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SELECTED TECHNICAL PROFILES FOR PHARMACEUTICAL-RELATED PACKAGING MATERIALS *

A case study of Yugoslavia

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UNIDO Consultants

* The views expressed in this paper are the author's and do not necessarily reflect the views of the Secretariat of UNIDO. Mention of firm names and commercial products does not imply the endorsement of UNIDO. This document has not been edited.

** Centre for International Co-operation and Development (CICD), Ljubljana, Yugoslavia.

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I. INTRODUCTION

In every modern industry, packaging is becoming increasingly significant. The product and the package are becoming so interdependent that we cannot consider one without the other. Yet, surprisingly little literature is devoted to the technology development and packaging industry trends.

In the production and distribution of pharmaceuticals, packaging plays an even more important role as it does in packaging some other products. If with others, packaging is sometimes meant mainly as protection and decoration, with pharmaceuticals, packaging is an integral part of the product. Pharmaceuticals, if not adequately protected, may deteriorate to the point of not only losing its efficacy but even becoming hazardous. Apart from failing to give adequate protection, wrongly chosen or inadequately tested packaging materials may themselves affect drug contents.

The compatibility of the pharmaceutical product with packaging materials is an important parameter which must be evaluated during the product development process. This partly explains the current strategy of large transnational corporations, who are developing not only their pharmaceutical industry, but parallel to it and closely integrated the packaging industry. So called integrated bottling and packaging system is based on integral, top-down design, developed for a predetermined product.

To fully answer the question on packaging, specifically needed for pharmaceuticals, anticipated trends, specification and suppliers of major intermediate materials required, one would need to look closely at each group of pharmaceuticals, and even at each of the major producers. What we tried to do in this paper is briefly describe the use of two main types of packaging: glass and plastics in Yugoslav pharmaceutical industry.

In spite of the fact that on one hand our pharmaceutical industry is relatively well developed and that particularly glass manufacturing has a long tradition, the already mentioned specifics relating to the packaging of pharmaceuticals are responsible for import of both, the intermediate materials and final packaging materials. In some cases, the reason is insufficient market where the quantities required don't justify domestic production of a particular packaging material, in some cases it is specific raw material not available and in some cases the licences request specific type of packaging not available in the country.

The main segment of the paper are the industrial profiles for production of selected packaging materials, for which technology is available with Yugoslav companies, who have been producing these materials for the needs of Yugoslav pharmaceutical industry. This means that for all the profiles presented the technology is commercially available and the companies possessing it are prepared to offer its transfer. The profiles are prepared according to the Centre's own methodology and are entered into Information System on Technologies and Projects (ISTP). ISTP by now has over 500 various technology/project profiles from all fields of industry. Additional information on any specific industrial profile is available with the Centre and is provided upon request to the potential investor. The Centre also acts as the intermediary between the potential investor and the company offering the technology.

II. CURRENT USE OF PACKAGING MATERIALS IN PHARMACEUTICAL INDUSTRY IN YUGOSLAVIA

Most commonly used packaging materials in Yugoslav pharmaceutical industry are:

- various types of glass
- plastics
- foils (paper, aluminium, regenerated cellulose film)

1. Glass

Due to its chemical inertness, glass has been used most widely. Glass bottles are also well suited for on-line bottling, which is especially important in packaging of various syrups.

Three different types of glass packaging are used:

- ampules
- vials and
- bottles.

The requirements for ampules of Yugoslav pharmaceutical manufacture are met by two domestic producers and for some types from import. The Yugoslav producers of ampules and vials depend on import of glass tubes, which are not manufactured in the country (the use of glass tubes is preferred because much lower input of material, energy, trained specialists, and auxiliary plants is required as for direct manufacturing of bottles). The import of glass tubes in recent years ranged from 3.282 to 3.723 tons. Main reason cited by the manufacturers is that the degree of technical complexity is such that only much larger production than required by local market would be economically feasible. The type of glass tubes imported depend on the type of final product needed by the pharmaceutical industry.

The production of ampuls and vials in Yugoslavia was 1.260 t in 1989 and for large requirements of the pharmaceutical industry considerable part of ampuls needed was imported - 93 t in 1989.

The ISO standards are used by Yugoslav pharmaceutical industry to describe the degree of alkali. For the degree of alkali in relation to hydrolytic group the standard ISO 42.02 is used for ampules. For bottles and vials JUS standards apply (JUS B.E.8-092). This standard divides the glass packaging into four different hydrolytic groups, depending on the degree of acids used in the production. This determines the scope for its use. From the data available the glass from IIIrd hydrolytic group is being used for bottles.

The bottles needed by Yugoslav pharmaceutical industry are neutro or boral glass (IInd hydrolytic group) as well as IV hydrolytic glass. Besides for packaging of drugs, bottles are being used also for storage of blood, infusion liquid, various solutions, serums and vaccines.

2. Plastics

The use of packaging materials of organic origin, such as synthetic polymers with their complex composition has grown a lot during last few decades in the developed countries. The formulations used in manufacturing plastic materials vary with the type of the product for which they are used. In using the plastics for packaging pharmaceuticals, a lot more attention needs to be paid to the issue of "migration": various quantities of unreacted components and some ingredients may be converted to different chemical compounds during processing. Migration from packaging materials to drug contents generally does not involve major macro-molecular components, such as the polymer itself, but is concerned with minor constituents which can and do affect the quality of the contained product.

These serious dilemmas along with the need to import the technologically more complex types of plastics have caused that the use of plastics for packaging in Yugoslav pharmaceutical industry is a lot lesser than one might expect in view of the trends globally. Part of the reason needs to be sought also in fact that the entire plastic industry is of newer date and has up to now concentrated on supplying larger clients (construction, automobile industry, electric and electronic industry). Pharmaceutical industry has been a minor user of standard types of plastics for packaging, and contrary to the global trends, the use of these materials is actually declining.

INDUSTRIAL PROFILES

Project PRODUCTION OF PHARMACEUTICAL CONTAINERS OF GLASS TUBES

Description

PRODUCT: glass containers / fiols, small bottles, test - tubes, jars, etc./:
- I. degree of quality: products suitable for use in normal temperature conditions
- II. degree of guality: products suitable for use under high temperature conditions and product made of Neutro glass.

APPLICATION: for medical use

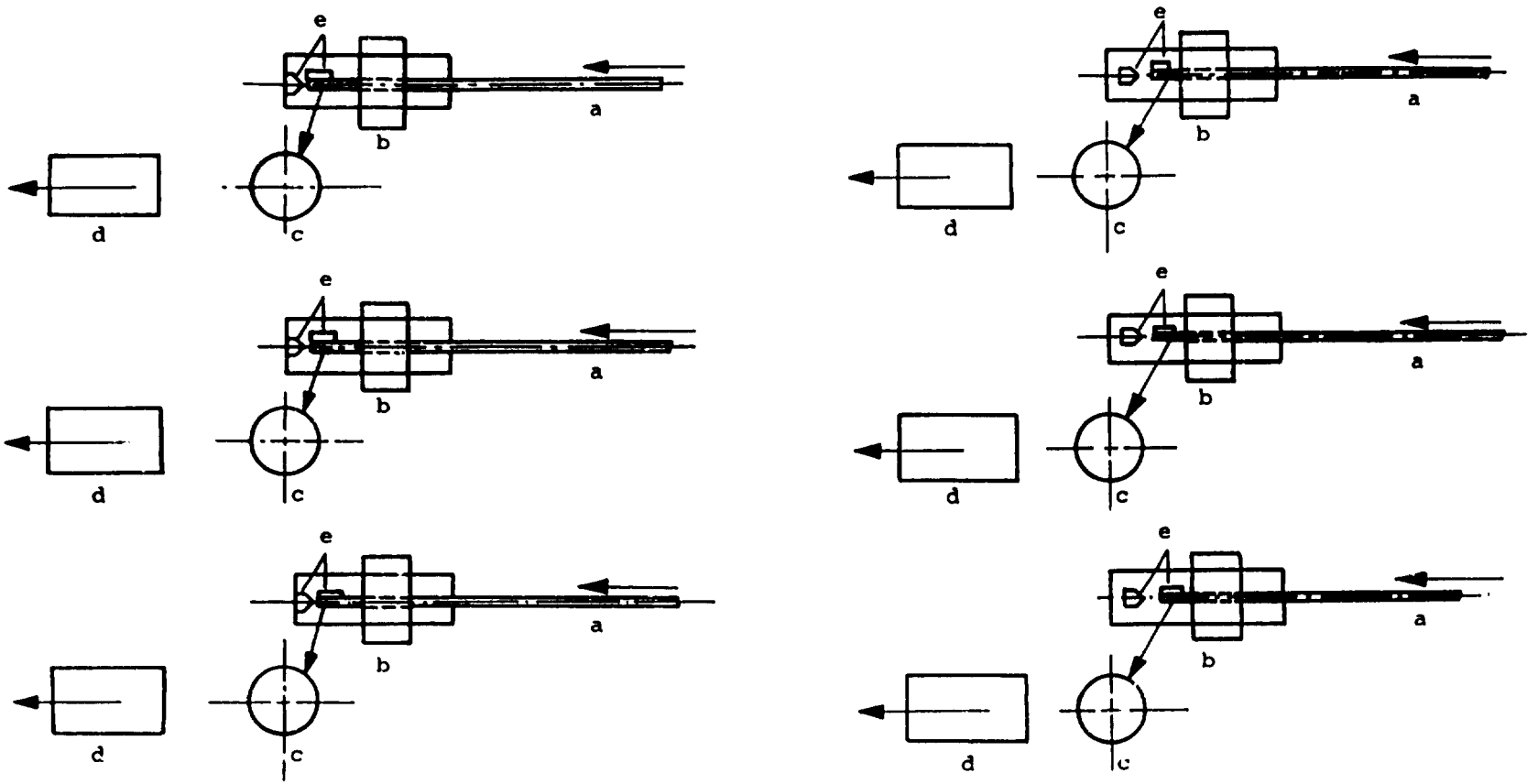
TEHNICAL DESCRIPTION: glass containers are made of glass tubes of various diameters, thickeness and quality/ sodium glass, etc./ Glass tubes/ as commercial product/ are shaped on special machines. Warming and softening of tubes is by propan - butan gas.
Production of glass containers is usually semi - automatic. For large series/ bottles for peniciline/ automatic machines, connected in computer controlled production lines, are used.

Estimated Project Cost	USD	-			
Estimated Technological Plant Cost	USD	120,000			
Capacity in (m,m^2,m^3,t,pcs) per year at 1 Shifts		1,000,000 - 5,000,000 pcs			
Floor Space (m^2)	Production	50			
	Storage	50			
	Other	30			
N° of Employees		Unskilled	Skilled	Tech.Staff	Other
		-	3	-	-
Contacting Mode	Enginnering [x]	Turn - key [ ]	Others [ ]		
Financial Aspects	As agreed				
Ecological Aspects	Clear process				

Additional Information

The production cycle is not limited and therefore the production can run in one or more shifts.
The price for technology equipment is given for 6 lines.

COMPLEX OF 6 MACHINES FOR THE PRODUCTION OF GLASS CONTAINERS



a - glass tube
b - forming machine
c - sorting machine
d - quality control, packing
e - burner and shapening tools

Project. PRODUCTION OF GLASS CONTAINERS

Description

PRODUCT: Glass containers for pharmaceutical use
- bottles for penicilin 15 ccm
- bottles for blood 200 ccm
- bottles for medical use all sizes from 10 to 200 ccm
- color white or braun

APPLICATION: pharmaceutical industry, medicine

TECHNOLOGICAL PROCESS: the process includes preparation of mixture, melting, forming, cooling, quality control and packing. The whole process is computer controlled and atomatically supervised.

Small glass containers for medical use are produced from neutro-glass on IS-HARTFORT high productive machines and rotary machines KUTSCHER. The capacity of these machines is up to 60,000,000 pcs bottles for peniciline in a year.

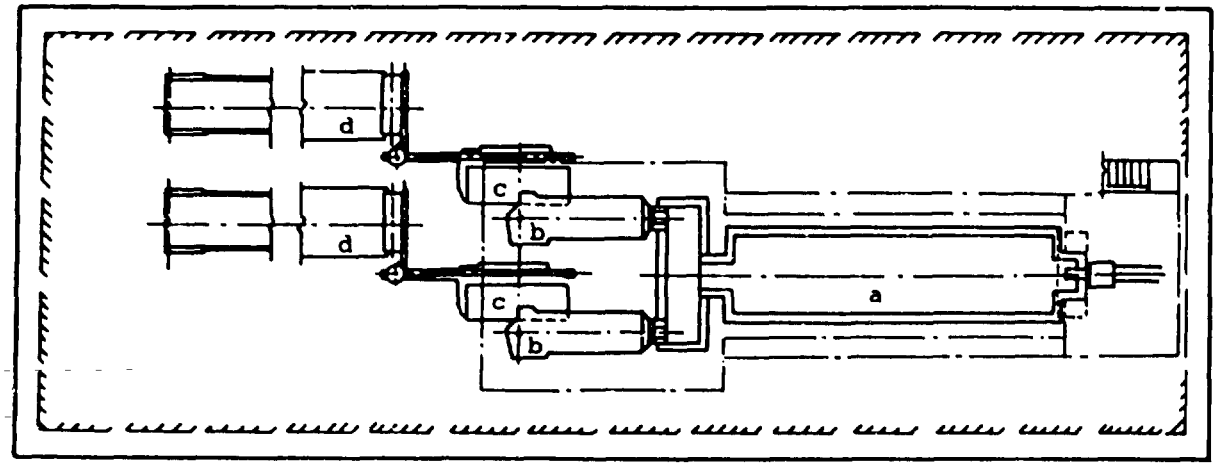
Estimated Project Cost	USD	5,500,000			
Estimated Technological Plant Cost	USD	4,500,000			
Capacity in (m,m^2,m^3,t,pcs) per year at 3 Shifts		up to 60,000,000 pcs			
Floor Space (m^2)	Production	1,500			
	Storage	800			
	Other	300			
N° of Employees		Unskilled	Skilled	Tech.Staff	Other
		6	16	2	-
Contacting Mode	Enginnering x	Turn-key ___	Others ___		
Financial Aspects	As agreed				
Ecological Aspects	Clear process				

Additional Information

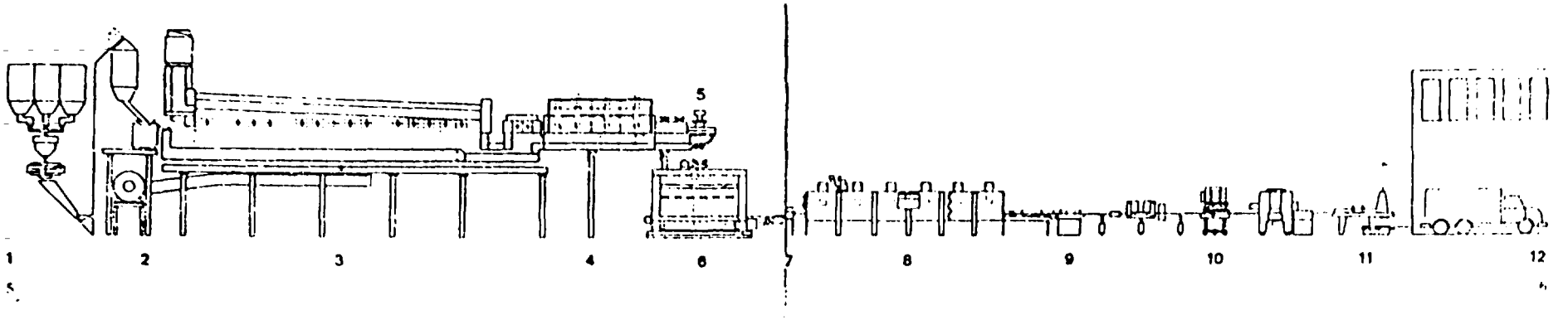
In most cases to one glass furnace belongs 3 machines. Each machine has one annealing lehr and suitable inspecting equipment. All other devices, including the preparation of mixture and raw material storage, are common for all machines.

All the equipment can be delivered from specialised suppliers.
We offer projecting, know-how, assembling, training of personnel and technical assistance.

PRODUCTION OF GLASS CONTAINERS



a - glass melting furnace
b - feeders
c - glass forming machine
d - annealing lehr



1 - batch plant
2 - batch charger
3 - furnace
4 - foreheart
5 - feeder
6 - glass forming machine
7 - stacker
8 - annealing lehr
9 - transport equipment
10 - inspection equipment
11 - packing machine
12 - warehouse

Project	PRODUCTION OF PLASTIC TUBES FOR SPECIAL PURPOSES

Description

PRODUCT: Plastic tubes - sizes from diam. 5mm to 50mm.

APPLICATION: the tubes are suitables for special use in the medicine and alimentary industry.

TECHICAL DESCRIPTION: for the production of tubes prescribed granulated raw material, suitable for special demands, is used.
The production is partially or fully automatic.
The production process is shown on the shema.

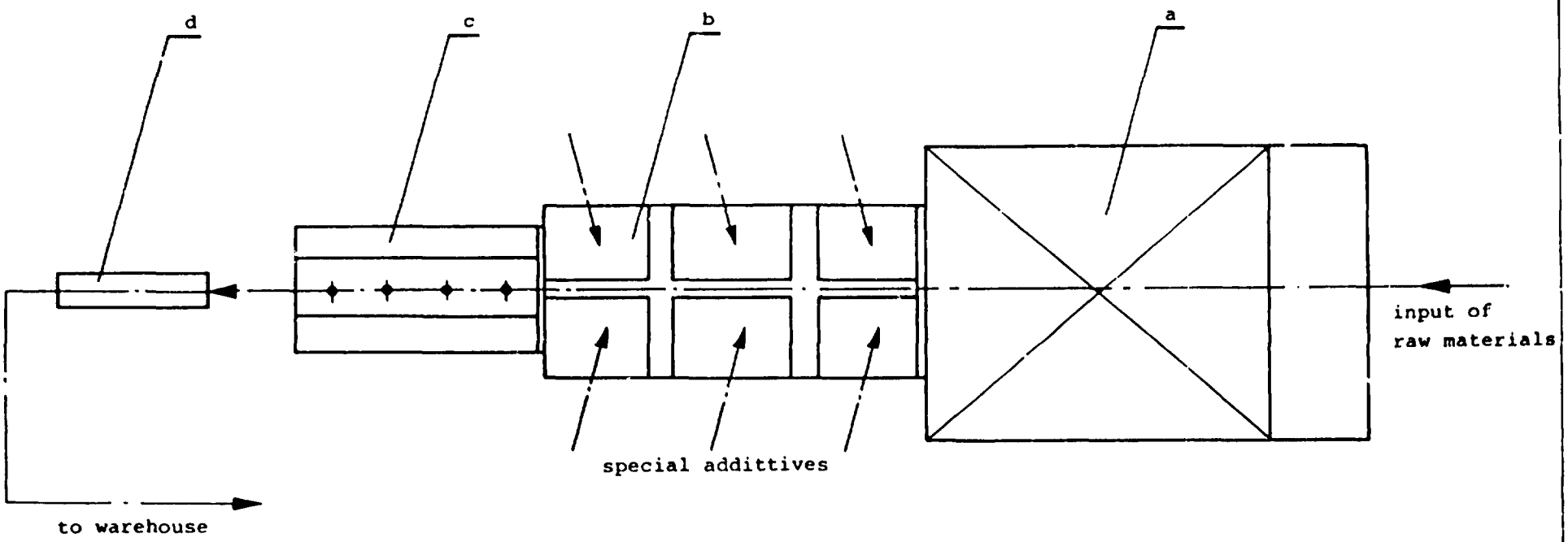
Estimated Project Cost	USD	-
Estimated Technological Plant Cost	USD	85.000
Capacity in (m,m^2,m^3,t,pcs) per year at 1 Shifts		200 - 800 t
Floor Space (m^2)	Production	100
	Storage	200
	Other	-
N° of Employees		Unskilled 1 / Skilled 1 / Tech.Staff - / Other -
Contacting Mode	Enginnering x	Turn - key ___ / Others x
Financial Aspects	As agreed	
Ecological Aspects	Clear process	

Additional Information

The price for technology equipment includs the production line and the costs for the transfer of know - how.

The instruction time for the workers is 3 months.

PRODUCTION OF PLASTIC TUBES



a - raw material container
b - adding of addittives (mixing)
c - homogenisation and melting
d - winding device

REMARQUE: several parallel production lines are possible

Project PRODUCTION OF ALU-CAPS FOR PENICILLIN BOTTLES

Description

PRODUCT: all kinds of aluminium caps and rubber diaphragms for closing the peniciline bottles.
The caps are ring, bayonet or screw-on type.
Dimensions from dia. 3 mm to dia. 150 mm.
Printed or pressed signs can be made on caps.

APPLICATION: pharmaceutical industry.

PRODUCTION PROCESS: the production is on two separate lines:
- line for the production of alu-caps
- production of diaphragms

The production is fully automatic.
On the same equipment also other products can be produced.

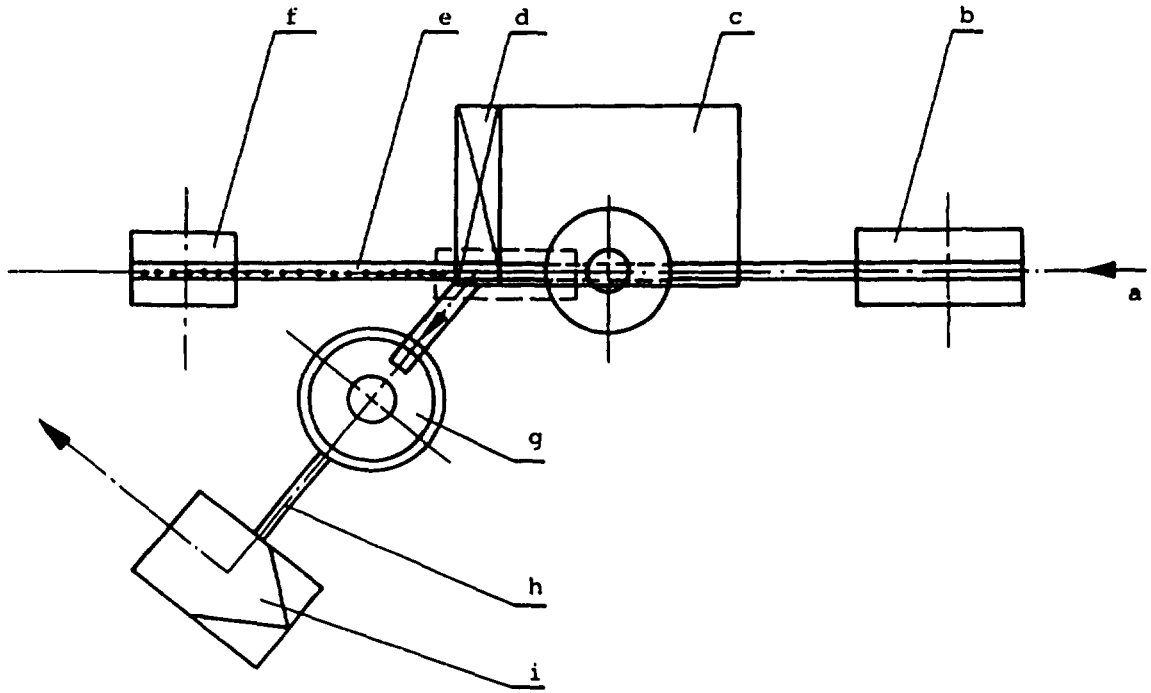
Estimated Project Cost	USD	-			
Estimated Technological Plant Cost	USD	60,000			
Capacity in (m,m^2,m^3,t,pcs) per year at 1 Shifts		9,000,000 pcs			
Floor Space (m^2)	Production	60			
	Storage	40			
	Other	20			
N° of Employees		Unskilled	Skilled	Tech.Staff	Other
		1	1	-	-
Contacting Mode	Enginnering x	Turn-key		Others	
Financial Aspects	As agreed				
Ecological Aspects	Clear process				

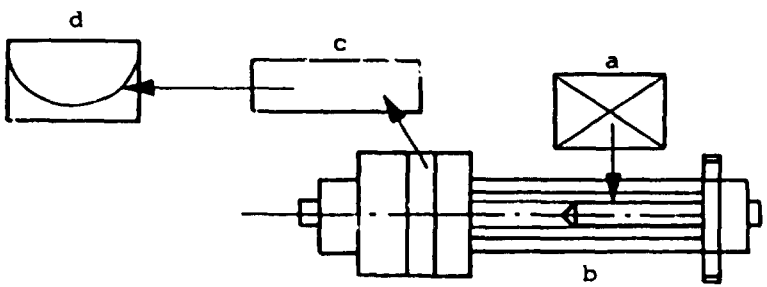
Additional Information

Beside the machines the quality of tools that are used is important.

PRODUCTION OF ALU-CAPS

a - aluminium band
b - winding reel
c - press
d - automatic control
e - used aluminium band
f - winding reel for used alu-band
g - sorting of caps
h - conveyor
i - packing





a - charging
b - production of diaphragms
c - sorting
d - control packing

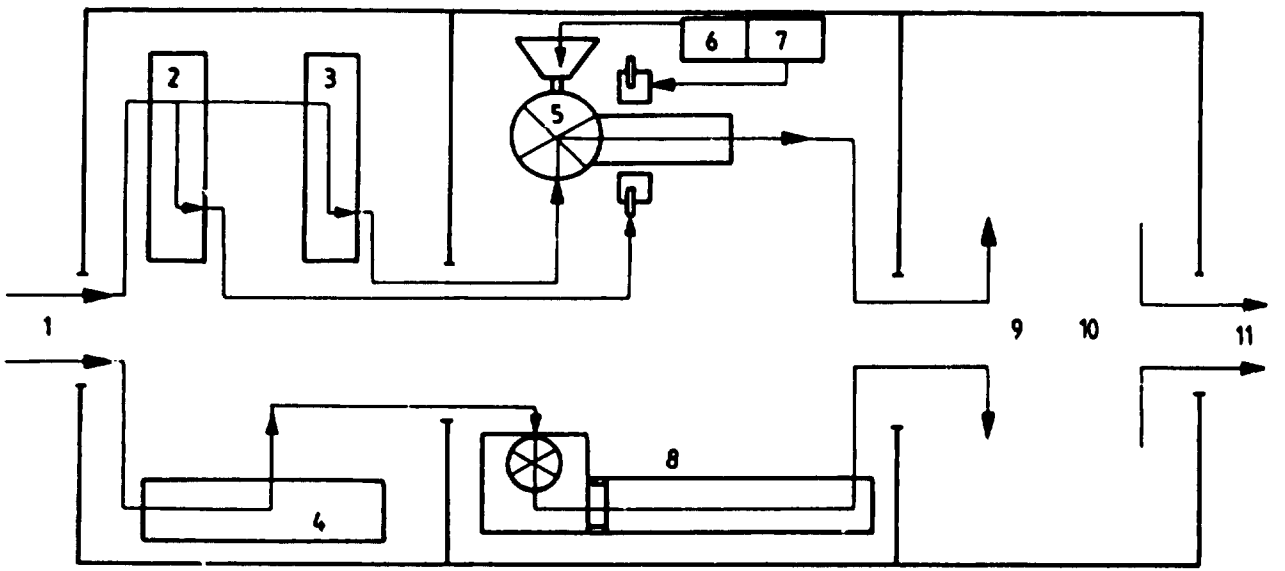
Project	PRODUCTION OF PLASTIC CONTAINERS		
Description			
PRODUCT: plastic fioles/ small containers/ with caps. The cap can be filled with silica gel. Dimensions upon request of the user.			
APPLICATION: pharmaceutical industry, for filling with pils and other substancies, also hygroscopic.			
PRODUCTION PROCESS: the production process consist of input of raw materials, production of fioles and caps, labeling, filling of caps with silicagel, final assembling, quality control and packing.			
Estimated Project Cost	USD	–	
Estimated Technological Plant Cost	USD	60,000	
Capacity in (m,m^2,m^3,t,pcs) per year at 1 Shifts		1,000,000 pcs	
Floor Space (m^2)	Production	100	
	Storage	50	
	Other	50	
N° of Employees		Unskilled	Skilled / Tech.Staff / Other
		10	2 / – / –
Contacting Mode	Enginnering x	Turn – key x	Others ___
Financial Aspects	As agreed		
Ecological Aspects	Clear process		

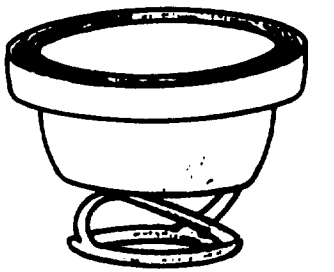
Additional Information

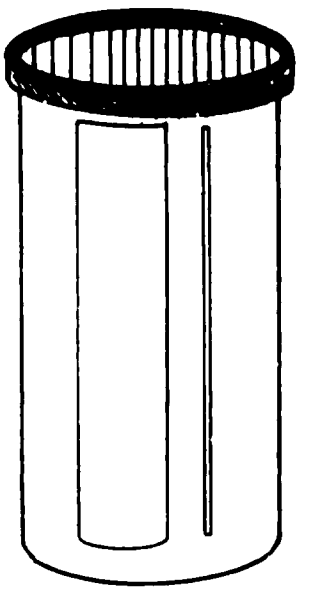
Input materials:
- polyetylene of low density
- polypropylene
- silica gel
- printing ink
- polyetylene rings

Design of the fioles in accordance to the demand of the market.
Original technology.

PRODUCTION OF PLASTIC CONTAINERS







1 - input of raw materials
2 - injection moulding machine
3 - injection moulding machine
4 - injection moulding machine
5 - filling with silica gel and assembling
6 - container with silica gel
7 - container with rings
8 - printing machine
9 - final controle
10 - packing
11 - output of final products

Project	PRODUCTION OF COLLAPSIBLE PLASTIC BOTTLES

Description

PRODUCT: plastic collapsible bottle with cap. Volume up to 250 ml.

APPLICATION: the bottles are suitable for filling with various substances.

PRODUCTION PROCESS: The process includes input of raw material, production of bottles, production of caps and labeling.

The process is suitable for a production of various types and dimensions of bottles.

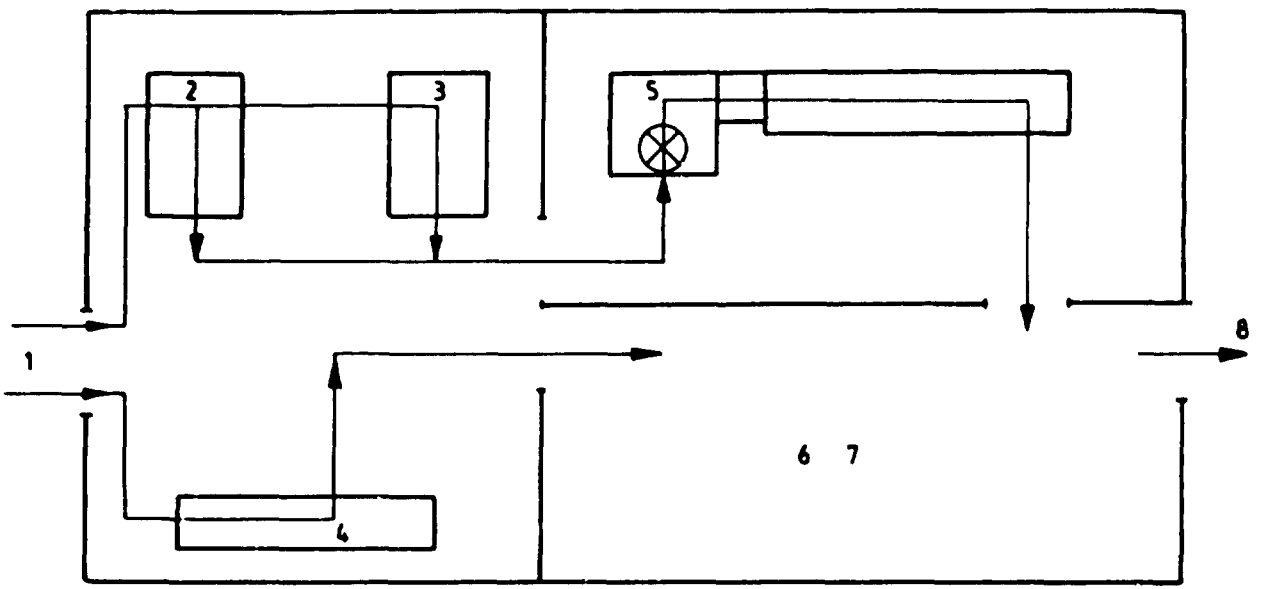
Estimated Project Cost	USD	–			
Estimated Technological Plant Cost	USD	110,000			
Capacity in (m,m^2,m^3,t,pcs) per year at 1 Shifts		1,200,000 pcs			
Floor Space (m^2)	Production	100			
	Storage	50			
	Other	50			
N° of Employees		Unskilled	Skilled	Tech.Staff	Other
		9	1	–	–
Contacting Mode	Enginnering x	Turn-key x	Others x		
Financial Aspects	As agreed				
Ecological Aspects	Clear process				

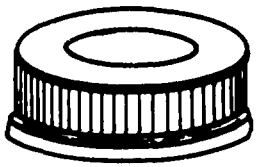
Additional Information

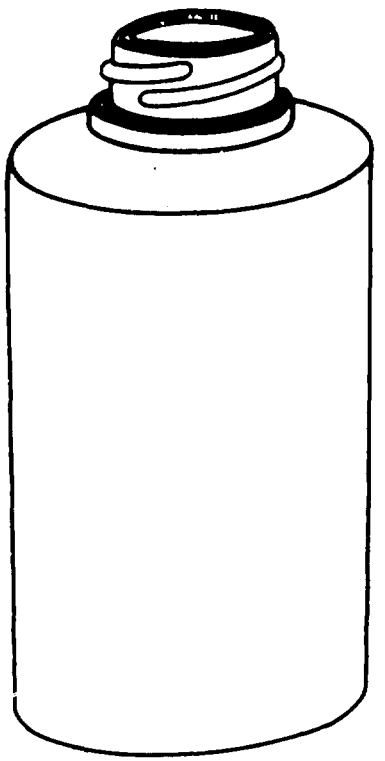
Input material: – polyethylene of high or low density
– polypropylene
– printing ink

The design of the bottle and cap is optional / upon the request of the buyer.
Original technology.

PRODUCTION OF COLLAPSIBLE PLASTIC BOTTLES (LAY OUT)







1 - input raw material
2,3 - blowing machine for the production of plastic bottles
4 - injection moulder
5 - printing machine
6 - quality control
7 - packing
8 - output of final products

Project PRODUCTION AND FILLING LINE FOR SMALL BOTTLES AND JARS

Description

PRODUCT: Small bottles and jars, made of plastic. Production and filling weithout intermediate storage.

APPLICATION: Pharmaceutical and alimentary industry. Filling material are liquids or powder.

PROCESS DESCRIPTION: The production process is complitelly mechanised and consist of the machine for the production of plastic bottles with injection, conveyor, of filling machine with capping and labeling device, of packing machine and sorting on pallets.
The line is suitable for the production of large series, due to the synchronisation of the whole working process.

Estimated Project Cost	USD	1,200,000
Estimated Technological Plant Cost	USD	650,000
Capacity in (m,m^2,m^3,t,pcs) per year at 3 Shifts		12,000,000 - 21,000,000 pcs
Floor Space (m^2)	Production	600
	Storage	400
	Other	300

N° of Employees	Unskilled	Skilled	Tech.Staff	Other
	3	4	1	-

Contacting Mode: Enginnering x Turn-key ___ Others ___

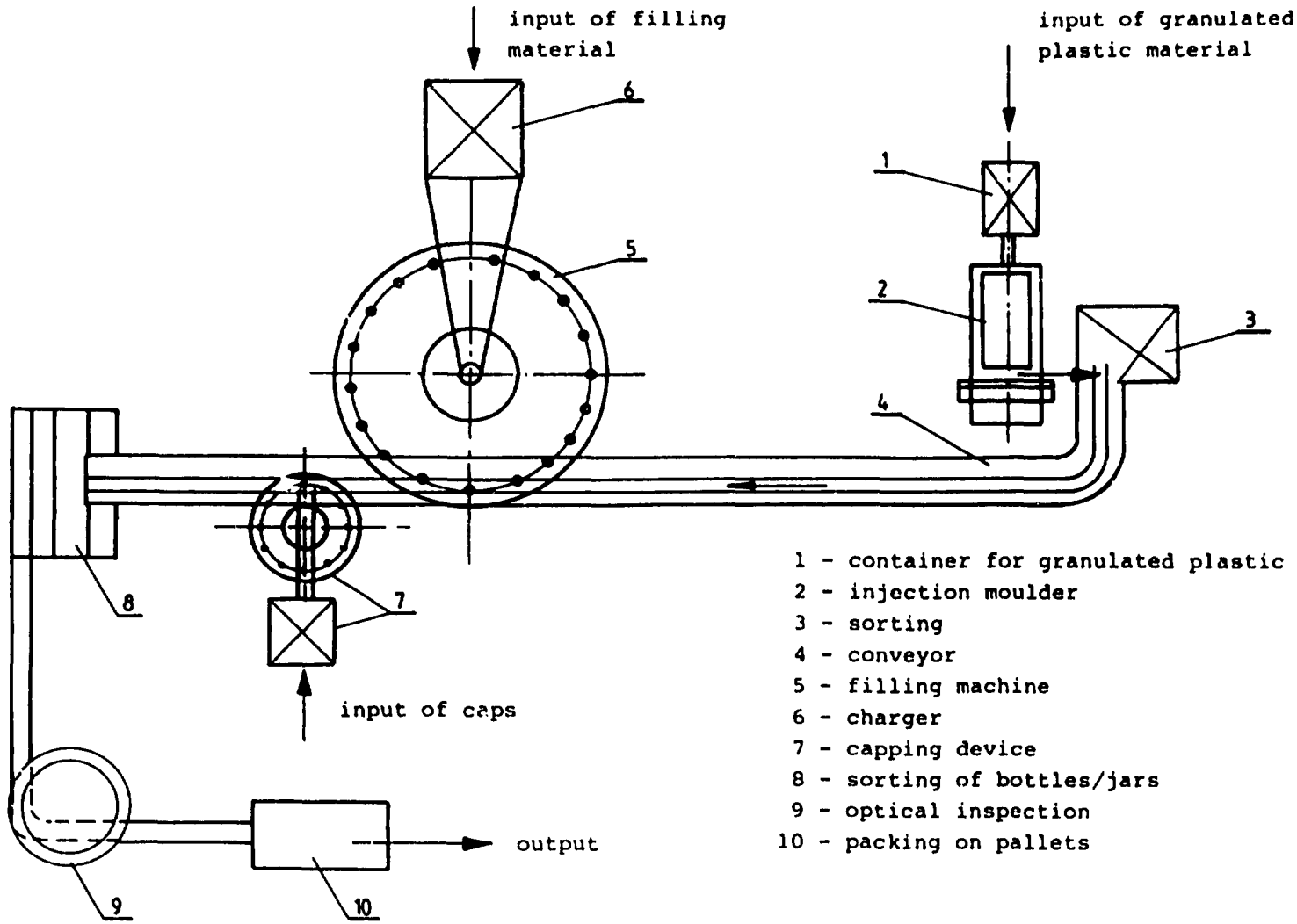
Financial Aspects: As agreed

Ecological Aspects: Clear process

Additional Information

- Input material: various granulated raw material for the production of plastic containers.
- Filling material: liquid or powder.

PRODUCTION AND FILLING LINE FOR SMALL BOTTLES AND JARS



1 - container for granulated plastic material
2 - injection moulder
3 - sorting
4 - conveyor
5 - filling machine
6 - charger
7 - capping device
8 - sorting of bottles/jars
9 - optical inspection
10 - packing on pallets

Project PRODUCTION OF STERILE PAPER BAGS FOR MEDICAL USE

Description

PRODUCT: - sterile paper bags, dimensions min. 90 x 50 x 125 mm
- formatied sterile packing paper, format A1

APPLICATION: protection of sterilized instruments in the medicine

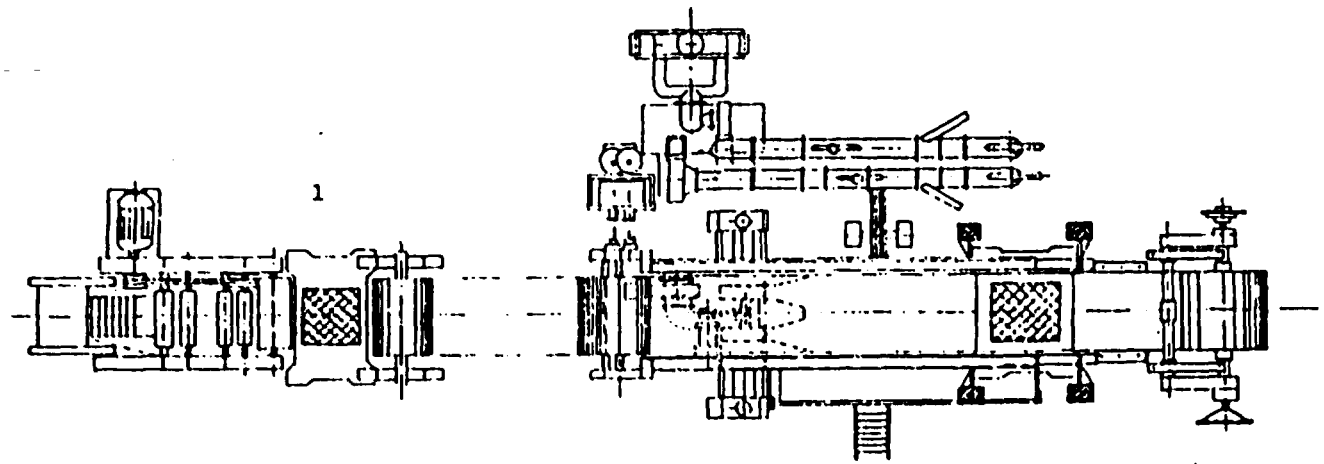
PRODUCTION PROCESS:
- Bags: First the undersite of the paper is coated with thermo sensitive emulsion paste. After drying the top side of the paper is printed with commercial printings, then coated first with indicator colour and finally also with thermo sensitive emulsion paste. On a bag forming machine bags are formed from coated and printed paper. Bags are then packed in boxes, 1000 psc. each.
- Formatized pac'ing paper: Paper in rolls is cut first on roll cutter, then formatized and packed in boxes with 1000 pcs. papers each.

Estimated Project Cost	USD	1,800,000			
Estimated Technological Plant Cost	USD	180,000			
Capacity in (m,m^2,m^3,t,pcs) per year at 2 Shifts		82,000,000 bags and 2,100,000 papers			
Floor Space (m^2)	Production	1,000			
	Storage	500			
	Other	350			
N° of Employees		Unskilled	Skilled	Tech.Staff	Other
		1	5	1	-
Contacting Mode	Enginnering [x]	Turn-key [ ]	Others [x]		
Financial Aspects	As agreed				
Ecological Aspects	Clear process				

Additional Information

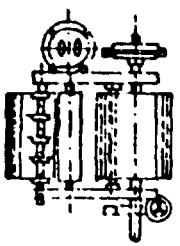
The very long time of drying in the printing machine results in the use of thermosensitive emulsion and indicator colour, that cannot be dried in high temperatures.

PRODUCTION OF STERILE BAGS AND PACKING PAPER



1 - printing machine
2 - basic line for production of bags
3 - longitudinal cutting machine
4 - traverse cutting machine

3



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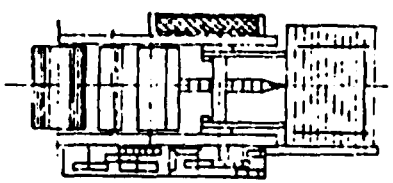

EXPLANATORY NOTES

Profiles for glass-based materials

1. The production of glass packaging for the pharmaceutical industry from glass tubes (see pp. 5 and 6) is a simple and not demanding process. The input is an intermediary product: glass tubes, usually available on the market in all dimensions and qualities. The equipment for processing glass tubes into various types of packaging is available in all industrialized countries; Germany, France, Belgium and USA are the best known suppliers.

Energy

The production is not energy-intensive. Electricity is required for operation of machines and gas propane - butane for melting of the tubes.

Labour

Training facilities are usually available with the supplier of equipment. Training of three to six months is required for semi-skilled workers and one to three years for skilled glass-blowers.

2. This project (see pp. 7 and 8) represents a technology for the production of glass tubes for a wide variety of uses. The production process is fully automated and thus requires highly qualified labour force for its management and specialists in machinery. such as electrical engineers, computer controllers and chemists.

For the purpose of economic efficiency (economies of scale), the production series should be relatively large. The production process requires large quantities of raw materials and it is therefore advisable to locate the plant close to the source of basic inputs. Various types of glass require different ratios between the main components. The following table reflects possible combinations of inputs for various types of glass:

S102	from 68%	to	72.4%
AL203 + T103	4.1		0.35%
Fe03	0.038		0.033
Ca0	10.82		14.40
Cu0	0.0009		0.0005
Na20	16.63		12.50
S03	0.12		0.14

The combination of components depends on the quality required and the purpose for which the glass will be used.

Type of production

Mass production: bottles for penicillin, bottles for various syrups.

Standard production: bottles for liquid pharmaceuticals according to given specifications, colourless or brown colour, and containers for pills and ointments.

Specialized production bottles for blood storage, poisonous liquids or other technically highly complex packaging (high temperature resistant, for example).

Energy requirements

For the production of glass containers electricity is required for machine operation and gas or crude oil as technical fuels.

Economic factors

In addition to the main production facilities the following ancillary facilities are required: unit for preparation of specialized tools, mixture unit, compressor unit, energy supply unit, storage facilities for raw materials, for packaging and for storage of final products. All these units are required if the production process described in the project profile is to work effectively. Experience has shown that economically most viable production is such that specialized production is developed parallel to the mass-production plant.

For an economically effective production the following factors need to be carefully observed:

- size of the end market;
- raw materials availability;
- energy availability;
- availability of sufficiently skilled manpower;
- relatively short transportation: close to the inputs and to the end market;
- environment protection measures, particularly in the mixture unit (dust particles).

Profiles for plastic and paper-based materials

1. The production of plastic packaging (see pp. 9-18) can be performed in two ways: by squirting and by blowing.

For packaging produced by the process of squirting, the granules are warmed up to a specific temperature, then squirted on the specifically prepared set of tools. The products produced this way have their inner surface either flat or slightly conically outwards.

For the blowing process, the basic input are plastic tubes as intermediary products. Such tubes are put into a mould placed on the machine. With hot air the tubes are warmed up and then blown into the desired form. In this way also such types of packaging can be produced that have different shapes on the inside (like bottles, for example). The thickness of the end product is equal to the thickness of the tube used as an input.

The production process is not energy-intensive, except for regular use of electricity for running of the machines; small quantities of propane - butane are used.

The operation of the production process is not demanding (skilled labour), but the machine maintenance requires highly skilled workforce (electric and machine engineers).

The production process is ecologically safe.

2. The project (see pp. 19 and 20) presents the processing of sterile paper into paper bags. For the production process the required input is paper of a specific quality, according to the end use. The presented process is run automatically: cutting, shaping and styling of the bags and even packaging the bags into carton boxes can be done fully automatically.

This production is not energy-intensive and is environment-safe.

The production process requires skilled workers, with specific training by the supplier of the machines . The same applies to maintenance personnel.

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