

LYSOPHARM™

OVERVIEW

Lysopharm is Bioseutica's pharmaceutical grade Lysozyme product which is produced specifically for formulations in health and wellness products. Lysopharm is produced under cGMP guidelines and meets the stringent quality requirements required for today's health products.

As a natural, non-specific immune factor, Lysozyme has been employed in a range of health products around the world.

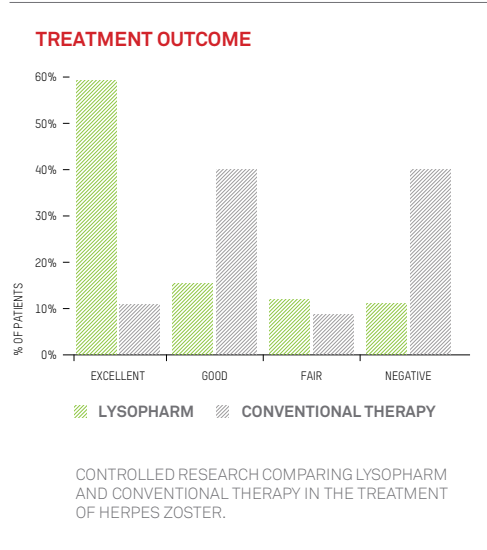
In Asia, Lysopharm is commonly formulated in OTC health products used to treat colds, infection, and inflammatory conditions such as chronic sinusitis. In Europe, Lysopharm is formulated in health products for the maintenance of oral health, treatment of sore throat and healing of skin. More recently in the United States, Lysopharm has been formulated into a range of oral care products including toothpaste, mouthwash, and oral gel.

BIOLOGICAL PROPERTIES

Lysozyme embodies three main biological activities which are of significance to human health. These include antibacterial action, antiviral action and modulation of the immune response.

The antibacterial effects of Lysozyme are achieved through destabilization and degradation of the bacterial cell wall, while the antiviral activities have been attributed to interference with syncytia formation and binding of viral nucleic acids. The anti-inflammatory and immune potentiating properties of lysozyme have been well documented, however the mode of action is complex and has not yet been fully elucidated.

Bioseutica is the first company in the world to have a DRUG MASTER FILE for the use of Lysopharm in pharmaceutical applications.



PHARMACOLOGICAL PROPERTIES

Oral Lysozyme acts directly in the oral cavity or gastrointestinal tract to impede the growth and colonization of pathogenic bacteria.

Oral Lysozyme also works indirectly through interactions with immune inductive sites of the gastrointestinal tract and systemic components of the immune system. The result is an immune modulating effect that is beneficial in a range of health afflictions where the immune system is in a depressed or imbalanced state.

Topical Lysozyme acts locally at the site of tissue damage to control microbial dissemination and inflammation. These activities combine to speed the reparative process of damaged skin.

LYSOPHARM PRODUCTION

- Manufactured for world markets since 1947.
- Market innovators and creators of new applications.
- Advanced manufacturing process (cGMP, HACCP or ISO).
- Proven and consistent high quality (activity= >95%)
- Stringent and reliable analytical methods.
- DMF - CTD for Japan.

PRODUCT CHARACTERISTICS

- DESCRIPTION:**
WHITE CRYSTALS WITH SWEETISH TASTE
- SOLUBILITY:**
VERY SOLUBLE IN WATER, INSOLUBLE IN ORGANIC SOLVENTS
- PH:** 3.3 ± 0.3
- WATER CONTENT:** < 5%
- TOTAL NITROGEN CONTENT:** 17.3 ± 0.5%
- AMINIC NITROGEN CONTENT:** < 0.8%
- CHLORIDE CONTENT:** 3.7 ± 0.5%
- TURBIDIMETRIC ASSAY ACTIVITY:**
970 MCG/MG OF LYSOZYME HCL STANDARD CALCULATED ON THE ANHYDROUS PRODUCT
- CHEMICAL ASSAY ACTIVITY:**
98 % OF LYSOZYME HCL STANDARD CALCULATED ON THE ANHYDROUS PRODUCT

POTENTIAL IMPURITIES FROM THE MANUFACTURING PROCESS

- SULPHATED ASH :** <1.5 %
- HEAVY METALS :** < 10 PPM
- COLOR OF SOLUTION:**
< 0.150 ABS. AT 360 NM
< 0.120 ABS. AT 380 NM
< 0.080 ABS. AT 410 NM
- CLARITY OF SOLUTION:**
> 90 % T [20% SOL]
- CLARITY OF SOLUTION (540 NM):**
> 95 % T [10% SOL]
> 70 % T [10% SOL. at PH 9]

MICROBIAL PURITY

- TOTAL BACTERIAL COUNT:** < 1000 CFU / G
- COMBINED YEAST AND MOLDS:**
< 100 CFU / G
- COLIFORMS:** < 30 CFU / G
- SALMONELLA:** ABSENT IN 25 G
- E. COLI, ST. AUREUS, PS. AERUGINOSA:**
ABSENT IN 1 G

* SPECIFICATIONS MAY VARY BY PLANT. FOR PLANT SPECIFIC DOCUMENTATION CONTACT YOUR BIOSEUTICA REPRESENTATIVE.