PharmSol

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BRAZIL PHARMACEUTICAL MARKET: A STRATEGIC OPPORTUNITY

Brazil continues to be one of the most attractive pharmaceutical markets globally, driven by its large population, increasing healthcare expenditure, economic growth, and a well-established public healthcare system. The country remains the largest pharmaceutical market in Latin America, outperforming regional competitors such as Mexico and Argentina in both market size and growth.

Recent estimates place the Brazilian pharmaceutical market at approx. USD 55 to 60 billion, with projections indicating substantial growth to approx. USD 90-100 billion by 2040, supported by strong demand for both prescription and generic medicines.

ANVISA GMP CERTIFICATION

The Gateway to Market Entry

ANVISA GMP certification remains a critical prerequisite for pharmaceutical manufacturers seeking access to Brazil. ANVISA facility inspection can be initiated without prior dossier submission. Inspection and certification timelines are approximately 10-12 months. GMP certificates are valid for 3 years for OSD facilities and 2 years for sterile facilities.

CADIFA

A New Era for API Manufacturers

Brazil has significantly transformed its API regulatory framework through RDC 359/2020, RDC 361/2020, and RDC 362/2020. Under the new regulations, API facilities must obtain CADIFA (Carta de Adequação do Dossiê de Insumo Farmacêutico Ativo) approval. CADIFA confirms ANVISA acceptance of the API DMF. Since August 2023, pharmaceutical companies registering products in Brazil must source APIs from CADIFA-approved manufacturers. CADIFA-approved facilities are publicly listed by ANVISA, increasing visibility and commercial opportunities.

With a limited number of approved API facilities currently available, CADIFA certification offers a significant competitive advantage for API manufacturers seeking access to the Brazilian market.

How PharmSol Can Support Your Brazil Market Entry Journey

P**harmSol** offers comprehensive market access, regulatory and compliance support to pharmaceutical companies seeking entry into the Brazilian market. Our services include:

- Market access, Product registrations in Brazil
- Regulatory strategy for Finished Dosage Forms (FDFs) and APIs
- ANVISA GMP inspection and facility accreditation support for API, FDF facilities
- Coordination and support for Pharmaceutical Equivalence (PE) and Bioequivalence (BE) studies

STRATEGIC TAKEAWAY

Brazil presents substantial opportunities for both Finished Dosage Form (FDF) and API manufacturers. Early planning for ANVISA GMP certification, Pharmaceutical Equivalence studies, and CADIFA approval can significantly accelerate market entry and position companies for long-term growth in Latin America's largest pharmaceutical market.