CIN : U74900TN2024PTC173560
TAN : CHEI12236A
PAN : AAHCI8603H
GSTIN : 33AAHCI8603H1ZN

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PROJECT REPORT

Market Survey cum Detailed Techno Economic Feasibility Report for manufacturing the Monoclonal Antibodies (mAbs) Product

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1. EXECUTIVE SUMMARY

- USD 7.71 billion in 2024, with projected growth to USD 13.11 billion by 2033 (CAGR ~6.1%) *ref: India Monoclonal Antibodies Market Size, Share, Report 2033*
- Another estimate focuses narrowly on cancer mAbs, valuing the market at USD 8.15 billion in 2023, rising to USD 19.76 billion by 2030 (CAGR ~13.5%) India

Ref : Cancer Monoclonal Antibodies Market Size & Outlook, 2030

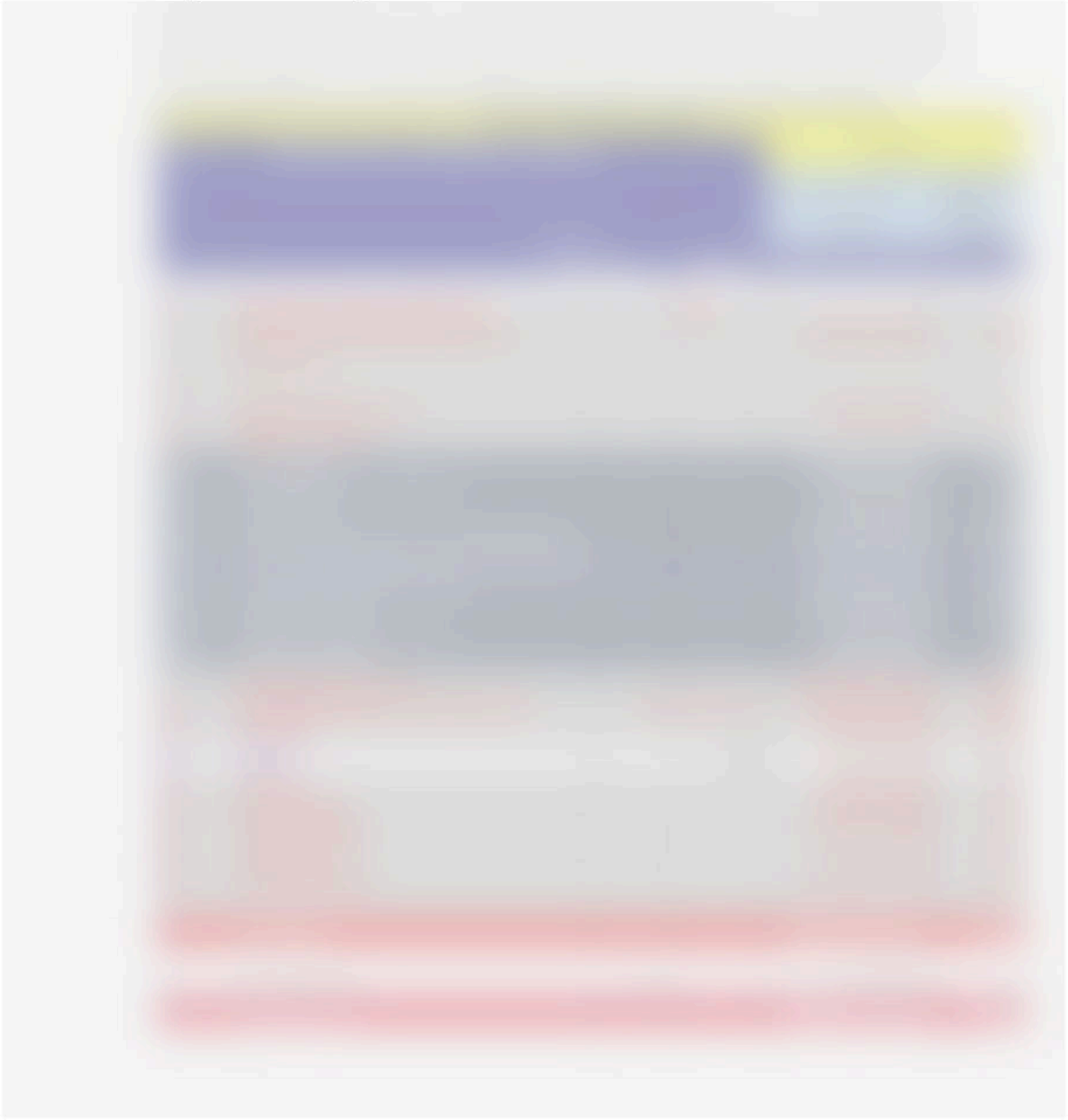
India is witnessing a significant rise in demand for mAbs, driven by their effectiveness in treating cancers, autoimmune, and infectious diseases. This growth is underpinned by supportive government initiatives:

- **Make in India**: Promotes indigenous manufacturing of biologics and reduces import dependency.
- **Biopharma Policy**: Encourages innovation and local production of biosimilars.
- **Funding and Support**: Government grants, startup funding, and global partnerships bolster the biopharma sector.
- **Regulatory Strengthening**: DCGI has accelerated pathways for biologic approvals.
- **R&D Incentives**: Supported by DBT and ICMR to drive innovation.

Recent developments include increased FDA/DCGI biosimilar approvals, new biosimilar launches, and export growth in markets like Africa, Southeast Asia, and Latin America.

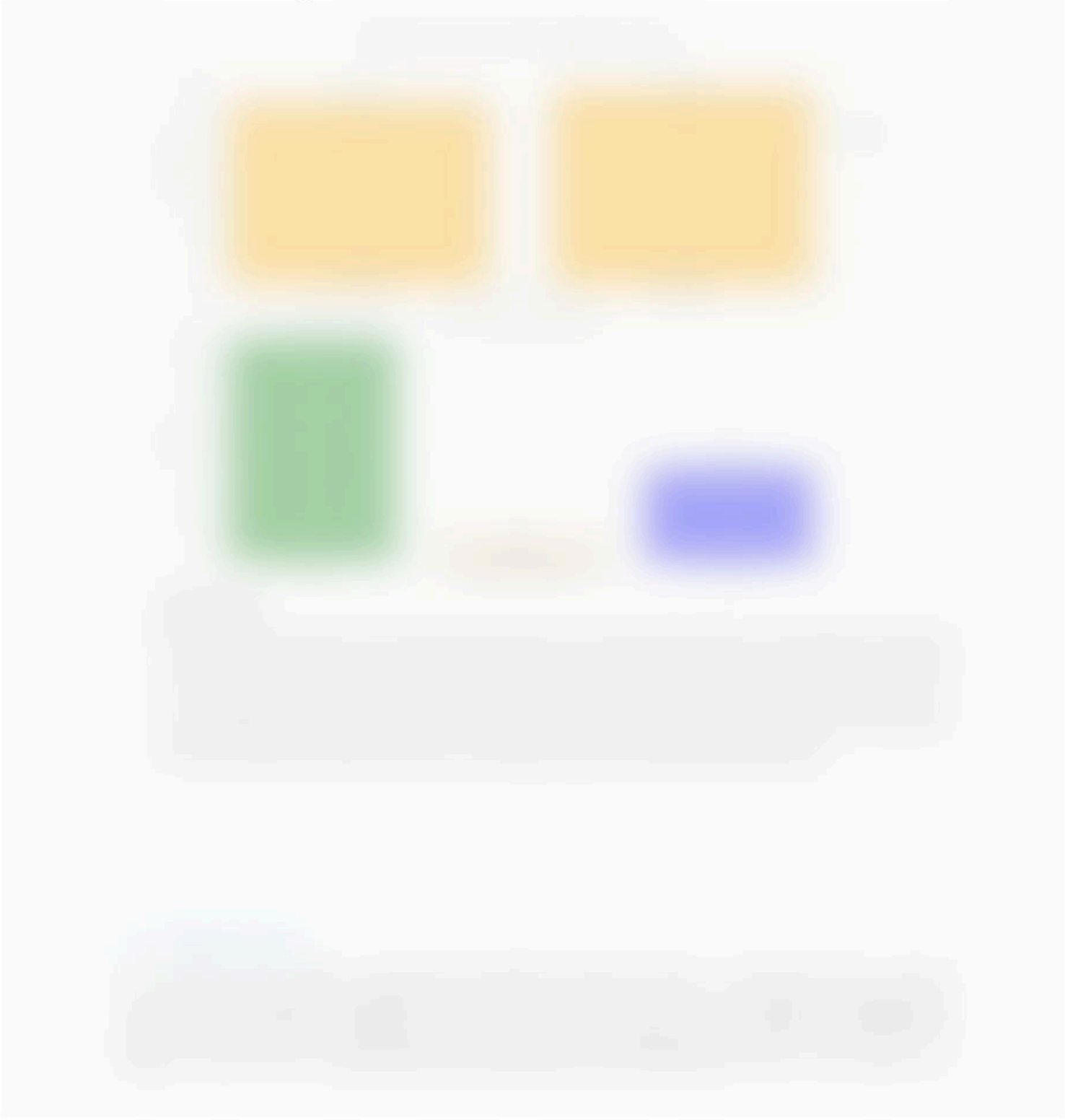
ISHA'S GMP Consultancy Pvt. Ltd. was engaged to conduct a market and economic feasibility study for the proposed mAbs manufacturing project. The analysis considered disease prevalence, evolving healthcare infrastructure, and the need for affordable therapeutics. The plant economics study was based on available data and market trends related to chronic diseases, advanced therapeutics, and biosimilar adoption.

Project Cost summary:



Economic & Financial Highlights

IV. Margin Performance



underpinned by multiple synergistic factors including an increasing burden of chronic and life-threatening diseases, enhanced awareness of biologic therapies among clinicians and patients, and the integration of biologics into national healthcare protocols.

Segment Spotlight: Oncology mAbs

Among the various therapeutic areas, **oncology-focused monoclonal antibodies** constitute a high-growth segment, projected to grow at a **CAGR of 13.5%**, reaching approximately **USD 19.76 billion by 2030**. The demand surge in oncology is largely driven by:

- Rising cancer incidence rates across India.
- Introduction of advanced immunotherapies as part of first- and second-line treatments.
- Greater accessibility to diagnostics enabling earlier disease detection and treatment initiation.

This creates a lucrative opportunity for targeted monoclonal antibodies, including checkpoint inhibitors and biosimilars of blockbuster drugs such as trastuzumab, rituximab, and bevacizumab.

Ecosystem Enablers

India's biopharmaceutical ecosystem is undergoing a transformation, characterized by:

- **A Proactive Regulatory Framework:** Regulatory bodies like the Central Drugs Standard Control Organization (CDSCO) and Department of Biotechnology (DBT) are facilitating accelerated approval pathways for biosimilars and streamlining clinical trial regulations.
- **Skilled Workforce:** A large pool of scientists, process engineers, and regulatory professionals with experience in biologics supports R&D and GMP-grade manufacturing.
- **Export Potential:** Indian mAbs are increasingly being exported to **emerging markets** in Africa, Southeast Asia, and Latin America, where cost-effective biosimilars are in high demand due to their affordability and therapeutic equivalence.

3.1 Key Market Players

The Indian mAbs landscape includes prominent domestic and multinational players:

- **Biocon Biologics** – A leader in biosimilar development with global partnerships (e.g., Viatris).
- **Dr. Reddy's Laboratories** – Actively expanding its oncology and biosimilar pipeline.
- **Cipla** – Known for its biosimilar portfolio and focus on affordability.
- **Zydus Lifesciences** – A significant player in both discovery-led and biosimilar biologics.

Additionally, collaborations with global giants such as Roche, Amgen, and Pfizer for co-development or distribution are adding depth and credibility to India's biopharma sector.

3.2 Challenges and Opportunities

Despite strong growth indicators, the market faces persistent challenges:

- **Affordability**: High production and import costs render innovator mAbs inaccessible to a large portion of the Indian population.
- **Healthcare Access Disparities**: Limited insurance coverage and regional disparities in healthcare infrastructure impede equitable distribution.
- **Cold Chain and Logistics**: Biologics require stringent storage and transport conditions, adding to logistical complexities.

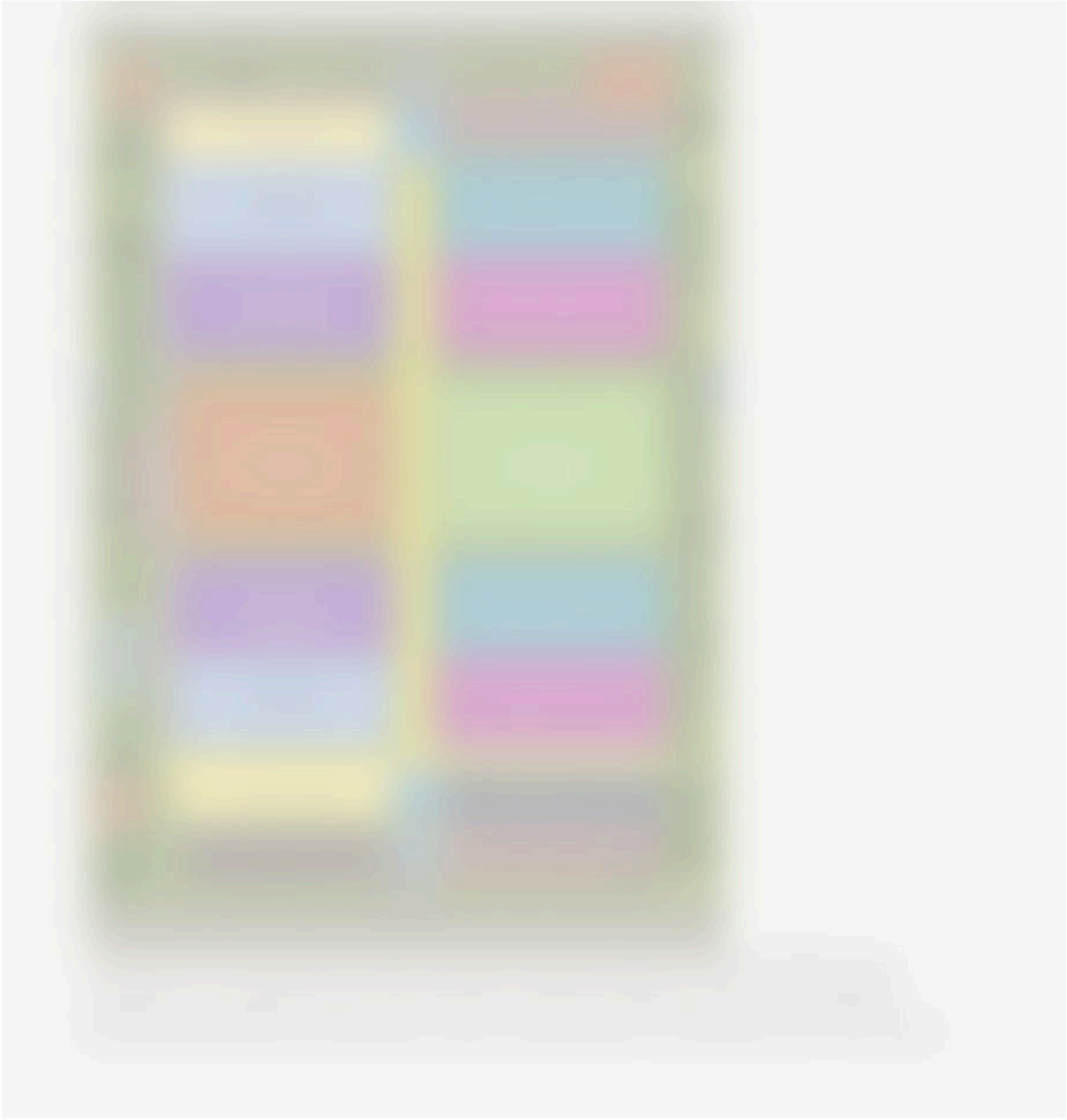
However, these challenges open up **strategic opportunities**:

- **Biosimilars and Cost-Efficient Manufacturing**: India's capability to develop cost-effective biosimilars provides a clear route to addressing affordability concerns while maintaining therapeutic efficacy.
- **Public-Private Partnerships (PPP)**: Government-backed initiatives such as Ayushman Bharat and Make in India support investment in domestic biologics manufacturing and R&D.

3. PROJECT OVERVIEW

3.1 Equipment Lis

3.1 Site plan



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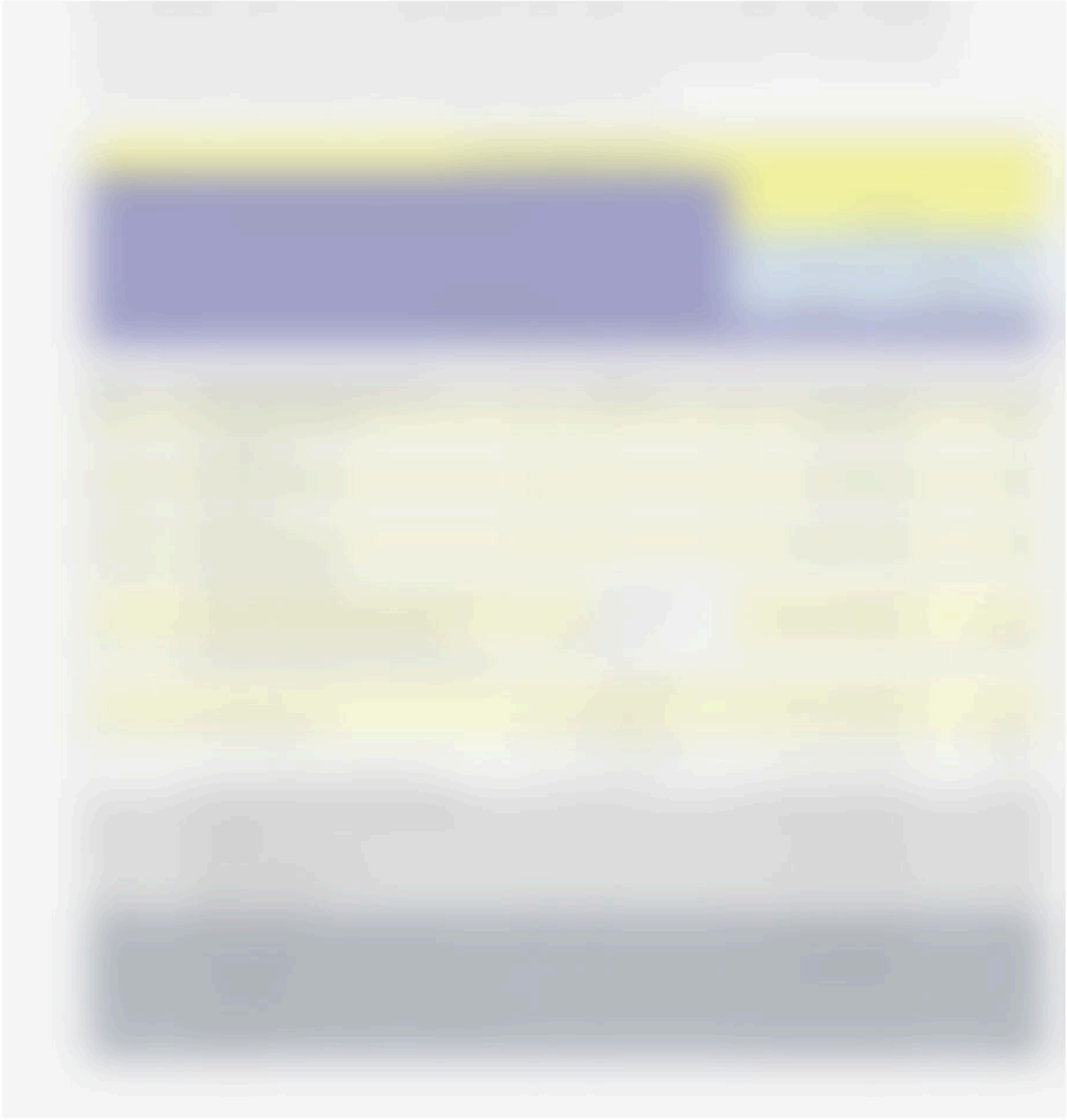
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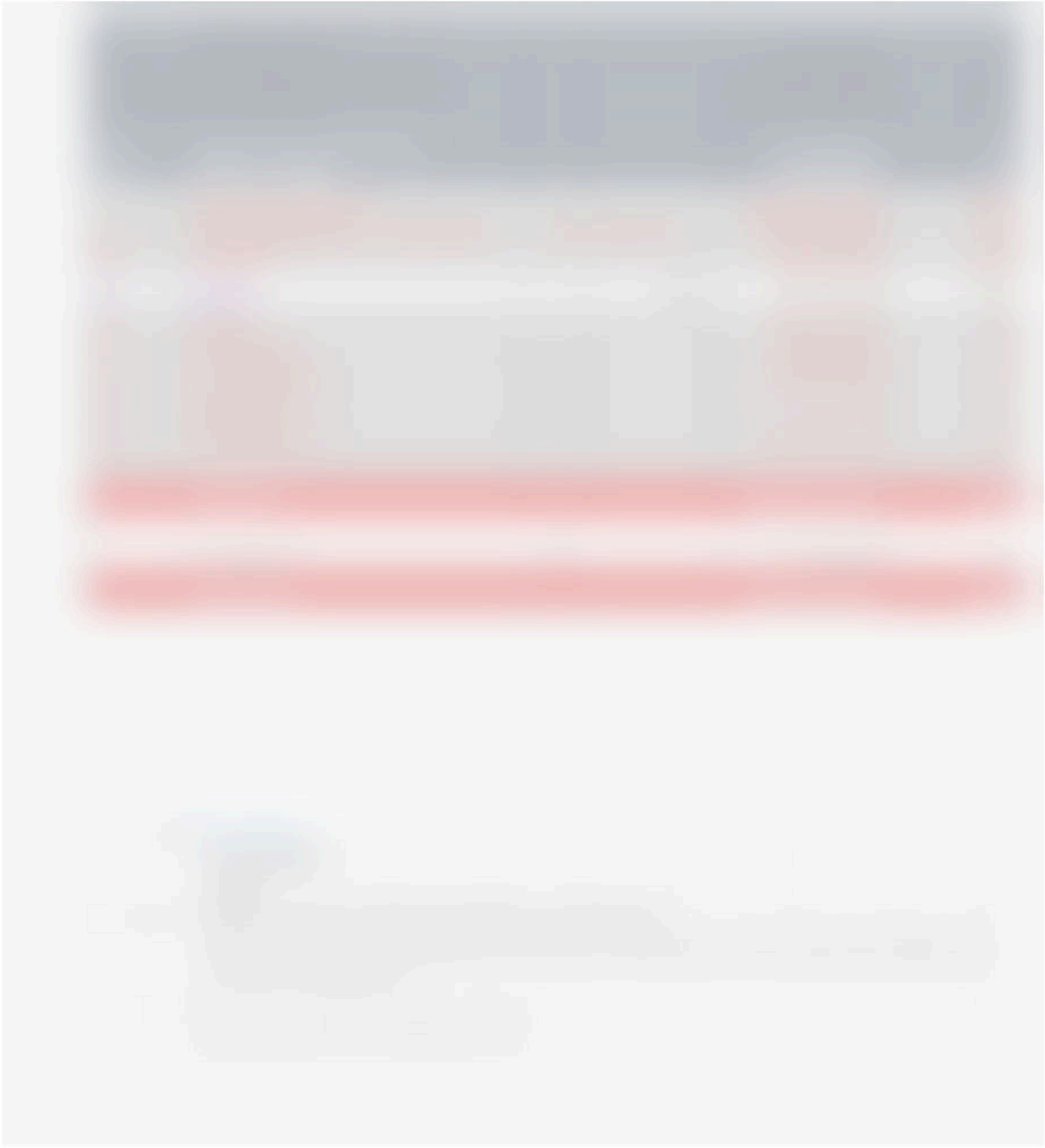
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4. SITE LOCATION

5. PROCESS OVERVIEW

6. PLANT ECONOMICS





6.3 ETP Equipment Cost

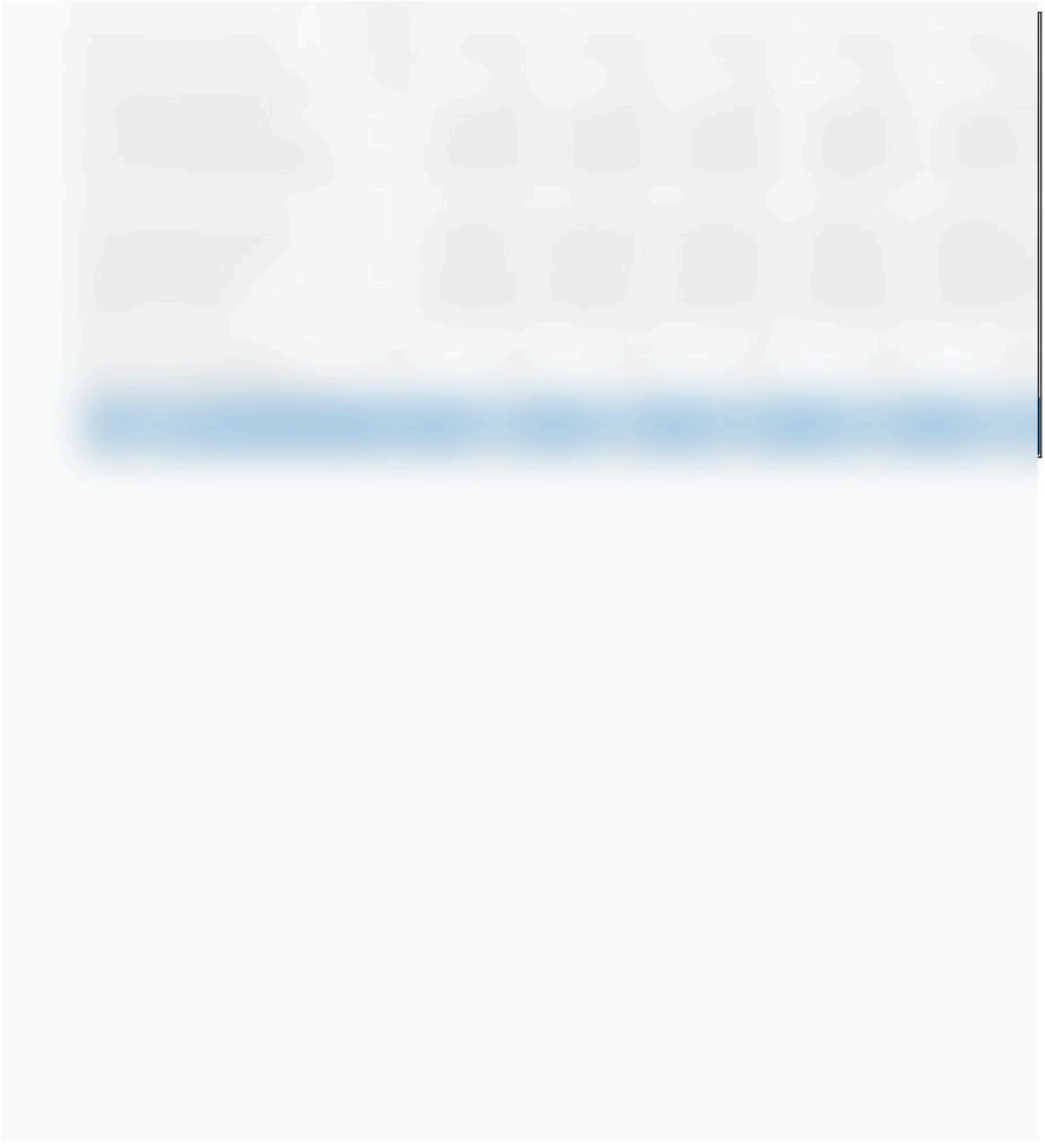
6.5 Equipment Cost

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6.10 Projected Cash Flow



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