

CERTIFICATE OF ANALYSIS



LYSOZYME GRANULATE

Lot # 4108LG02
Date of Production March 21, 2008
Expiry date March 31, 2010

Physical properties

Synonyms of Lysozyme (E1105)
Chemical name
Source
Description
Storage

Specifications

Muramidase; Mucopolysaccharide N-acetylmuramoylhydrolase
E.C. (Enzyme Commission) No: 3.2.1.17
Chicken egg white
White to off-white Granulated Lysozyme-hydrochloride
In original packaging, cool, dry (<65%RH) and clean

Identification

pH of a 2% (aq) at 20-25°C
Solubility at 640 nm of a 2% (aq)
Purity on the anhydrous basis (w/w)
Activity in FIP Units/mg protein*

Specifications

Between 3.0 - 3.6
Minimum 95 % T
Minimum 95 %
Minimum 35 x 10³

Actual

3.4
100 % T
>95 %
(41 ± 1) x 10³

Chemical properties

Water content (Karl Fischer)
Residue on ignition
Chloride
Nitrogen
Arsenic
Cadmium
Lead
Mercury
Heavy metals (as Pb)

Specifications

Maximum 6.0 %
Maximum 1.5 %
Maximum 3.5 %
17.3 % ± 0.5 %
Maximum 1 ppm
Maximum 1 ppm
Maximum 2 ppm
Maximum 1 ppm
Maximum 10 ppm

Actual

5.7 %
0.1 %
<3.5 %
test passed
test passed
test passed
test passed
test passed

Microbiological properties

Total bacterial count
Acetic acid bacteria
Lactic acid bacteria
Yeast
Molds
Enterobacteriaceae
Salmonellae
Staphylococcus aureus
Escherichia coli

Specifications

Less than 100/g
Less than 100/g
Absent in 10 g
Less than 10/g
Less than 10/g
Absent in 1 g
Absent in 100 g
Absent in 1 g
Absent in 1 g

Actual

<10/g
<10/g
Absent in 10 g
<10/g
<10/g
Absent in 1 g
Absent in 100 g
Absent in 1 g
Absent in 1 g

*One FIP Unit produces a Δ_{450nm} of 0.001 per minute at pH 7.00 and at 25 °C using a suspension of FIP *Micrococcus luteus* as substrate in a 3.01 ml reaction mixture (Pharmaceutical Enzymes edited by A. Lauwers and S. Scharpe, July 1997, 375-379). The literature value of a 1% Lysozyme-hydrochloride solution A_{280nm} is 26.35.

DATE OF APPROVAL : April 2, 2008

QUALITY CONTROL :

QUALITY ASSURANCE :

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