

*Technical Report*

# Understanding the Role of Magnesium Stearate in CanXida Remove (RMV Formula)

Magnesium stearate is often debated for its biosafety, digestive biocompatibility, and its effect on drug absorption. The latest research in this regard shows that magnesium stearate is a safe and gut-friendly additive, which was reiterated in the latest FDA evaluation of the substance in Jun 2023.

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## **Executive Summary**

Magnesium stearate is a commonly used additive in food products, supplement formulations, and pharmaceutical compounding. Its biosafety and biocompatibility for human consumption have been categorized as a “Generally Recognized as Safe” (GRAS) substance since its approval in 1921 till the latest evaluation by FDA in Jun 2023. Its higher stability and relatively non-toxic profile inspired its use in CanXida Remove (Formula RMV) sustained-release tablets. It provides lubrication during the manufacturing process, protection of bioactive ingredients from humidity and oxidation, as well as maintaining the sustained-release profile of CanXida Remove (Formula RMV) tablets.

The CanXida Remove (Formula RMV) formulation is designed as tablets instead of capsules owing to the fact that capsules provide insufficient formulation profile and compatibility with plant extracts and bioactive compounds present in the formula. The manufacturing process is also cost-effective and consumer-friendly which reduces the cost burden and provides an environmentally safe, sustainable, and vegan-friendly formulation with no compromise on quality and efficiency.

## 1. Introduction

Magnesium stearate is the most widely used additive in foods, supplements, and pharmaceutical formulations with over 48,000 registered labels of supplements and more than 35,000 labels registered in prescription medicines in the NIH databases. It is commonly used as a boundary lubricant during the manufacturing process to ensure the quality and ingredients concentration of formulated products. Its role beyond lubrication involves improving the shelf life of active pharmaceutical ingredients, regulating drug release, and absorption of active ingredients in the medicine.

### 1.1. Magnesium Stearate in Medicines

One of the inactive ingredients in the CanXida Remove (Formula RMV) formulation is magnesium stearate which is sometimes debated whether it is safe to consume or not. The National Institute of Health (NIH) gives magnesium stearate the lowest ranking in chemical hazards (signal “Warning” or symbol “!”) if its concentration reaches 39% or above in compound form or in the mixture (compound ID 11177) but it is considered safe at quantities up to 5% in the foods or medicines and is approved by FDA, with the latest review of magnesium stearate held on June 7, 2023 (Title 21, CITE: 21CFR184.1440). It can be explained by the analogy of acetic acid in vinegar. Vinegar is a 4 – 6% acetic acid solution in water and is perfectly safe to consume but if we make a concentrated solution of acetic acid in water it is corrosive to skin and eyes and even dissolves metals. Although the concerns of customers are not completely unfounded but might need a different perspective to fully understand the hazard labeling of a chemical substance in relation to its composition.

It is also worth mentioning that the longest-used medication in human history, *Ciprofloxacin*, uses magnesium stearate as an additive in all its formulation (Syrup, Intravenous, and Tablets) since 1994 (Roy, J. 2011). No prominent side effect would have gone unnoticed for so long.

### 1.2. Magnesium Stearate in CanXida Remove (Formula RMV)

Magnesium stearate is one of the excipients in the CanXida Remove (Formula RMV) and is responsible for providing suitable conditions for the active pharmaceutical ingredients during storage as well as in the digestive tract to release the medicine in a more controlled manner. Excipients are substances that do not provide pharmaceutical bioactivity but rather impart stable conditions for the active bioactive compounds in the formulation during manufacturing and storage. These are also necessary to regulate drug behavior after it is ingested and regulate its release and absorption by interacting with gut secretions such as gastric acid, bile, etc. CanXida Remove (Formula RMV) tablets are formulated as extended-release and magnesium stearate plays a pivotal role in it as well.

Magnesium stearate quantity does not exceed 0.3% to 3%, as recommended by FDA and WHO, in the CanXida Remove formulation. Magnesium stearate used in tablets is a clinical grade (UNII: 70097M6I30) that comes with the highest purity as compared to commercial grade magnesium stearate which often contains impurities from the manufacturing process. These impurities add to a fair share of side effects manifested by commercial-grade magnesium stearate.

*Overview of properties and physical parameters of magnesium stearate.  
Sources: FDA, PubChem, and American Chemical Society databases*

**Other Names:** Magnesium distearate  
Magnesium octadecanoate

**Molecular Formula:**  $\text{Mg}(\text{C}_{18}\text{H}_{35}\text{O}_2)_2$

**Molecular Weight:** 591.2 g/mol

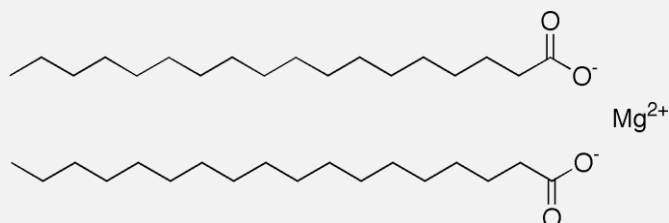
**Melting Point:** 88 °C

**Moieties:**

Parent Compound: Stearic acid

1. Magnesium  $\text{Mg}^{+2}$ 
  - a. Charge +2
  - b. Ratio 1
2. Stearate  $\text{C}_{18}\text{H}_{35}\text{O}_2$ 
  - a. Charge -1
  - b. Ratio 2

**Structural Formula:**



**Substance IDs:**

FDA UNII: 70097M6I30  
PubChem SID: 134977058  
PubChem CID: 11177

**Approval Date:** 1921

**Latest FDA Review:** June 2023

**Classification:** **Generally Recognized as Safe (GRAS)**  
FDA CFR Code: 21 CFR 184.1440  
**Dietary Supplement Label Database (DSLID)**  
DSLID Code: 1248

## 2. Properties of Magnesium Stearate

Magnesium stearate is a magnesium salt of edible fatty acid called stearic acid. It is used as a lubricant, antifoaming agent, anticaking agent, as well as a release agent in pharmaceuticals and supplements. It can also be found in routinely used products such as herbs and spices, chewing gums, and baking products. It is generally categorized as GRAS (Generally Recognized as Safe) substance and is used as a food additive in Europe, China, Australia, Japan, New Zealand, and the USA.

### 2.1. Biochemical Properties

It is an off-white to white crystalline powder with a greasy touch. It is insoluble in water. However, it dissolves in acidic conditions and releases magnesium ions and stearic acid components. It is stable

under standard storage conditions and does not decompose. In pure form, it consists of 4 – 5% magnesium, 90% of stearic acid, or 40% stearic acid with 50% palmitic acid. Around 2% of the compound is stearic acid in free form (not bound with magnesium).

### 2.2. Biosafety Profile

Upon ingestion, it dissolves in the stomach releasing magnesium and stearic acid. A report published by WHO Expert Committee on Food Additives and Contaminants (Joint F.A.O, 2016) found that magnesium stearate is practically non-toxic. The standard dosage of magnesium stearate, found in supplements and food products, does not produce dermal irritation or corrosive effects, and no ocular as well as respiratory irritations, were observed in mice models. These conclusions were based on numerous studies citing similar results (Hobbs et al 2017, Javadzadeh et al

**Table 1:** Results of survey on use levels and food applications of magnesium stearate. Sources (Yang et al 2015, WHO Joint F.A.O, 2015). GSFA: Codex General Standard for Food Additives (food additives database).

GSFA Category No.	GSFA Food Category	Technical Functions	Proposed Food Uses	Average Use Level (mg/kg)	Maximum Use Level (mg/kg)
05.2	Confectionery including hard and soft candy, nougats, etc.	Anticaking agent, lubricant, binder	Hard candy, pressed mint (05.2.1)	10, 000	13, 000
			Mint pastille (05.2.1)	5, 000	9, 500
05.3	Chewing gum	Emulsifier, anticaking agent, drying agent	Chewing gum	100–10 000	20, 000
07.0	Bakery wares	Foaming agent, emulsifier	Rusks, baking powder	>500	2, 500
12.2.1	Herbs and spices	Anticaking agent, hydrophobation agent	Spices, herbs	>500	10, 000
13.6	Food supplements	Lubricant, anticaking agent, emulsifier, thickener	Food supplements: tablets, capsules, powders	13, 000	30, 000

2012, Yang et al 2015). WHO recommended daily intake of magnesium stearate is 44 mg/kg for children and 83 mg/kg for adults. Table 1 shows the amount of magnesium stearate in different food products of everyday use.

Both magnesium and stearic acid are found naturally in the human body. There are well-established metabolic processes that utilize, store, or eliminate these products as per the requirements of the body. Apart from dietary intake, the human body can also synthesize its own stearic acid depending on metabolic needs. The harmful effect of any substance is associated with the accumulation of the substance itself or its undesirable by-products in the body and neither is the case for magnesium stearate.

### 2.3. Digestive Profile

Magnesium stearate breaks down in the stomach into magnesium ions and stearic acid, most of which is absorbed in the small intestine. Small quantities of stearic acid are also absorbed in the colon. However, stearic acid is a non-essential nutrient as the human body can synthesize it on its own. Its absorption is as-per-need basis in comparison to magnesium. A systematic review of multiple studies published in the journal “*Molecular Nutrition and Food Research*” demonstrated that magnesium stearate and other additives in the formulation of tablets do not affect the absorption of nutrients such as vitamin D (Grossmann et al 2010). There is no scientific evidence to support the claim that magnesium stearate interferes with nutrient absorption.

### 3. Myths and Misconceptions

There is a general misconception that magnesium stearate is associated with decreased immune function and nutrient/drug absorption in the digestive system. Most of these claims are borrowed

from either some blogging sites or some opinion articles from scientific journals. These claims have been refuted through rigorous and repeated scientific studies. A group of researchers from Griffith University, USA, reported that a symbiotic supplement formulated with magnesium stearate improves gut microbiome and improves immune function (West et al 2012). Similarly, the slow dissolution of tablets in some formulations is misinterpreted as poor nutrient availability. However, it is not true and rather a property necessary for extended-release formulations as demonstrated by Ariyasu, A., and coworkers (Ariyasu et al 2016).

### 4. Benefits and Uses

The benefits of magnesium stearate in pharmaceutical formulations include:

- Provides lubrication during pill manufacturing to reduce heat produced by compression pressure. It ensures quality and minimizes the loss of active pharmaceutical ingredients.
- It has the ability to make films around the components of the formulation and maintains uniformity by avoiding hardening and aggregation.
- It is required in small quantities as compared to conventional lubricants.
- It helps maintain the extended-release profile of the formulation.

Magnesium stearate has been used in medicines, supplements, and food products since 1921 and has consistently been categorized as safe to consume by WHO and FDA. Some of the products with magnesium stearate are given in Tables 2 and 3.

**Table 2:** Some of well-established and NIH-registered supplement brands using magnesium stearate as an additive and have been on the market for more than 10 years. Showing the top 34 of 48,134 results. Source: NIH, Office of Dietary Supplement Database. Retrieved on 16 Aug 2023.

DSLID ID	Product Name	Brand Name	Registration	Market Status
1228	Maximum Strength L-Arginine 1000 mg	Vitamin World	2011	On Market
1283	Theanine	Natrol	2011	On Market
1314	5-HTP L-5-Hydroxy Tryptophan 200 mg	Vitamin World	2011	On Market
1758	L-Lysine 500 mg	Viva Vitamins	2011	On Market
2123	Bulk-Up Weight Gainer Chocolate	Tapout Sports Nutrition	2011	On Market
2438	BCAA Muscle Guard	InterActive Nutrition	2011	On Market
2461	Amino 1000	Precision Engineered	2011	On Market
2946	Slendesta Potato Protein Extract 15 mg	Doctor's A-Z	2011	On Market
3092	CytoGainer Vanilla Shake	CytoSport	2011	On Market
3150	Nitro-Tech Crunchy Chocolate Crisp	MuscleTech	2011	On Market
3151	Nitro-Tech Delicious Vanilla Swirl	MuscleTech	2011	On Market
3182	Amino Supreme	Bricker Labs	2011	On Market
3623	100% Whey Protein Fuel Strawberry Smash	Twin Lab	2011	On Market
3785	Gelatin	Nature's Bounty	2011	On Market
5380	Branched Chain Amino Acid	Douglas Laboratories	2012	On Market
5731	Gluta-Lyn 1500	Sci-Fit	2012	On Market
5759	Probiotic-SR Vanilla	MHP Maximum Human Performance	2012	On Market
5792	L-Lysine 1000 mg	Sundown Naturals	2012	On Market
6051	HGH Complex	Vitabase	2012	On Market
6138	L-Theanine	XYMOGEN	2012	On Market
6388	5-HTP 100 mg	VitaCeutical Labs	2012	On Market
6390	L-Carnitine 500 mg	VitaCeutical Labs	2012	On Market
6450	Amino Acid Complex	VitaCeutical Labs	2012	On Market
6558	Nitropump NOS	MET-Rx	2012	On Market
6907	MaxAmino 1200	Vitabase	2012	On Market
7257	Natural Gelatin 600 mg	Windmill	2012	On Market
7261	L-Lysine HCl 500 mg	Windmill	2012	On Market
7415	Bovine Collagen	Vitabase	2012	On Market
7492	L-Lysine 500 mg	Equaline	2012	On Market
7707	Natural L-Formula Lysine 500 mg	Longs Wellness	2012	On Market
7740	Natural L-Lysine 500 mg	Sunmark	2012	On Market
7744	MaxAmino 1200	Vitabase	2012	On Market
8055	L-Tyrosine	Douglas Laboratories	2012	On Market
8058	Taurine	Douglas Laboratories	2012	On Market



**Table 3:** Some of the FDA-approved medicine packagers using magnesium stearate as an additive. Showing the top 14 of 35,738 results of FDA-registered labels. Source: NIH DailyMed. Retrieved on 16 Aug 2023.

Drug Name	NDC Code	Packager
WARFARIN SODIUM TABLET	21695-672-30, 21695-673-30, 21695-673-60	REBEL DISTRIBUTORS CORP
WARFARIN SODIUM TABLET	43353-049-30, 43353-049-60, 43353-050-15	APHENA PHARMA SOLUTIONS - TENNESSEE, LLC
PHENOBARBITAL TABLET	62135-405-12, 62135-406-60, 62135-407-60	CHARTWELL RX, LLC
HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLET	16590-112-30, 16590-112-60, 16590-112-72	STAT RX USA LLC
ABILIFY (ARIPIRAZOLE) TABLET	59148-006-13, 59148-006-92, 59148-007-13	OTSUKA AMERICA PHARMACEUTICAL, INC
NAMZARIC	0456-1207-30, 0456-1214-11, 0456-1214-30	ALLERGAN, INC.
VIIBRYD (VILAZODONE HYDROCHLORIDE) TABLET	0456-1100-31, 0456-1101-30, 0456-1110-30, 0456-1120-30	ALLERGAN, INC.
AMLODIPINE AND ATORVASTATIN TABLETS, FILM COATED	0378-4513-93, 0378-4514-93, 0378-4515-93, 0378-4516-93	MYLAN PHARMACEUTICALS INC
COREG CR (CARVEDILOL PHOSPHATE) CAPSULE	0007-3370-13, 0007-3371-13, 0007-3372-13, 0007-3373-13	GLAXOSMITHKLINE LLC
ATORVASTATIN CALCIUM TABLET, FILM COATED	69097-897-05, 69097-897-15, 69097-898-05, 69097-898-12	CIPLA USA INC
AMOXICILLIN (AMOXICILLIN) CAPSULE AMOXICILLIN (AMOXICILLIN) TABLET, FILM COATED	63304-514-01, 63304-514-05, 63304-515-01, 63304-515-04	RANBAXY PHARMACEUTICAL INC
LEVOXYL (LEVOTHYROXINE SODIUM) TABLET	54868-3849-1, 54868-4087-1, 54868-4092-1, 54868-4092-2	PHYSICIANS TOTAL CARE, INC.
LEVOTHYROXINE SODIUM TABLET	51138-040-30, 51138-041-30, 51138-042-30, 51138-043-30	MED-HEALTH PHARMA, LLC
CADUET (AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM) TABLET, FILM COATED	54868-1207-0, 54868-1207-1, 54868-3287-0, 54868-3287-1	PHYSICIANS TOTAL CARE, INC.

## 5. Comparison of Magnesium Stearate to Other Flow Agents

Magnesium stearate is often the first choice for preparing solid oral formulations, especially for extended-release tablets. It is due to the fact that magnesium stearate has demonstrated biosafety and is trusted by

many in food, drugs, and supplements. Its vegetable origin is another positive aspect that makes it suitable for vegan-friendly formulations.

While lubricants are chosen on the basis of efficiency to reduce friction during the manufacturing process, these additive

**Table 4:** Some of the common additives and lubricants used in a solid oral formulation.

Excipient	Properties	Pros/Cons	Brand Names
Magnesium Stearate	Vegetable Origin, Stable, Lubricant, and slow-release agent	Non-toxic even at higher quantities, inexpensive, quantities, e.g., 0.5% in tablets	Magnesium stearate 5712, Magnesium stearate Hyqual.
Hydroxypropyl methylcellulose	Slow-release agent, Insoluble in water, lubricant	Inert and non-toxic	Hypromellose, Methocel Premium
Lactose monohydrate	Diluent and bulking agent.	Inexpensive Reacts with amino acids, cannot be used with whole plant extracts, allergies	Pharmatose 150M, Tablettose 80
Sodium starch glycolate	Disintegrant, soluble in water, flow-agent	Not suitable for slow-release formulation	Primojel
Sodium stearyl fumarate	Lubricant	Behaves like magnesium stearate, less hydrophobic than magnesium stearate	Pruv
Hydrogenated vegetable oil	Vegetable origin, lubricant, slow-release agent	Behaves like magnesium stearate, prone to oxidation	Sterotex K
Stearic acid	Vegetable origin, lubricant	Behaves like magnesium stearate	Stearic acid 2236
Talc (Hydrated magnesium silicate)	Lubricant, glidant, insoluble in water	Does not support slow-release formulation.	Talc

compounds also impart technical characteristics to tablets such as disintegration time, tablet strength, indentation hardness, brittleness, and tablet friability. A recent study published by Paul, S. and Sun, C. from the Department of Pharmaceutics, College of Pharmacy, University of Minnesota, United States demonstrated that magnesium stearate provides more balanced characteristics to tablets when compared to other mainstream lubricants (Paul and Sun 2018).

## **6. Role of Magnesium Stearate in CanXida Remove Formulation**

Magnesium stearate provides the following advantages to the CanXida Remove (Formula RMV):.

- It reduces friction during compression for the manufacturing of CanXida Remove (Formula RMV) tablets.
- It reduces heat generation and ingredient loss during the manufacturing process.
- It is inexpensive and reduces the cost of manufacturing.
- It is stable at room temperature and storage conditions, with no decomposition to harmful compounds.
- It does not interact with the active ingredients, especially amino acids which are abundantly present in the plant extracts.
- It facilitates the sustained-release profile of CanXida Remove (Formula RMV) tablets along with other slow-release agents.
- It is required in small quantities per tablet, making it possible to prepare smaller size tablets that are easy to swallow and light on the digestive tract.

- It is procured from plant-based sources which makes formulation suitable for vegans and vegetarians.
- It protects ingredients from oxidation and humidity by making fine coatings. It improves the shelf life of the formulation.
- It is compatible with other inactive ingredients included in the formulation.
- It is metabolically safe and digestible.
- Magnesium stearate is responsible for maintaining formulation in solid form and making it available for absorption at the same time. It discourages the clumping of ingredients.
- It provides stable disintegration to CanXida Remove (Formula RMV) tablets after ingestion.

## **7. The Great Debate: Capsule vs Tablet**

Solid medication and powders are orally administered using capsules or tablets. The formulation strategies are often decided by different factors such as drug composition, absorption profile, quality of active ingredients, as well as its compatibility with the excipients. One provides advantages over others in certain features.

In the case of CanXida Remove (Formula RMV), it consists of plant whole-cell extracts, purified bioactive compounds, and parts of medicinal plants in powdered form. A capsular formulation will require larger size capsules to fit all these ingredients which will be hard to swallow. While a tablet can fit all these ingredients in a compact and small size which is not only palatable and easy to swallow but also provides better shelf life and storage conditions. The advantages and disadvantages of capsules and tablets can be well understood in detail in the following comparison.

## Capsule vs Tablets: Advantages and Disadvantages

Tablets	Capsules
<b>Advantages</b>	
<ul style="list-style-type: none"> <li>• Raw material and manufacturing are cost-effective.</li> <li>• Faster production and turnaround time.</li> <li>• Controllable size, color, shape, and taste.</li> <li>• Small sizes can fit comparatively larger quantities of ingredients.</li> <li>• Better stability.</li> <li>• Longer shelf life and storage period.</li> <li>• Drug release can be controlled by formulating as sustained-release, extended-release, or delayed release.</li> <li>• Can be manufactured as chewable</li> </ul>	<ul style="list-style-type: none"> <li>• Fast-acting drug release</li> <li>• Tasteless</li> <li>• Cannot be tampered with by breaking and splitting.</li> <li>• Can enclose liquids such as essential oils and other compounds of non-aqueous nature.</li> </ul>
<b>Disadvantages</b>	
<ul style="list-style-type: none"> <li>• Although tablets can be coated to mask unpleasant taste, some uncoated tablets can give an unpleasant taste.</li> <li>• Slower acting</li> <li>• Uneven digestion</li> <li>• Cannot carry liquid ingredients</li> </ul>	<ul style="list-style-type: none"> <li>• Raw materials and manufacturing are costly.</li> <li>• Slower turnaround time</li> <li>• Can only carry small quantities of active pharmaceutical ingredients.</li> <li>• Have short shelf life and storage durability.</li> <li>• Burst release of the drug may not work with certain ingredients.</li> <li>• Controlled release of drugs is not feasible.</li> <li>• Large size as compared to tablets due to less compact manufacturing.</li> <li>• May include animal products and are not suitable for vegan-friendly formulations.</li> <li>• Less durable</li> <li>• Susceptible to humidity and temperature fluctuations</li> </ul>

## 8. Importance of Tablet Formulation for CanXida Remove (Formula RMV)

CanXida Remove (Formula RMV) contains bioactive compounds of organic nature which require special formulation to preserve the full potency. Capsular formulations do not provide suitable raw materials as well as sufficient capacity to hold the diversity of ingredients present in CanXida Remove (Formula RMV) into a single formulation.

The tablet formulation of CanXida Remove (Formula RMV) was inspired by the unique features it provides to maintain the bioactivity of a wide range of ingredients of organic origin. Tablets are manufactured using a compression technique which makes it possible to include sufficient quantities of plant extracts and powders in smaller volumes. Bioactive compounds present in plant extracts should be protected from humidity and oxidative activity which is lacking in capsule formulation.

Another advantage that comes with the formulation is that tablets are designed as sustained release to ensure a homogenous distribution of the desired bioactive compounds in the digestive system. As capsules are unequipped with sustained release qualities, hence deemed unfit for this product.

### 8.1. Sustainability and Environment Impacts of CanXida Remove (Formula RMV) Tablets

Besides manufacturing and biochemical parameters of formulation, it was also kept in mind to produce a customer-oriented, sustainable, and environmentally friendly product. CanXida Remove (Formula RMV) tablets are manufactured using cost-effective methods with less energy consumption ensuring environmental safety. While capsular formulation can be prepared in environmentally sustainable

manufacturing, it increases the cost of production with economic burden at the customer end.

It is also worth mentioning that ingredients, both active and inactive, in the CanXida Remove (Formula RMV) are sourced from plants. It makes this formulation vegan-friendly. Capsules are often manufactured from animal products and may not be fit for consumption by people with different food preferences.

## 9. Conclusion

After consulting with the latest research reports and product reviews by WHO and FDA on magnesium stearate, it is fair to conclude that it is a perfectly safe compound to consume. Its safety is associated with the fact that both of its components, magnesium, and stearic acid, are naturally present, metabolized, and regulated in the human body.

The choice to manufacture CanXida Remove (Formula RMV) tablets instead of capsules is backed by the superior quality provided by tablet formulation as compared to capsules in all biochemical, environmental, economic, and social aspects. Magnesium stearate plays a crucial role in providing a sustained-release formulation in tablet form.

At CanXida, we're unwavering in our commitment to transparency, efficacy, and the well-being of our customers. We understand concerns surrounding ingredients, but rest assured, our choice to use magnesium stearate is grounded in scientific evidence, manufacturing best practices, and a commitment to quality. We're always open to feedback and are dedicated to educating and serving our community with the best health solutions possible.

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