



CYTO & HiPo Oral Solid

BSP Pharmaceuticals is a Contract Development and Manufacturing Organization focused on innovative cytotoxic and non cytotoxic products for oncology, immuno-oncology, CNS and other relevant therapeutic indications.

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

BSP Pharmaceuticals provides a full range of integrated services aimed to support the entire life cycle of a product as described below:



THE PLANT HAS BEEN DESIGNED TO ACHIEVE AN OCCUPATIONAL EXPOSURE LIMIT (OEL) :

- 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.

**<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



HEADQUARTER AND MANUFACTURING PLANT

BSP Pharmaceuticals S.p.A.

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DRUG PRODUCT ORAL CAPABILITIES

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.

CONVENTIONAL



TABLETS/minTABLETS
COATED AND
UNCOATED



CAPSULES

SPECIAL



LIQUID FILLED HARD
GELATINE CAPSULES

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.

**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



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