



博瑞策生物技术（上海）有限公司
BRC BIOTECHNOLOGY (SHANGHAI) CO., LTD.



助力您药物安全检测的忠实合作伙伴





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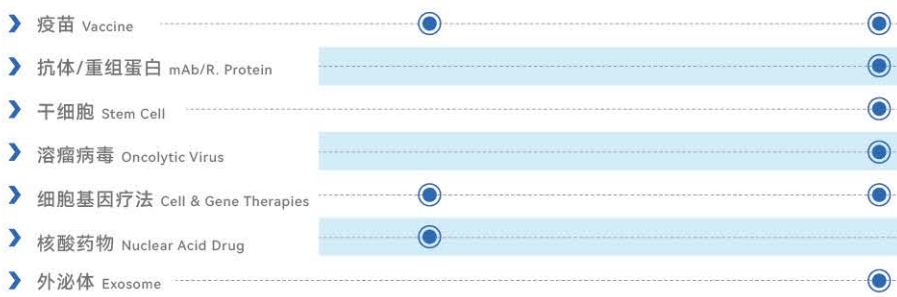


博瑞策生物技术（上海）有限公司成立于2022年，位于上海市自由贸易试验区自贸壹号生命科学产业园，建设有~6,000平米符合cGMP和生物安全二级（BSL-2）标准的检测服务、商务办公以及培训中心。我们致力于在细胞基因治疗、抗体、疫苗、核酸药物等领域提供专业合规的生物安全检测、方法学开发、靶点验证评价以及相关检测试剂盒产品。作为助力您成功的生物安全检测合作伙伴，我们为中国生物医药安全提供国际一流的本土服务。

BRC Biotechnology (Shanghai) Co., LTD. , founded in 2022, has built a ~6,000m² world-class development, service and training platform in Simbay Park of Shanghai Free Trade Pilot Zone, meeting cGMP and Biosafety Level 2 (BSL-2) standards. We are committed to provide the professional and compliance target validation, biosafety testing and assay development in cell and gene therapies, monoclonal antibody, vaccine, and nuclear acid drugs. As your reliable biotech-service partner on the way to success, we are bringing the world-class one-stop service close to you.

博瑞策生物服务能力

BRC BIOTECH SERVICE CAPABILITIES



BRC BIOTECHNOLOGY (SHANGHAI)

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下游工艺
Down Stream Process

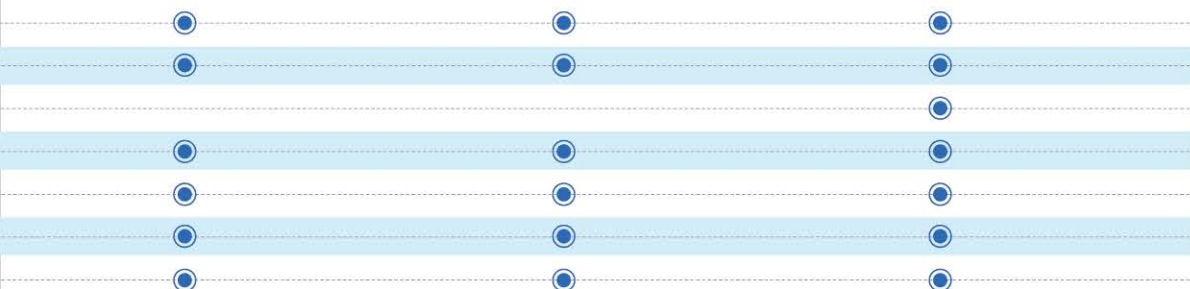


制剂罐装
Formulation & Filling

未纯化原液
Unpurified Bulk
IND/BLA批放行
IND/BLA Lot Release

纯化原液
Purified Bulk
IND/BLA批放行
IND/BLA Lot Release

药物制剂产品
Final Product
放行检测
Lot Release



大肠杆菌/质粒产品 E.coli / Plasmid

- ① 鉴别 Identity
 - ☑ 随机扩增多态 DNA 分析 Identification with randomly amplified polymorphic DNA
- ① 活力 Viability
 - ☑ 菌活力 Bacterial viability in microbial bank
- ① 纯度 Purity
 - ☑ 细菌库纯度检测 Purity testing of microbial bank
 - ☑ 革兰氏染色 Gram's staining
 - ☑ 噬菌体检查 Bacteriophage detection
- ① 生化标记检测 Biochemical Marker
 - ☑ 基因型/表型检测 Genotype/phenotype testing
- ① 遗传稳定性 Genetic Stability
 - ☑ 菌种库质粒保留率 Retention of plasmid in microbial bank
 - ☑ 质粒酶切检查 Plasmid Identity by restriction enzyme analysis
 - ☑ 质粒拷贝数 Plasmid copy number detection in microbial bank
 - ☑ 质粒全序列测定 Sequencing analysis of recombinant plasmid

宿主细胞 Host Cell

- ① 细胞株鉴定 Identity
 - ☑ 细胞株鉴定 Cell line identification
- ① 纯度检测 Purify
 - ☑ 无菌检测 Sterility testing by direct inoculation
 - ☑ 支原体检测 Test for presence of Mycoplasma
 - ☑ 分支杆菌检测 Test for presence of Mycobacterium
- ① 病毒因子检测 Adventitious Virus
 - ☑ 体外指示细胞共培养法 *in vitro* assay for adventitious contamination
 - ☑ 动物体内法检测外源因子 *in vitro* assay for adventitious agent
 - ☑ 扫描电镜检测 TEM
 - ☑ 抗体生成实验 Antibody Production Assay
 - ☑ 猪源病毒共培养检测 *in vitro* assay for porcine viral contaminants
 - ☑ 牛源病毒体外共培养检测 *in vitro* assay for bovine viral contaminants
 - ☑ 特异病毒PCR检测 Specific Virus Detection Using QPCR
- ① 遗传稳定性 Genetic Stability
 - ☑ 目标基因测序 Sequencing of inserted gene
 - ☑ 限制性内切酶分析 Restriction enzyme analysis
 - ☑ 目标基因拷贝数分析 Gene copy number detection
 - ☑ 鉴定DNA序列定位 Localization of DNA sequences

下游工艺 Down Stream Process

- ① 未纯化原液检测 Unpurified Bulk
 - ☑ 生物负荷检测 Bioburden
 - ☑ 支原体快速检测 Rapid testing for Mycoplasma
 - ☑ 逆转录病毒样颗粒检测 Testing for retrovirus-like particles
 - ☑ 扫描电镜检测 Transmission electron microscope
 - ☑ 体外指示细胞共培养法 *in vitro* assay for adventitious contaminations

药物制剂产品 Formulation & Filling

- ① 药物中间品检测 Drug Substance
 - ☑ 无菌检测 Sterility testing
 - ☑ 内毒素检测 Endotoxin
 - ☑ 宿主DNA残留 Residual CHO DNA
 - ☑ 宿主蛋白残留 Residual CHO cell protein
 - ☑ 蛋白A残留 Residual Protein A
- ① 药物终产品检测 Drug Product
 - ☑ 产品特异性测试 Product Specific Identity Assay
 - ☑ 生物活性检测 Biological Activity
 - ☑ 总蛋白测试 Total Protein
 - ☑ 渗透压检测 Osmolality
 - ☑ pH pH
 - ☑ 电导率 Conductivity
 - ☑ 可见颗粒 Particulates
 - ☑ 外观 Appearance



检项同时符合中国药典，美国药典，欧盟药典，WHO等相关规定要求；
Assay compliant to ChP, USP, EP and WHO guidance

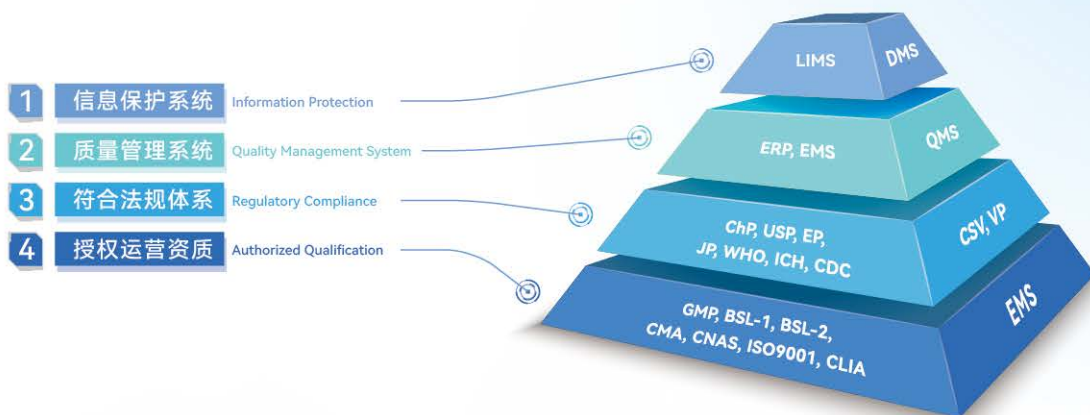


具体检测项目将博瑞策生物技术专家将根据药物形态和申报主体要求提供
Specific testing proposal will be provided by BRC Biotech Technical Expert according your products and regulatory

质量体系构建合规保障

Quality System to Build Compliance Guarantee

博瑞策生物依据最新法规要求和药品良好生产实践（GMP）经验构筑合规化服务能力



全面的质量管理体系

Comprehensive Quality Management System



BRC BIOTECHNOLOGY

我们将患者用药安全作为己任

共同构筑药物安全和人类健康的守护



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