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Methods for quantitative analysis of lysozyme in pharmaceutical and biochemical studies: a comparative review.

Svetlana M. Filimonova Daniil D. Rachitsky

Rachitsky Daniil Dmitrievich

Institute of Pharmacy, Federal State Autonomus Educational Institution of Higher Education I.M. Sechenov First Moscow State Medical University of Ministry of Health of the Russian Federation (Sechenovskiy University), 119435 Moscow, Russia

Aim and Objectives

Aim:

To study and evaluate methods for the quantitative determination of lysozyme in pharmaceutical dosage forms.

Background and Significance: Lysozyme is an enzyme widely distributed in human biological fluids (tears, saliva, blood, mucus) and plays an important role in the body’s natural antimicrobial defense. It is used in various pharmaceutical dosage forms as an active ingredient due to its antibacterial, anti-inflammatory, and regenerative properties. According to the Russian State Register of Medicinal Products, lysozyme is used as an active pharmaceutical ingredient in the following dosage forms: tablets in combination with pyridoxine, lyophilisate for solution, suppositories in combination with bifidobacteria.

Objectives: To analyze approaches for quantitative determination of lysozyme in tablets.

Materials and Methods

- A literature search was performed using Google Scholar and PubMed databases with the keywords “lysozyme”, “assay” and “quantative determination” to collect information on existing analytical methods for lysozyme determination.

Conclusions

Given the broad biomedical significance of lysozyme and its use in different dosage forms, there is a clear need to develop and validate reliable analytical methods for the quality control of lysozyme-based pharmaceutical products.

Main results

Method	Recognition reagent	LOD	LOQ	Detection range	Matrix
Turbidimetric	Micrococcus lysodeikticus	1.94 µg/mL	3.86µg/ mL		Buffer
Turbidimetric	Micrococcus lysodeikticus	Nd*	Nd	2.3-23.8 units/ml	Cell culture systems
Fluorescence technique	Micrococcus lysodeikticus labeled with fluorescein	Nd	Nd	0.47-5.28 units/ml	
ELISA	Purified rabbit polyclonal anti-chicken lysozyme antibody	0.264 µg/mL		0.38 -4.8 µg/mL	Hen egg white
Electrochemical aptasensor	Aptamer/amino-rGO/ionic liquid/amino-mesosilica nanoparticles	2.1*10 ⁻³ pM		10 ⁻² –2*10 ⁵ pM	Egg white, serum, tears, wine
Reversed-phase high-performance liquid chromatography	Reversed-phase polymeric column (PLRP-S 250 4.6 mm, 300 Å pore size, 5 µm particle size)	2.07 µg/g	4.13 µg /g	3.3–16.7 µg/g	Cheese
Fluorometric	Chitin azure	Nd	Nd	Nd	Blood sample
Colorimetric assay	β-d-galactosyl chitotetraose derivative [Gal(GlcN) ₃ D]			2-31 µg	Buffer solution
FPA	Fluorescein isothiocyanate-labeled peptidoglycan	Nd	Nd	Nd	Rheumatoid synovial fluids
FPA	Fluorescein isothiocyanate-labeled chitooligosaccharide				tears
FPA	Fluorescein isothiocyanate-labeled chitooligosaccharide	4.5 µg/mL	5.0 µg/mL	5.0-70 µg/mL	Tablets

