



شركة بيت جالا لصناعة الادوية

Beit Jala Pharmaceutical Co.

*Social & Environmental Impact Report
for New Sterile Production Line*

Beit Jala, West Bank and Gaza

July 2013

Social & Environmental Impacts report

Description of the Project

Beit Jala Pharmaceutical Co. "BJP" is a Palestinian company established in 1969 in Beit Jala in the center of Palestine to the south of Jerusalem for the purpose of manufacturing generic pharmaceutical products.

BJP has the following production lines:

- Solid dosage form production line: producing plain, sugar and film coated tablets, powders and capsules.
- Liquids production line: producing syrups, suspensions, and solutions.
- Sterile liquid production line: producing eye drops.
- Semi-solids production line: producing ointments, creams, gels and suppositories.

The current production capacity of BJP is 5,000,000 units per year. It can be doubled by another working shift and by exploiting the maximum capacity of production lines. The capacity of the new sterile line is about 36,000 Ampoule/day and 18,000 bottles per day.

The main market is Palestine and Middle East Countries such as Algeria, Jordan, Oman, Yemen, Iraq, and Mauritania. The company is working on opening more markets in east Africa and Asia such as Sudan, Tanzania, Ethiopia and Macao, in addition to Europe (Poland and Czechoslovakia).

BJP is certified for European Union (EU) Good Manufacturing Practice (GMP), Jordanian GMP (JFDA), and International Organization for Standardization for ISO 9001:2008 for Quality Management Systems and ISO 14001:2004 for Environmental Management Systems; in addition to Palestinian GMP based on WHO guidelines.

The project is adding a new sterile production line, imported from Germany and Italy with capacities of about 36,000 Ampoule/day and 18,000 bottles per day, for manufacturing of sterile preparations in the form of liquids intended to be used Intra Venous (IV), Intra Muscular (IM) ampoules and sterile eye drops. This production line will be established according to international standards (GMP). The project is assessed against the environmental and social (E&S) requirements of the Multilateral Investment Guarantee Agency (MIGA), World Bank Group, the Performance Standards (PSs) on Social and Environmental Sustainability dated 2007. Based on available information the project will not require additional land acquisition and PS 5: Land Acquisition and Involuntary Resettlement are not expected to be applicable as there is no physical or economic displacement. PS 6: Biodiversity Conservation and Sustainable Natural Resource Management is not expected to be applicable as project sites are mostly in urban areas in West Bank with no biodiversity/International Union for Conservation of Nature (IUCN) protected sites. PS 7: Indigenous Peoples does not apply as no impacts on such individuals or groups are expected. While PS 8: Cultural Heritage does not apply as no sites of cultural significance have been identified on or near areas affected by project.

The diagram below shows all three production lines currently functioning at BJP Co. where line No. 4 is the new sterile products line.

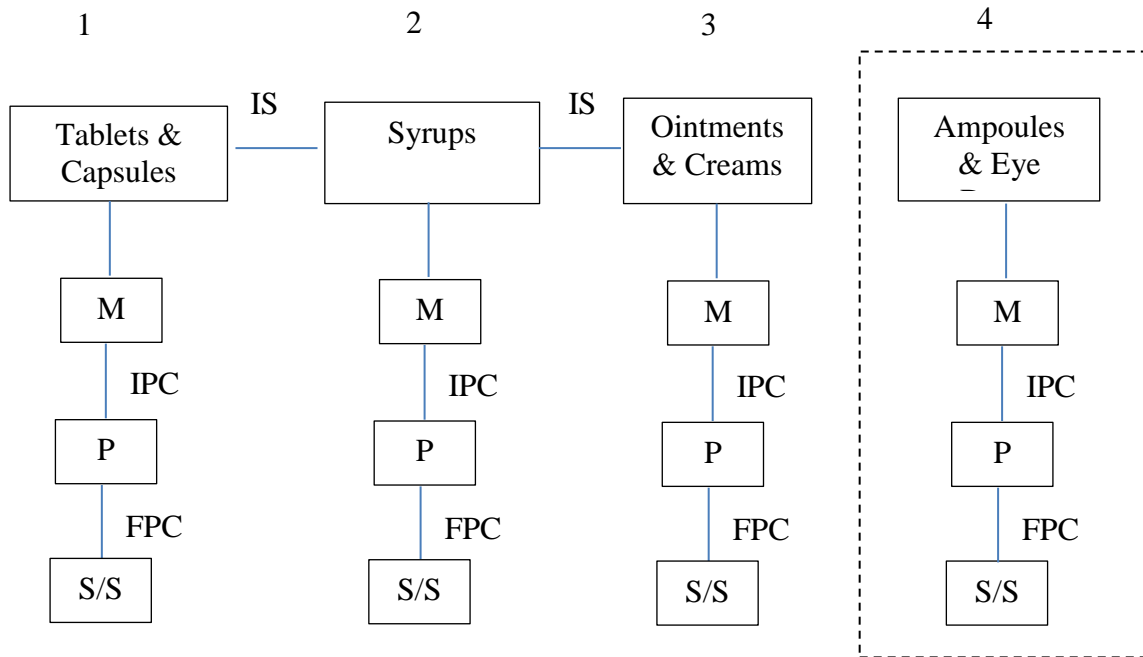


Figure 1: Production Lines Chains

Legend:

IS: Infra structure (utilities, HVAC system, purified water system, water for injection, Compressed air, etc.)

M: Manufacturing.

P: Packaging.

IPC: In process control.

FPC: finished product control.

S/S: Shipping / Storage.

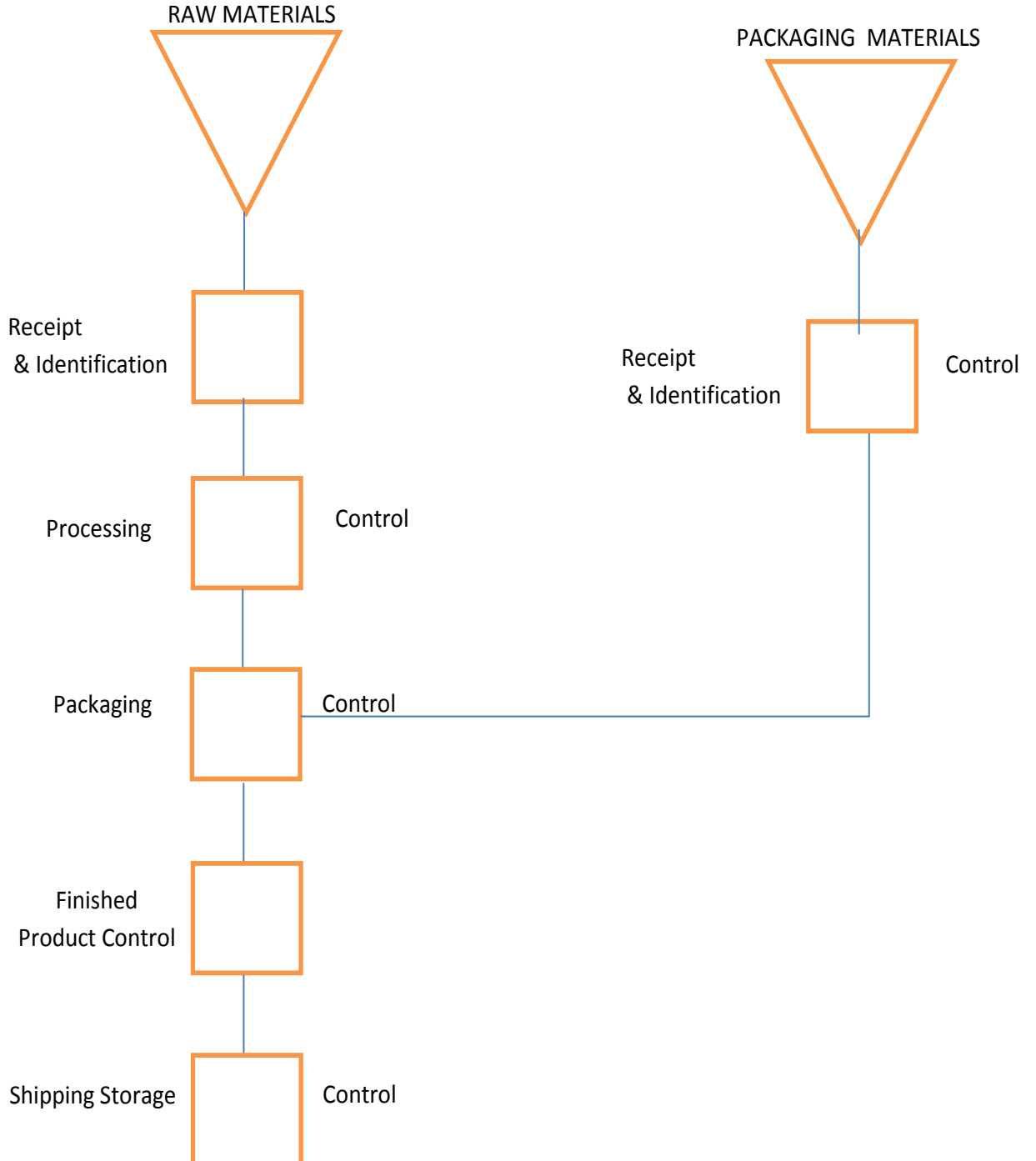


Figure 2: Sterile manufacturing and packaging flow chart

Key Impacts and Mitigation

Social and Environmental Assessment and Management Systems

Social and Environmental Assessment

According to national law, the company is not required to prepare an environmental impact assessment for the respective authority and an environmental clearance is not required for production line expansion. Environmental impact assessment will be prepared for the new sterile liquid production line as a part of the company commitment policy towards minimizing risks that negatively impact the environment.

Management Program

The company has in place an Environmental Management System against the requirements of ISO 14001:2004. The management system includes detailed roles and responsibilities as well as reporting requirements to ensure that issues related to air pollution, vapors, noise level and waste management in the plant is well taken care of. Internal audits are part of Beit Jala Pharma quality assurance system which is set according to the requirements of ISO 9001:2008. Immediate corrective actions are placed and monitored for implementation by the quality assurance manager.

Organizational Capacity

Environment management system is managed by environmental committee (EC), Management Representative for Environment (MRE); Environmental Committees consists of MRE & department managers/ representatives. Roles and responsibilities of MRE include:

1. Control of environmental management system documentation.
2. Ensure that Internal Audits are scheduled, carried out and reported to the management.
3. Organize periodic Management Review Meetings.
4. Ensure that reporting and implementation of corrective and follow-up actions are actually performed on time.
5. Managing the process of determination and evaluation of environmental aspects for company processes, products, activities, services and company contractor's activities in coordination with department managers.
6. Determination of legal requirements and other requirements related to company environmental aspects.
7. Follow up of implementation and changes on these requirements.
8. Managing the processes of determination objectives, targets and programs in coordination with personnel and environmental committee taking into account the financial resources.
9. Managing environmental monitoring and measurement by determining the mechanisms and responsible operators.
10. Preparing the periodic environmental evaluation report and the evaluation of compliance with environmental requirements and environmental performance.
11. Managing, following up and replying the contacts and inquiries internally and externally.

12. Reporting to top management about the effectiveness of EMS and action plans.
13. Training of company employees according to training requirements which are determined by department managers through the training program of the company. Also contractors are trained if applicable.

EC is responsible for approval of environment aspects, impacts evaluation, legal and other requirements, objectives, targets and programs.

Monitoring and Reporting

Top management monitors the implementation of ISO 14001:2004 system through the reports of the MRE. The periodic environment performance evaluation report is discussed in the management review meeting to ensure the effectiveness of the system to assess the opportunities for improvement and to correct.

Emergency Preparedness and Response

The company established procedures to identify potential emergency situations and potential accidents that can have impacts on life and safety of workers and environment. The procedure is implemented by keeping a list of all risks and emergency cases which is updated whenever new risk resulted due to new activity, service or product. Safety officer(s) prepare instructions to deal with the risks and hazards. Yearly plan is prepared to verify emergency preparedness and response. In case failure occurs a corrective action plan will be implemented. Safety officer(s) checks periodically the work environment according to special checklist. In addition when an accident happens, the security officer(s) prepares a report about the place, cause and losses and determines Corrective action preventive action (CAPA) action to prevent recurrence/occurrence of the accident.

Training

The company policy is that all new hire employees are trained on the environmental management system. Each employee shall be trained annually on BJP quality and environmental management system related to his/her job, quality and environmental policies, related department quality objectives and job related skills by attending discussion session conducted by their managers/supervisors and management representative for environment. At the beginning of each year, each department manager shall identify his employees training requirements including the environmental training needs "Environmental policy, emergency preparedness, significant environmental impacts...). External training is attended according to the availability of training courses, also upon requirements.

Labor and working conditions

Human Resource Policy and Procedures

The company has a human resources (HR) policy that complies with national labor and employment law, including their rights related wages and benefits, hours of work, over time, leave for illness, vacation, maternity and bonuses. Number of workforce for new production line is approximately 25 – 30 full-time employees including about 20 – 30 % females. Upon completion of the project and within a period of three years an

expected number of 26 additional full time employees will be employed. The HR policy ensures that BJP abides by the rules prevailing in Palestine concerning the recruiting of workforce. Workers are granted two breaks each day in addition to a break intended for prayers, in addition to overtime payment paid at a rate equivalent to 150% of the regularly paid hours, 50% coverage of health insurance, and an extra month bonus at the end of each fiscal year. The company enables employees to be enrolled in post graduate studies, which grants them a special wage increment.

Workplace health and safety

BJP promotes safe and healthy conditions to protect health of workers and employee by the following:

- Controlling the temperature and humidity of all plant areas to be according to limits by heat, ventilation and conditioning system (HVAC).
- Providing workers with special gowning for each area such as suits, lab coats, goggles, masks and shoes.
- Providing sound regulators for those who are working in areas in which noise level exceeds limits.
- Availability of emergency kits at the shop floor.
- All company areas are supplied with fine extinguisher filled with Halotron gas.
- Periodic medical test is done for all employees according to type of work.

Worker's Organizations

The workers of BJP have a union to protect their rights regarding working conditions and terms of employment, also fulfilling their needs according to working law. The responsibilities include:

- Improving their economic, social, cultural, health and working environment, conditions and terms of employment.
- Protecting the employees' rights from risky working environment.

Non-Discrimination and Equal Opportunity

BJP has a non-discrimination policy. The company is committed towards preventing any type of discrimination that is based on gender, origin, color and religion. The policy ensures that there is no discrimination in rights, wages, training opportunities, increments or any other privileges due to gender, religion, and race.

Child and forced labor

Beit Jala Pharma is committed to employ people above eighteen (18) years of age; in addition it strongly emphasizes this point with all suppliers.

Pollution Prevention and Resource Efficiency

Resource Usage

The project is expected to utilize about 245 Kw/hr of energy supplied from the national grid. Water consumption is about 8 m³/day. The quantity of water used for producing the products complies with the WHO GMP. The existing capacity of the boiler is 713 Kw expected to increase by 25 kW which is not working with full capacity. After new plant running the increase in the working consumption will approximately 25 kW.

- The designer and the manufacturer of the equipment and utilities are asked to make the power consumption as minimum as possible.
- Water system treatment unit is designed to have the optimum water consumption.
- To decrease the exhaust emissions: the same exiting boiler will be used for this new plant.
- Air filters will be installed on the air exhaust fans.

Solid waste

Non-significant increase of the amounts of non-pharmaceutical and pharmaceutical waste will result from this project. Non-pharmaceutical waste such as glass is recycled and pharmaceutical waste is treated by an Israeli company "Tabib" in a way complying with environmental standards.

Community Activities

Below are some community activities that BJP is involved in:

- BJP sponsors training seminars for doctors in the different hospitals.
- The company contributes in the tuition of two schools of medicine students, it also sponsors free open medical days by making available all relevant needed medicines for the poor or for refugee camps patients.
- The company is committed to contribute in tuition fees of students of the school of pharmacy and school of medicine.
- The company is committed to sponsor free of charge medicines to Non-governmental organizations (NJOs).

Environmental and Social Management Plan

No.	Risk Identification	Mitigation Measures	Responsible Person	Time Line for Completion
1.	During performance of civil works in the project, risk of high noise and accidents which might be harmful to workers	Noise: Providing workers with sound regulators. Accidents: Providing safety tools (head cover, goggles, protective shoes, gloves)	Project manager + Contractor & follow up from general safety officer.	Dec. 2013
2.	During installation and commissioning of water for injection system. The following risks may occur: - During welding of stainless steel pipes (may cause harmful for worker eyes). - Steam generator (distillator): risk of explosion or leakage from pipes since the water temperature is 85°C.	Welding: providing special goggles and protective tools. Steam generator: special gowning such as overall.		Feb. 2014
3.	Compressed air system. Risk of explosion and pipes welding.	Special goggles and protective tools. Special gowning such as overall.		Mar. 2014
4.	Gases: Nitrogen & LPG which used in the process of ampoules welding.	Protective precautions during installation.		Mar. 2014