



QC Laboratories

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 analytical services aimed to support the complex testing panel of a product:

CHEMICAL

MICROBIOLOGICAL

BIOCHEMICAL

QUALITY CONTROL LABORATORIES

QC SERVICES OFFERED INCLUDE:



ANALYTICAL METHODS: Development & Optimization
Transfer/Validation product release testing and stability

CLEANING CONTROLS: Cleanability & Compatibility studies; Cleaning methods development and validation

STABILITY & PHOTOSTABILITY STUDIES

ENVIRONMENTAL MONITORING

RAW MATERIALS TESTING

IN PROCESS CONTROLS

FINAL RELEASE



HEADQUARTER AND MANUFACTURING PLANT

BSP Pharmaceuticals S.p.A.

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BSPPHARMACEUTICALS.COM



QC Laboratories

CHEMICAL & MICROBIOLOGICAL



BSP provides comprehensive support for chemical and microbiological testing, including bioburden, endotoxins, and sterility, along with advanced biochemical assays like cytotoxicity and binding assays. Whether for drug substances or drug products, our expertise ensures that your testing needs are met according to the set specifications. From routine bioassays to

BIOCHEMICAL



complex characterization, BSP's fully validated assays adhere to cGMP standards, making them suitable for regulatory submissions. We also offer specialized capabilities for ADC & other bioconjugates ensuring to offer an integrated analytical service to support the full release of drug substance and drug product.

ANALYTICAL SERVICES

All the main conventional analytical instruments are available in the QC Laboratories to support IPC and full testing of the product.

Full set of analytical techniques includes:

- **MOLECULAR WEIGHT OR SIZE:** SEC-HPLC, Bioanalyzer (under reducing and /or non-reducing conditions) and other appropriate techniques.
- **POTENCY ASSAYS:** Ligand binding, ELISA, Monoclonal antibody assays, Binding assays (microplate reader, CE and other appropriate techniques).
- **ISOFORM PATTERN:** by isoelectric focusing (iCE280) or other appropriate techniques.
- **EXTINCTION COEFFICIENT:** by UV/visible spectrophotometry.
- **ELECTROPHORETIC:** (bioanalyzer), Imaged Capillary Isoelectric Focusing (iCIEF), Western-blot, capillary electrophoresis (CE system), SDS-PAGE, Isoelectric Focusing (IEF)
- **LIQUID CHROMATOGRAPHIC PATTERNS:** size exclusion chromatography, reverse-phase liquid chromatography, ion-exchange liquid chromatography, affinity chromatography.
- **SPECIFIC CYTOTOXICITY MAB AND FREE TOXIN IDENTIFICATION:** by LC/MS/MS.
- **OTHERS**



TO ACCESS AND DOWNLOAD THE FULL LIST OF SERVICES PLEASE SCAN THE QR CODE

