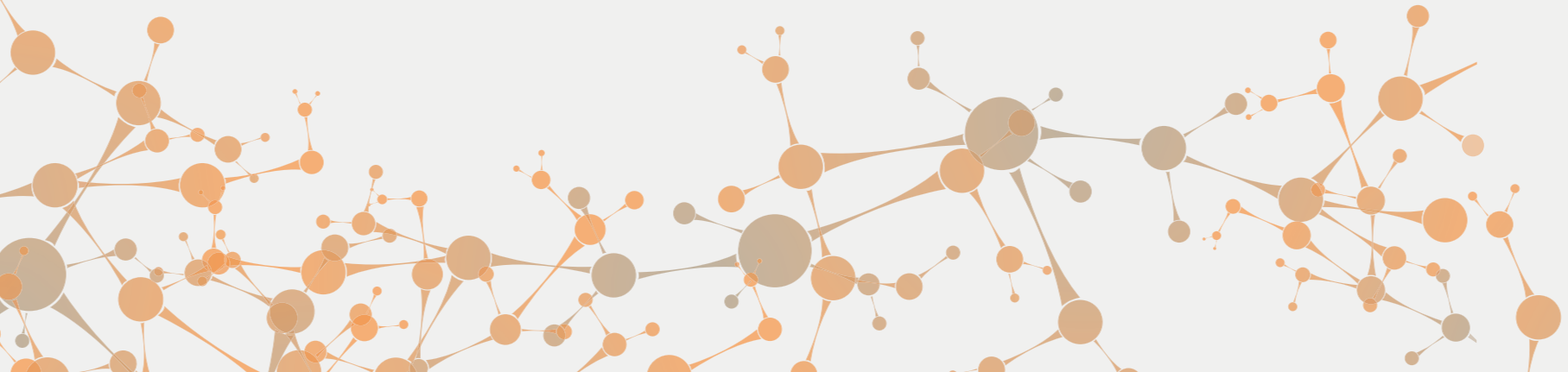
BSP PHARMACEUTICALS

Oral Solid



ONE STOP SHOP IN THE SUPPLY CHAIN OF ANTICANCER PRODUCTS

BSP Pharmaceuticals is a Contract Development and Manufacturing Organization focused on production of anticancer and cytotoxic drugs as small molecules and ADC compounds.

BSP Pharmaceuticals provides a full range of integrated services aimed to support the entire life cycle of a product.

From the formulation and process development/optimization, through scale up/scale down studies, we can drive the product to cGMP manufacturing for clinical and commercial needs.

QC laboratories are equipped to run all analytical testing (chemical and microbiological) on raw materials, components, in process controls, release and stability testing.

Internal Regulatory Affairs team to manage data collection and document preparation for DMF and CMC to support filing activities.

DEVELOPMENT
Formulation, Process, Analytical methods

SCALE UP/DOWN
Process Robustness and Characterization

QUALITY CONTROL
Release, Stability, Process comparability testing

MANUFACTURING
Clinical and Commercial Supply

REGISTRATION
Regulatory Support for DMF and CMC Preparation

The Manufacturing plant is located in Italy, 40 miles southbound of Rome.

A single campus extended to more than 58 acres hosts all the main buildings supporting the capacities to manage a wide range of batch sizes.

1 | DEVELOPMENT LABORATORY
1 | DEPARTMENT with multiple lines suitable to manufacture Clinical and Commercial products

This work mode and the proper combination of expertise allows:
- To switch quickly from **development to commercial** production.
- To make the **scale-up** of the product internally without the need to transfer the product elsewhere.
- To **reduce** technical issues and constraints when changing manufacturing scales and batch sizes.

A COMPLETE MANUFACTURING AREA

FULLY DEDICATED
TO ORAL DOSAGE FORMS

The special design of the equipments, the complete customization of line's configuration and the use of isolators as primary containment systems, enable full segregation of the High Potent APIs during each step of the process, including **intermediates preparation, material transfer** and **final collection of the product.**

All the manufacturing steps occur in a **classified environment**, with reduced and controlled microbiological level, specifically designed to minimize the risk of contamination of products intended for patients with low level of immune defenses.

- **Handling** of highly potent active materials take place within closed systems (isolators), avoiding direct exposure to the surrounding in any step of the manufacturing process.
- **Movement** of raw materials (including High Potent APIs) and intermediates is managed using closed containers (bins or charge containers).
- **Transfer of components** in and out of isolators occurs through Rapid Transfer Port (RTP) and High Containment Transfer valves.

With the **highest level of technology** and the most innovative solutions applied to all manufacturing areas, BSP can fulfill the most stringent requirements for handling **conventional oral dosage forms** as well the **next generation** of anticancer and cytotoxic products characterized by complex, **non conventional and innovative formulations** on Development, Clinical and Commercial scale.

CONVENTIONAL

TABLETES COATED AND UNCOATED

CAPSULES

SPECIAL

LIQUID FILLED HARD GELATINE CAPSULES

CAPABILITIES

TECHNOLOGIES

- **WET GRANULATION** with aqueous and organic solvent based formulations
  Different equipment configuration available to perform
  Multi-steps process by high shear mixing and granulation followed by fluid bed drying.
  Single-step process by conventional fluid bed granulation or roto granulation.
- **DRY GRANULATION** by rolling compactor.
- **DRY BLENDING** by high shear mixing and diffusion blending.
- **FILM COATING** with sugar, aqueous and organic solvent based coating.

NON CONVENTIONAL FORMULATIONS

ORGANIC SOLVENT BASED FORMULATION

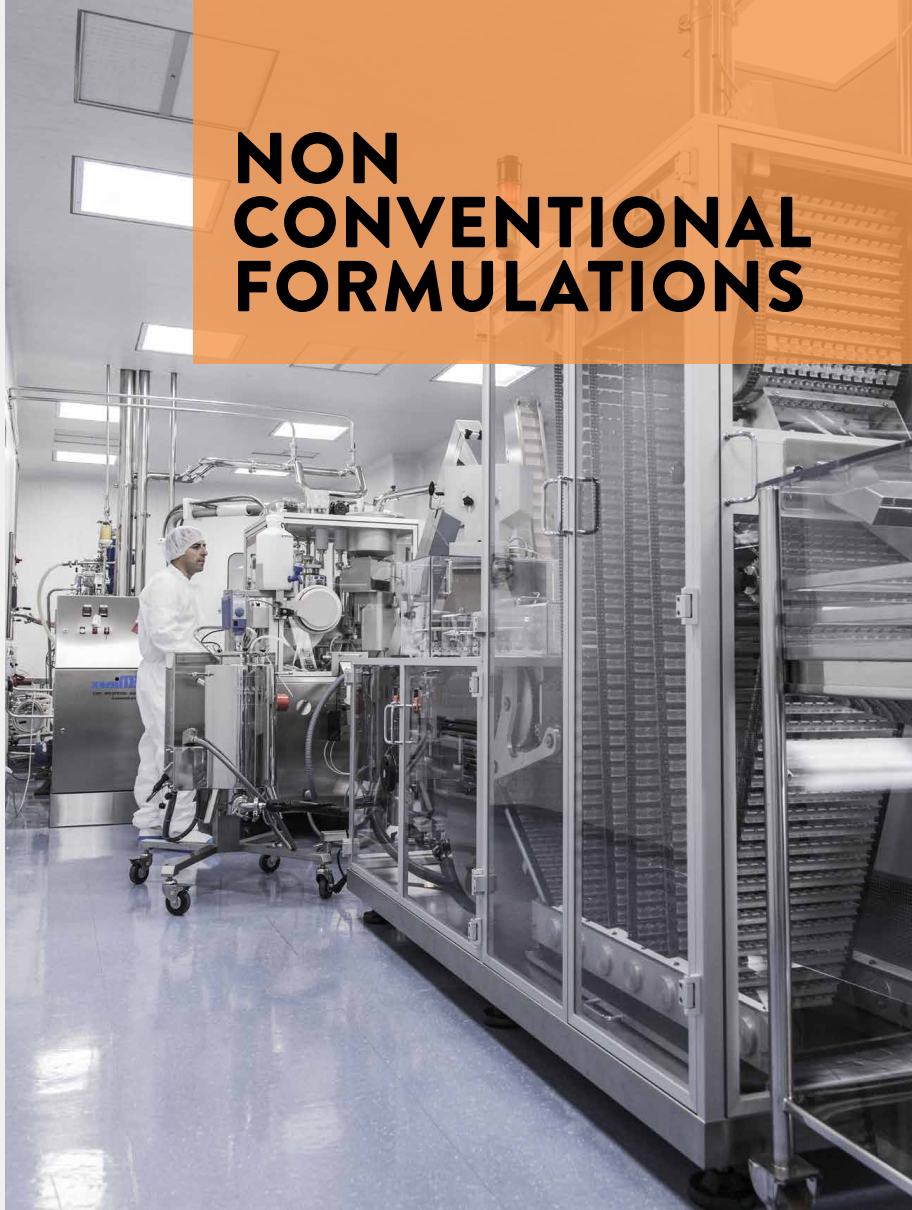
All the equipment have been designed to be **explosion proof** with the proper requirements to handle **organic solvent based formulation**, during intermediates manufacturing (e.g. wet granulation) and final dosage manufacturing (e.g. film coating).

LIPID-BASED FORMULATION

Lipid-based formulation such as emulsion and suspension, can be manufactured using special technologies and equipment, including:

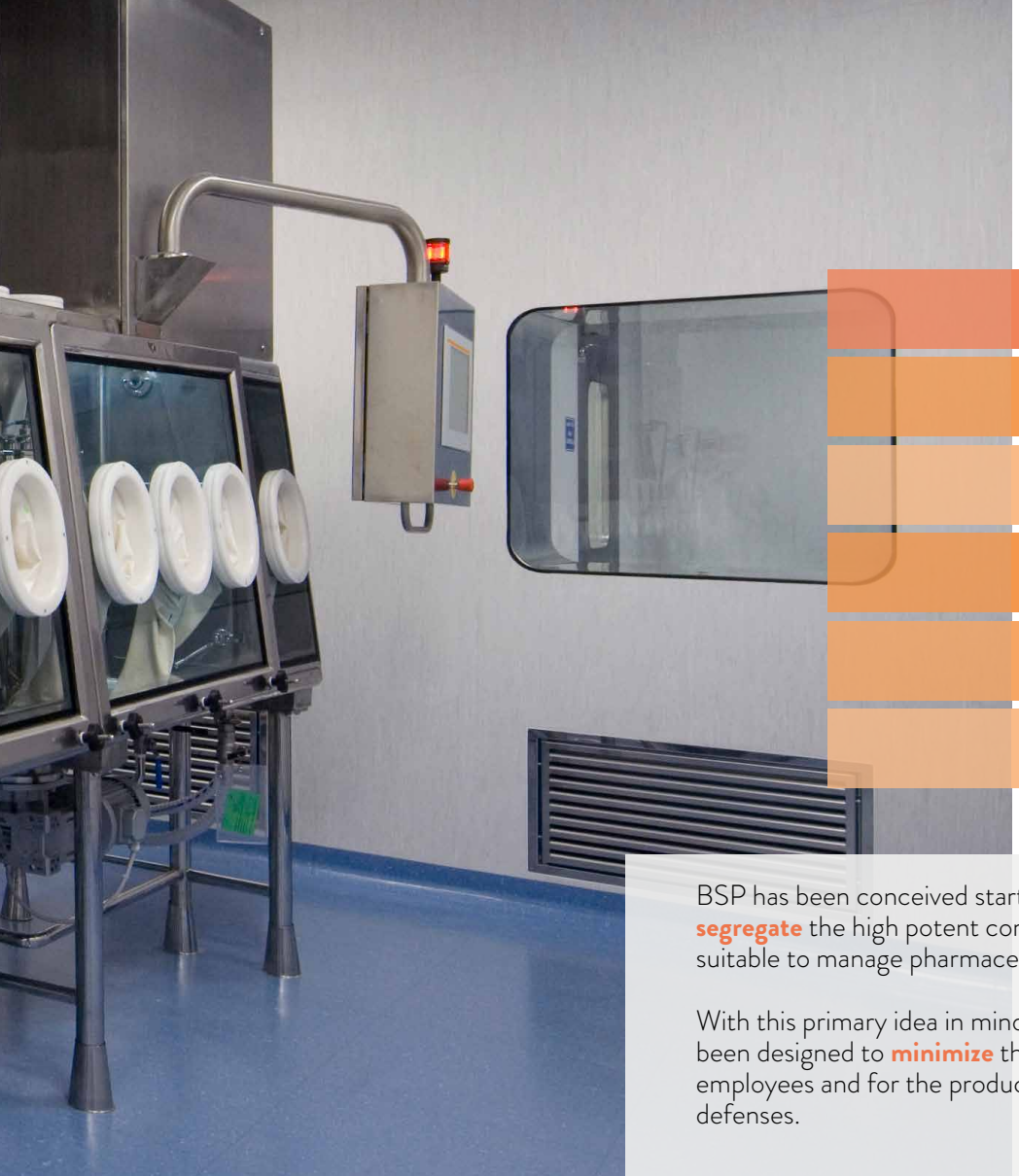
- **LOW AND HIGH PRESSURE OMOGENIZER**
- **LIQUID FILLING CAPSULES MACHINES**
- **BANDING/SEALING MACHINES**

The possibility to formulate water-sensitive APIs (not suitable for injectable dosage forms) and the wide range of lipidic excipients available to design to most suitable media to incorporate the API, make this special capability highly recommended for High Potent Anticancer products with low solubility and low bioavailability.
Hard gelatin capsules can be filled with dispersion or solution of the API in an oily based formulation.
The final oral dose administration, make the therapy easier and much more acceptable for patients.



AN HIGH CONTAINMENT FACILITY

DESIGNED TO HANDLE HIGH POTENT AND CYTOTOXIC COMPOUNDS



The plant has been designed to achieve an Occupational Exposure Limit (OEL):

<10 nanograms/m³

CONTAINMENT GRANTED BY

INSULATING SYSTEM
ISOLATOR, CONTAINMENT VALVES

PRESSURE CASCADE FROM OPERATIONAL
TO SURROUNDING AREAS

CONTINUOUS MONITORING
OF DIFFERENTIAL PRESSURES AND RELATED ALARM SYSTEM

DEDICATED AIR HANDLING SYSTEM

ABSOLUTE FILTER OF EXHAUST AIR

CONTAMINATED WASTED MATERIAL
SEGREGATION, INACTIVATION AND DISPOSAL

BSP has been conceived starting from a basic but essential operating requirement: **segregate** the high potent components from the surrounding and create a system suitable to manage pharmaceutical processes.

With this primary idea in mind, layouts, flows of materials and personnel, air flows have been designed to **minimize** the risk of contamination for the environment, for the employees and for the product that is intended for patients with low level of immune defenses.

ORAL DOSAGE FORMS CAPABILITIES

CLINICAL AND COMMERCIAL MANUFACTURING

A UNIQUE MANUFACTURING SYSTEM, WITH FIRST-IN-CLASS TECHNOLOGY AND SPECIALLY DESIGNED FOR ANTICANCER DRUGS, WITH THE FLEXIBILITY TO MANAGE SMALL MOLECULES AND COMPLEX INNOVATIVE FORMULATIONS.

DEDUSTING AND METAL CHECK
for capsules and tablets

VISUAL INSPECTION
for capsules and tablets

100 % CHECK WEIGHT
off line with automatic sorting units

BANDING
for liquid or powder filled capsules

PRIMARY & SECONDARY PACKAGING
for commercial products
Blister | **Bottle**


ACTIVE
ARIA 120
ARIA

DEVELOPMENT
CAPABILITIES

BSP Oral Department has dedicated Laboratories and skilled scientists to support formulation, process development and process optimization services.
BSP Development Team works on both conventional and innovative formulations including **LIPID-BASED FORMULATIONS** such as emulsion and suspension.

BSP can also perform all the ancillary studies that can support process characterization and robustness aimed to facilitate the product scale-up delivering the product from R&D to cGMP stage.

STRONG INTEGRATION
between development and cGMP manufacturing

ANALYTICAL METHODS DEVELOPMENT AND OPTIMIZATION to support manufacturing during early stages

PRE-FORMULATION STUDIES to identify the most suitable components and the most effective dosage forms

FORMULATION STUDIES to identify the lead compound with the best properties and profile

PROCESS ROBUSTNESS to identify and investigate the proper key process parameters and characterize all the manufacturing ranges

SCALE UP & SCALE DOWN STUDIES to determine all the critical process parameters and support the transfer to cGMP manufacturing stage

All the pharmaceutical forms produced, can be manufactured in the development laboratories with pilot scale machines that reproduce the operating conditions of industrial lines.
An extended working team that integrates scientific backgrounds and manufacturing expertise supports the characterization of the products transferred within the plant, contributing to an accurate comprehension of the criticality of either process and product.

ANALYTICAL SERVICES

All conventional analytical testing and instruments are available to support IPC and final release testing

- METHODS DEVELOPMENT & OPTIMIZATION
- METHODS VALIDATION & TRANSFER
- CLEANABILITY & COMPATIBILITY STUDIES
- CLEANING METHODS DEVELOPMENT AND VALIDATION
- STABILITY & PHOTOSTABILITY STUDIES
- IN PROCESS CONTROLS
- RAW MATERIALS TESTING
- FINAL RELEASE

SUPPORT

FORMULATION/PROCESS DEVELOPMENT

DEVELOP

OPTIMIZE VALIDATE AND TRANSFER ANALYTICAL METHODS

CHARACTERIZE

PRODUCT STABILITY PROFILE

PROCESS

COMPARABILITY TESTING

BSP PHARMACEUTICALS

CMO
LEADERSHIP AWARDS 2019
CAPABILITIES, EXPERTISE, RELIBILITY, SERVICE
LEADERSHIP AWARDS 2018
CAPABILITIES, COMPATIBILITIES, EXPERTISE
RELIBILITY, QUALITY, DEVELOPMENT

HEADQUARTER AND MANUFACTURING PLANT

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