DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 1**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

1. Your firm failed to conduct media fills that closely simulate aseptic production operations that incorporate worse-case, most challenging, and stressful conditions. For example, your current media fill qualification procedure simulates a maximum fill of (b) (4) vials, and (b) (4) vials; however, your Lidocaine eye drops formulation (formula# 18491) is filled into 1-ml syringes in quantities between (b) (4) units over an extended duration.

*DATES OF INSPECTION*

9/20/2021(Mon), 9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 10/01/2021(Fri)
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."