DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Biotechnology Manufacturing CDER/OPQ/OPF/DIA, WO Bldg 51,Room 2269 10903 New Hampshire Ave, Silver Spring, MD 20993 Email: OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	3/23-31/2022
	FEI NUMBER 3007255826

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Aldo Braca, CEO & President

FIRM NAME	STREET ADDRESS
BSP Pharmaceuticals S.p.A.	Via Appia km 65,561
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Latina Scalo LT, Italy 04013	Drug Product Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the media fill program is deficient in that:
a) acceptance criterion for yield (total units incubated/total number of units filled) has not been established for media fills. For example, during the review of media fills report for (b) (4) (b) (4) rejected vials were discarded out of a total of (b) (4) filled vials. Rejected vials were included in the report but no acceptance criterion was established for the number of rejected vials.

b) media fill batch record (b) (4) demonstrated that there were (b) (4) vials rejected for out of IPC weigh range on the batch report printout. You recorded only (b) (4) out of (b) (4) vials rejected on the batch record reconciliation form. You failed to include (b) (4) rejected vials for low fill volume, and used "very low fill volume" as justification for excluding them from the reconciliation form.

OBSERVATION 2

Complaint handling procedures describing the handling of written and oral complaint related to drug products are deficient.

Specifically, complaint investigation process is deficient. For example, complaint No. M-RR-21-055 received from a customer on 04/09/2021 (September 4, 2021) for observing foreign particles in (b) (4) vial of (b) (4) drug product lot # (b) (4) Your investigation report demonstrated that you repeated visual inspection on the retain samples of the (b) (4) vials but failed to (b) (4) the retain sample vials before visually inspect vials for foreign particles.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Thuy T. Nguyen -S Digitally signed by Thuy T. Nguyen -S Date: 2022.03.31 04:52:33 -07'00' Yasamin Ameri -S Digitally signed by Yasamin Ameri -S Date: 2022.03.31 04:51:06 -07'00'	Thuy Nguyen, Branch Chief Yasamin Ameri, Investigator	03/31/2022

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FIRM NAME	STREET ADDRESS
BSP Pharmaceuticals S.p.A.	Via Appia km 65,561
CITY, STATE AND ZIP CODE Latina Scalo LT, Italy 04013	TYPE OF ESTABLISHMENT INSPECTED Drug Product Manufacturer

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, qualification of equipment used in production of (b) (4) drug product are deficient in that you failed to properly qualify equipment for their intended use. for example:

a) Qualification of (b) (4) in in Sterile (b) (4) and Sterile (b) (4) production area, failed to study the ability of the (b) (4) (b) (4) for removal of foreign particles that might be adhered inside (b) (4) of (b) (4)
b) Qualification of (b) (4) RABs (b) (4) integrity tester in Sterile (b) (4) production area failed to validate equipment's software program which operates the (b) (4) integrity tester unit in Sterile (b) (4)

OBSERVATION 4

Input to and output from the computer, related systems of formulas, and records or data are not checked for accuracy.

Specifically, control over electronic data generated from computerized systems in production and QC laboratory is deficient in that you failed to:

a) implement control measures on all systems to prevent change in data/parameters or result of analysis in validate standalone systems, e.g. HPLC, UPLC, GC
b) review electronic raw data generated by these systems on the system
c) review audit trails for all systems.

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	Thuy T. Nguyen -S Digitally signed by Thuy T. Nguyen -S Date: 2022.03.31 04:53:25 -07'00' Yasamin Ameri -S Digitally signed by Yasamin Ameri -S Date: 2022.03.31 04:51:41 -07'00'	Thuy Nguyen, Branch Chief Yasamin Ameri, Investigator	03/31/2022