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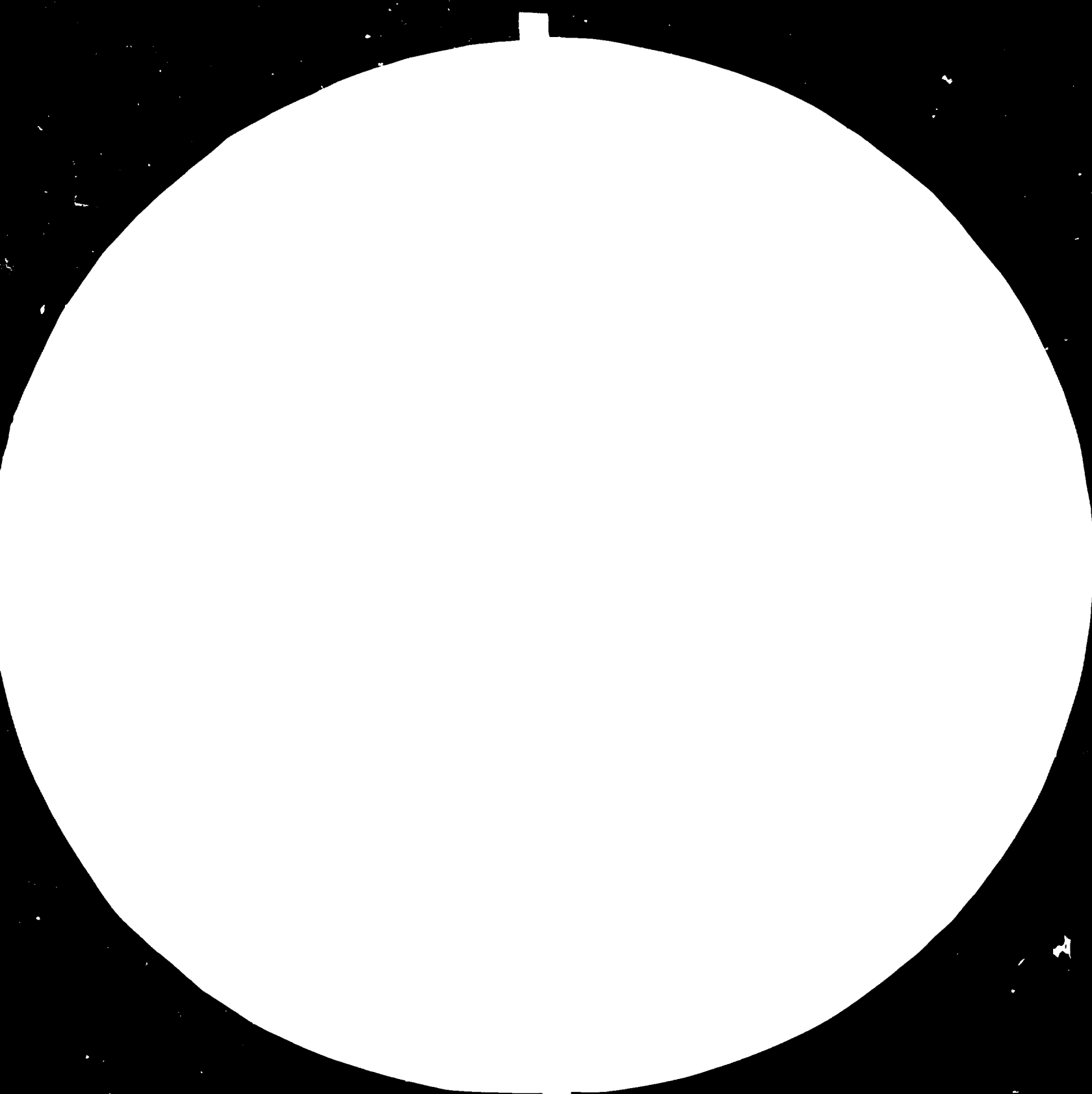
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MICROCOPY RESOLUTION TEST CHART

NATIONAL BUREAU OF STANDARDS
STANDARDS REFERENCE MATERIAL NUMBER
ANSI and ISO TEST CHART No. 2

14383

REPORT OF A

MISSION TO BANGLADESH AND NEPAL (Pharmaceutical industry)

16 SEPTEMBER - 4 OCTOBER 1984

BY

ERICH HORVATH
UNIDO CONSULTANT

3100

1984 E. Horvath

BACKGROUND

(a) Bangladesh

During UNIDO IV, both the Minister of Industry and the Permanent Secretary requested assistance in joint ventures and other investment projects in the pharmaceutical industry, within the framework of follow-up to the Investment Promotion Meeting held in Bangladesh in 1982.

(b) Nepal

As follow-up to the Nepal Investment Promotion Meeting held in June 1984, a general assessment was requested by several Nepalese project sponsors regarding pharmaceutical joint ventures based on medicinal plants, with the objective of becoming independent from imported active ingredients.

(c) Pakistan

During the Nepal Investment Promotion Meeting in June 1984, Mr. Soomro proposed mixed Nepai-Pakistan joint ventures as well as pharmaceutical investment projects in Pakistan and asked for assistance in this respect from the Investment Co-operative Programme. During UNIDO IV, this request was confirmed by the Minister of Industry.

TERMS OF REFERENCE

1. To assist project sponsors in Bangladesh and Pakista. in establishing joint ventures in the pharmaceutical industry.
2. To elaborate project profiles on pharmaceutical projects.
3. To discuss technical and economic details of investment projects which are under consideration by private and public project sponsors in Bangladesh and Pakistan, based on available questionnaires. The work should lead to the setting up of a pharmaceutical plant in Bangladesh and a pharmaceutical plant in Pakistan, each producing a number of pharmaceutical products.
4. To identify cheap sources for the active ingredients for such pharmaceutical products outside normal commercial channels.
5. To identify possibilities to also use medicinal plants for isolating active compounds to be produced by the planned joint ventures.

NEPAL

Nepal's pharmaceutical market is relatively small: NRs 200 million (US\$ 11.75 million equivalent). For this reason, no large transnational pharmaceutical concern operates in the country, which imports almost 90 per cent of its pharmaceuticals from India.

Most of the medicinal plants used for pharmaceuticals are grown in Nepal. Because the country is land-locked, export has proven difficult, and Nepal depends on Indian ports and traders for the bulk of its export transactions.

1. Royal Drugs Ltd., Kathmandu

Local production of pharmaceuticals is to a value of NRs 25 million, of which the share of Royal Drugs Ltd. is NRs 19 million. Its General Manager, Dr. Shrestha, pointed out that the company develops its own products.

The company has modern machinery (purchased with donations from UNICEF), good storage facilities and well trained staff. However, production capacity is low.

Royal Drugs fills 50 million hard gelatin capsules, at an import cost of US\$ 150,000. Compared to the total sales value of about US\$ 1.2 million, this production is unnecessary.

While the company is not interested in obtaining production know-how, it would like to see the creation, with UNIDO's support, of an international raw material "bank" to offer cheap raw materials to producers of pharmaceuticals in developing countries.

2. Department of Medicinal Plants, Kathmandu

The Department of Medicinal Plants is well equipped. Its main function is basic research and development of extracts and essential oils, for which it has a pilot plant.

NEPAL (2)

3. Herbes Production and Processing Company Limited, Kathmandu

The enterprise was established as an offshoot of the Department of Medicinal Plants, with which it works closely. Its activities centre around the production of extracts and essential oils from local medicinal plants to substitute imported synthetic substances and the production and export of expensive extracts or active ingredients from medicinal plants. Because of the high cost of these products, they can be exported by air freight, and do not have to pass through India.

The plant, which was supplied by India, is still under construction and is only partly operational. The technology is outdated, and sensitive substances cannot be processed.

Summary and Recommendations

It is the opinion of the consultant that the establishment of a medicinal plants extraction unit in Nepal would be a viable operation to substitute expensive imports and earn foreign exchange savings through exports. UNIDO should assist in this effort, by locating suitable foreign partners and financing.

Prospects for exporting medicinal plant extracts seem to be good. European firms would be interested in securing a continuous and regular source of supply of extracts, and in return they would probably be willing to supply Nepalese enterprises with the know-how for producing the extracts and active ingredients, as well as to enter into buyback or compensation trade agreements.

MEETING WITH MR. SOOMRO (PAKISTAN)

As Mr. Soomro was unable to meet the consultant in Pakistan, due to an important engagement outside the country, a meeting was arranged at London Airport.

Mr. Soomro is the owner of several businesses in Pakistan and is interested in establishing a pharmaceutical production. To this end, he requested UNIDO's assistance in locating suitable joint venture partners, in the transfer of pharmaceutical production know-how, and, if necessary, in the mobilization of financial resources.

Although Mr. Soomro has sound general commercial experience, he lacks pharmaceutical production know-how and has only a general knowledge of the pharmaceutical market.

While in theory Pakistan's pharmaceutical market is open, in practice it is in the hands of the large transnational companies producing brand name products. There would therefore be large scope for producing generic products, based on imported active ingredients.

The consultant subsequently wrote to Mr. Soomro giving his suggestions for possible market opportunities (Annex I). He requested the entrepreneur to fill in the questionnaires the consultant had drawn up so as to obtain a better overview of the pharmaceutical market in Pakistan and obtain more details of the products Mr. Soomro envisages producing (Annexes II and III). After the consultant has analyzed the completed questionnaires, he will be in a position to provide more concrete advice, including setting up joint ventures and searching for suitable partners.

ANNEX I

Dr. Erich Horvath
Pharmaceutical Consult

Sundgauer Straße 162
1000 Berlin 37
West-Germany

Mr.
Iftikhar Ahmed Soomro
301, 3rd Floor,
Standard Insurance House
I.I. Chundrigar Road

Karachi
Pakistan

22. Oktober 1984

Dear Mr. Soomro,

I refer to our meeting at London Airport and our discussion about production of pharmaceuticals in Pakistan.

Subsequent I visited Bangladesh and Nepal so that I now have some experience and knowledge in this area. Probably the antibiotica market in Pakistan is of particular meaning, too so that it would be indicated to concentrate on this first.

If it is your intention to get a market response with low investment, I suggest following procedure:

1. Setup of a pharmaceutical production for empty hard gelatin capsules and liquids. Both can be packed in glass flasks. No highly trained staff is needed for these two pharmaceutical formulations.
The investment on machines and equipment for a capacity of 40.000 capsules and 200 l liquid per day would amount to less than US \$ 40.000.
2. Complementary the import of tablets, coated tablets in a bulk and their packing in Pakistan.
3. I suggest to concentrate on well-known substances even though generika products were not very successful as you mentioned.
If it is necessary this could be completed. In case of antibiotica through substances of the third generation.

GENERAL INFORMATION ON THE PHARMACEUTICAL MARKET
IN PAKISTAN

1. Total Sales

US\$ _____

Units: _____

2. Market Share

Transnationals: _____ %

Government firms: _____ %

Private firms: _____ %

Imported: _____ %

3. Distribution System

Wholesalers, pharmacies, others

4. Market Situation

Price bonds (maximum retail price)

Yes _____ No _____

Non-prescription:

Doctor's prescription:

INFORMATION ON THE PRODUCT

1. Brand name:

2. Active compound:
Name:
Amount:

3. Formulation:
(Capsules, tablets, coated tablets, liquid)

4. Packing size:

5. Packing material: (Aluminium foil, flasks, plastic tubes)

6. Maximum retail price/ex-factory price:

7. Other products of same formulation on the market:

8. Costs of 7. above:

9. Non-prescription/Doctor's prescription:

For 1.-5., in case you can send samples, you do not need to answer these questions.

BANGLADESH

A. Production of Empty Gelatin Capsules at Pharma Capsules Ltd., Dhaka

Before his departure for Bangladesh, the consultant was provided with a summary of the above project, in which certain discrepancies were evident. While in Bangladesh, the consultant was able to examine the detailed project studies by the Shilpa Bank and UNDP.

The consultant pointed out to Mr. Qureshi, Managing Director of Bangladesh Shilpa RIN Sangstha, that some of the basic project data was incorrect. For example: (a) the project assumed a price per thousand capsules of US\$ 3.50-4.00, whereas the current world market price is US\$ 2.00-2.50; and (b) the cost of an air conditioning system was estimated at US\$ 70,000, whereas a new quotation put this figure at US\$ 534,000. Mr. Qureshi informed that the Shilpa Bank's decision to extend a loan for the project had been based on the former calculations. By his Office Note of 22 September 1984, Mr. Qureshi set up a committee of persons to assist the consultant in re-examining various aspects of the project, particularly its size, price for raw materials, demand for products to be manufactured, technical aspects, and foreign exchange savings expected.

The consultant found that the original project for the production of hard gelatin capsules would not be profitable, nor would it generate foreign exchange savings. His findings and recommendations in this respect are attached at Annex A. (This report has already been mailed to Mr. Qureshi, at his request).

B. The Pharmaceutical Market

In 1982, turnover for pharmaceutical products in Bangladesh was valued at US\$ 70 million (about 35 million units). Of this, imported raw materials accounted for US\$ 20 million. The market is virtually controlled by eight transnational pharmaceutical companies producing locally; they account for 80 per cent of the market. The remaining 20 per cent is made up by a public state company and a small private business. Although Bangladesh's pharmaceutical products are cheap by European standards, a mere 15 per cent of the population can afford them. This situation is compounded by 100 per cent markups by retailers on antibiotics.

BANGLADESH (2)

1. ICI

ICI produces about 2.5 million units per year, through its own production and under licence from Shering (Federal Republic of Germany). Its production meets international standards as regards production area quality, documentation, storage and know-how. However, its machinery is obsolete. Despite relatively low prices for its products, ICI makes a substantial profit, thanks to low marketing costs.

2. EOCO

This state-owned enterprise was founded in 1973. Nine months ago a new, more or less independent management was instituted. The enterprise has an air-conditioned production area of 5,000 m². Most of its machines are modern, bought with donations from UNICEF. Its laboratory equipment is also modern, and meets European standards.

At present the company only sells in bulk to hospitals. Its prices are 50-70 per cent lower than those of the transnationals producing locally.

EOCO produces only 5-10 per cent of forecast output. The consultant estimates that the company could meet the country's entire demand for pharmaceuticals if some additional machinery were installed.

While the company's management is highly qualified, they seem to lack in practical knowledge of pharmaceuticals production and practical experience in quality control, production planning and material flow. For example, active substances are being filled in expensive, imported gelatin capsules, whereas European know-how for processing these substances into tablet form could be applied.

Mr. Holzhausen, UNDP Resident Representative for Bangladesh, visited the company and offered to support it in its efforts to increase efficiency. Whereas the company is interested in acquiring additional equipment and raw material supplies, it does not seem to have an interest in technology transfer or management expertise, although the company would certainly benefit from assistance in these areas.

PHARMA CAPSULES LIMITED

1. Introduction

The consultant does not have the specific know-how of the production of empty hard gelatine capsules, but he has visited different european factories of Pake Davis, Lilly and Scherer.

Being a production manager in Germany, medium sized, pharmaceutical companies (capsules filling capacity of 200 - 300 millions per year) he has an extensive experience in this area.

He knows about enormous difficulties which can be caused by rather insignificant lacks in capsule quality if they are filled on automatic machines.

Thereby he can estimate which sophisticated know-how and experiences are necessary to operate such a production plant. The expertise only examines facts in foreign currencies because costs in local currency (country, building, wages and so on) cannot be judged by the consultant. Therefore is the expectation of profit and loss of this project only an approach which should be specified.

2. Machinery and equipment to be imported:

The costs of investments of the offer made by Capsule Technology Int. Ltd. was compared to the offer by R + J Engineering Corporation to do so the costs were combined in groups. Both machines should be equipped with a set of pinbars for capsule size 1 where as one set of pinbars should be enough for size 0 and 2. (Annex I and II)

The consultant thinks that an airconditioning-system cannot be made available locally for these high specification (temperature 23° C by a allowable deviation of 1° C and by a relative humidity of 30 % RH to 60 % RH; (Prefeasibility studies on gelatine capsules, page 9) and therefore was the complete offer by Pharma Capsules Ltd. taken into consideration.

Annexure - Bangladesh Shilpa Rin Sangstha
Raw Material Costs

Capacity	Total C + F TK '000	Total Costs TK '000
500 mill.	6800	8450
437 mill	5940	7385
375 mill	5100	6338

5. The production capacity of the system in one year

It is relatively difficult to answer this question because both offers name only theoretical figures. The practical information by the Scherer company are made for mashine:
B1 (R+J): 30.000 - 35.000 capsules per hour.
Changing time for another product: 4 hours
Changing time for another capsule size: 2-4 days

277 working days per year should be taken into consideration (Prefeasibility study of gelatine capsules A 6/5).

Say: 260 working days in capsule producing operation.
The consultant suggests in the following calculations to take the possible range of capacity for the third year of operation into consideration.

Version I capacity: 437 mill./year
Version II capacity: 375 mill./year

6. Foreign exchange savings

Version I high capacity
high capsule price
low investment

C + F costs for 437 mill capsules, TK 62.50

Less:

C + F cost of imported raw materials 5.940

Interest on F/C loan (10 %)
(Investment US \$ mill 2.70) 6.750

Depreciation on imported machinery
(10 %) 6.750

19.440

TK in '000s

27.313

19.440

Net foreign exchange savings.

7.873

=====

Version II low capacity
low capsule price
high investment

TK in '000 s

C + F costs for 375 mill capsules, TK 50.00	18.750
Less:	
C + F cost of imported raw materials	5.100
Interest on F/C loan (10 %) of investment US \$ mill 2.90	7.250
Depreciation on imported machinery	<u>7.250</u>
	<u>19.600</u>
Foreign exchange loss.	<u>850</u>

7. Estimation on loss and profit

A loss of TK. 000s 2.000 to 10.000 could be expected.

8. In general

8.1. Size of the project:

The size of the plant is very small and actual only plants with at least 6 to 8 machines are told to be profitable.

This is also noticeable on the high investment which does not depend on the capacity towards the costs of the production machines.

8.2. Climatic conditions

Bangladesh is climatically an unfavourable country for such a project. High investments and high costs of operation are necessary to provide the required production conditions.

8.3. Staff and conditions of production

Even though the mashines are judged technically very complicated it is even more important to have a practical experience with the raw material gelatine to guarantee a smooth production. There are no scientific possibilities to examine the suitability of the natural product gelatine in the laboratory.

The process of production has to be adapted to the raw material. Also it is not possible to examine the quality of the produced capsules in the laboratory, the only way to receive information on that is to have a test on automatic filling machines.

Experts who have such experience are probably not present in Bangladesh. Note: the Indians are not able to compete with multinational companies in price and quality. The necessary three shift operation needs a permanent availability of the staff, raw materials and production utilities. Otherwise high losses of capacity and raw material arise.

Summary:

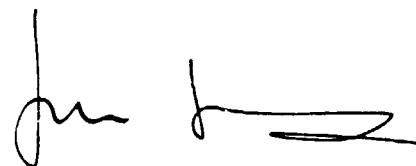
Most of the investment, all the know-how and the raw material have to be imported for realization of the project Pharma Capsules Ltd. The local market is small even though the increase is taken into consideration (it could be compared with 2 to 3 medium sized pharma firms in Germany).

A noticeable foreign exchange saving can only be reached by full-filling following points:

- an optimal production capacity
- world market quality and optimal selling-price.
- saleableness of the produced capsules

The risk is high that these requirements cannot be fulfilled. Expectations of profit can be excluded.

Berlin, 18.10.84



QUOTATION CAPSULE TECHNOLOGY INT. LTD.

1.	<u>Machinery</u>	US \$
1.1.	Two machines CTH-01 including two sets pinbars capsule size 1	1.214.036
1.2.	One set pinbars size 0 " " " size 2	74.100 74.100
1.4.	Two change parts	<u>12.482</u>
		1.374.718
2.	<u>Manufacturing supporting equipment</u>	264.660
	Additional "optional" 2.11, 2.13, 2.19 a	23.780
3.	<u>Spare parts</u>	92.026
4.	<u>Auxilliary Equipment</u>	534.740
5.	<u>Laboratory equipment</u>	24.200
6.	<u>Printing equipment</u>	
7.1.B	Two Markem 156 A MK 2 (Capacity 35.000 capsules per hour, Scherer information)	
6.2.B	Two change over parts	
6.3.B	Two spare parts	
6.5.B	Four print rolls	64.772
7.	Turn-key programm	<u>293.500</u>
	Total	US \$ <u><u>2.672.396</u></u>

QUOTATION R + J ENGINEERING CORPORATION

<u>Machinery</u>	US \$
A) Two machines B1	978.000
B) Two set pinbars size 1 One set pinbars size 0 One set pinbars size 2	<u>380.000</u>
	1.358.000
<u>Manufacturing supporting equipment</u>	
C) D) E) (production room) A) B) C) E) F) (melting room) A) (inspection room)	239.140
<u>Spare parts</u>	65.960
<u>Auxilliary Equipment</u> (Quotation Capsule Techn. Int. Ltd.)	534.740
<u>Laboratory Equipment</u>	38.400
<u>Printing Equipment</u>	
A), Two feed disc, one upper intk reservoir six gravure rolls (printing room)	71.560
<u>Turn-key programm</u>	<u>240.000</u>
Total	US \$ <u><u><u>2.547.800</u></u></u>

PHARMA CAPSULES LIMITED

DETAILS OF RAW MATERIALS AT 100% CAPACITY UTILIZATION

Item of Raw Materials	Total Quantity	Unit C&F cost	Total C&F cost	Customs duty (20%)	(Tk. in '000s)	
					Other cost	Total cost
A. IMPORTED						
Gelatine (P.grade)	60,000 kg	Tk. 110/kg	6600	1320	300	8220
Preservatives	300 kg	Tk. 94/kg	28	6	2	36
Oplacent additives	1,200 kg	Tk. 87/kg	104	21	5	130
Dyes	400 kg	Tk. 94/kg	38	8	3	49
			<u>6770</u>			<u>8450</u>
		Say	6800		Say	8450

B. LOCAL: Nil

The total C&F cost of imported raw materials is Tk.6.800 million which is about 80.5% of the total raw materials cost of Tk.8.450 million.

