capsule. It is an oxamic derivative, and piroxicam betadex are NSAIDs. Piroxicam betadex may have a more rapid onset of therapeutic effect due to its enhanced solubility. Both are used in musculoskeletal and joint disorders such as ankylosing spondylitis, osteoarthritis, rheumatoid arthritis including juvenile idiopathic arthritis, in soft-tissue disorders, in acute gout, and in postoperative pain.

##### **Structure:**



Chemical Structure of **Piroxicam**

### **Physicochemical Characteristics:**

#### **Description :**

A white or slightly yellow, crystalline powder. It shows polymorphism.

**Solubility:** Practically insoluble in water; slightly soluble in dehydrated alcohol; soluble in dichloromethane.

#### **Excipients:**

##### **(1) Tapioca Starch**

#### **Functional Category:**

As a Filler.

#### **Applications in Pharmaceutical Formulation or Technology**

Starch is absorbent and is widely used in dusting powders, either alone or mixed with zinc oxide or other similar substances. Starch is used as a surgical glove powder, but such use has been discouraged. It is incorporated in many tablets as a binder, diluent, or disintegrating agent. Pregelatinised starch is used similarly as a tablet binder.

**Description:** A tasteless, matt, white to slightly yellowish, very fine powder.

**Solubility:** Practically insoluble in cold water and in alcohol.

## **(2) Magnesium Stearate**

### **Functional Category:**

As a Lubricant.

### **Applications in Pharmaceutical Formulation or Technology**

Magnesium stearate is added as a lubricant to the granules in tablet-making and has been used as a dusting powder and in barrier creams.

**Description:** A white, very fine, light powder, greasy to the touch.

**Solubility:** Practically insoluble in water and in dehydrated alcohol.

## **(3) Talc**

### **Functional Category:**

As a Lubricant.

### **Applications in Pharmaceutical Formulation or Technology**

It is always used as a Lubricant in the pharmaceutical manufacturing.

**Description:** A white powder.

#### **(4) Silicon Dioxide**

**Functional Category:**

As a Lubricant.

**Applications in Pharmaceutical Formulation or Technology**

It is always used as a Lubricant in the pharmaceutical manufacturing.

**Description:** A white powder.

### 1.3.2 Labelling (outer & inner labels)

Will be submitted later