

Minutes of the 110th meeting of the Drug Control  
Committee held on 2.10.85

The 110th meeting of the Drug Control Committee was held on 2.10.85 at 11.30 a.m. in the chamber of Director, Drug Administration. In the absence of Prof. Waliullah, the chairman of the Drug Control Committee, Prof. A. Jabbar presided over the meeting.

The following members attended the meeting:

Dr. Munawara Binte Rahman  
Dr. Humayun K.M.A. Hye

Dr. Md. Jahangir, Dy. Director, Drug Administration attended the meeting as an observer.

Proceedings & Decisions

1. The minutes of the 109th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting:  
While discussing about the standard formula of the B-complex tablet & capsule as decided by the Committee it was further decided that a standard formula should be set for Multivitamin drops.
3. The following recipe which was submitted in place of Codeine was considered and decision taken as described below:

<u>Firm/Brand</u>	<u>Remark/Decision</u>
<u>Jayson, Dhaka</u> Codinol syrup (pholcodine 0.1%)	Approved with condition to change name to generic, delete overage, delete tatrazine & sunset yellow colour, change pack size to 100ml, specify indication as 'antitussive' only, delete the children dose & declare the warning 'not for children' on label, carton, etc; alternate colour may be allowed by the DDA.

4. The following recipes of import substitute drugs were placed and discussed:

<u>Square, Dhaka</u> Rantid tab (ranitidine 150mg)	Approved with condition to change name.
Perkimet tab Llevodopa 250mg + carbidopa 27mg)	Approved.
Dipantin tab (dipyridamole 50mg)	Approved.
<u>Peoples Pharma, Dhaka</u> Vasodil tab (dipyridamole 50mg)	Approved.
<u>Beximco, Dhaka</u> Ranitidine tab 150mg	Approved.

5. The following ~~xxxx~~ other recipes were placed and considered:

- Opsonin, Barisal
- a) Metocol inj  
(metoclopramide HCl)
  - b) Opsovit inj  
(vitamin B-complex)
- It appears from the previous inspection report that Opsonin has elaborate arrangement for manufacturing various types of drugs but there was no specific report about facilities in respect of production and quality control of sterile preparations. In view of this it was suggested that an inspection should be carried out by Prof. A. Jabbar along with one or more officers of the Drug Admn. to ascertain their facilities in respect of production and quality control of biological parenteral preparations.  
The decision regarding these products may be kept pending the inspection report is available.

The meeting ended with a vote of thanks to the chair.

*Confused*  
*M. Jabbar*  
9.10.85

The 111th meeting of the Drug Control Committee was held on 9.10.85 at 11.30 a.m. in the chamber of the Director, Drug Administration. In absence of the Chairman, Prof. A. Jabbar presided over the meeting. The following other members attended the meeting:

Prof. Syeda Feroza Begum  
Prof. Mofazzal Hossain  
Brig. Anis Waiz  
Mr. Kazi Abdul Fattah  
Dr. Humayun K.M.A. Hye

Dr. Md. Jahangir, Dy. Director, Drug Administration attended the meeting as an observer.

Proceedings & Decisions

1. The minutes of the 110th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting:  
While discussing about the inspection of M/s. Opsonin, Barisal, it was decided that Brig. Anis Waiz will accompany Prof. A. Jabbar to inspect the firm to assess their facilities for production and quality control of parenteral preparations.
3. The original copies of the clinical and pharmacological papers of Reprosmin (reproterol) tablet, syrup & injection and Xipamexan (xipamide) tablet of Fisons, submitted by the firm as desired by the DCC, were referred to Prof. Mofazzal Hossain for opinion.
4. The following recipes were placed and decisions taken are described below:

Delta Pharma, Dinajpur  
Kidicee liquid drop  
(ascorbic acid 50mg/ml)

Drug Intl., Dhaka  
Cloxpen drop  
(cloxacillin 100mg/ml)

Scientific Drug, Dhaka  
Enox nasal drop  
(ephedrine HCl 0.5%)

Medicon, Dhaka  
Mexacil cap  
(amoxycillin 250mg)

Mexacil paed. dry syrup  
(amoxycillin 125mg/5ml)

Ambee, Dhaka  
Amfuron tab  
(nitrofurantoin)

Beximco, Dhaka  
Isoprinosine tab & syrup

Decisions  
*Withdrew for consideration*  
Rejected because such preparation is not required as enough is available in market

Approved with condition to give proper specification for colour & flavour.

Rejected due to lack of proper manufacturing facilities.

Approved with condition to change name and subject to availability of facilities

-do-

Rejected because not required any more.  
*No further application will be at the moment as the preparation will be discontinued by the firm.*  
Kept pending for original clinical & pharmacological papers and *information reg* ~~free sale~~ *certificates from three countries.*

*Waiz*  
*18/10/85*

<u>KOH Lab., Dhaka</u> Sedinol/Sedanol tab (nitrazepam 5mg)	Approved with condition to change name.
Calvee tab (calcium pantothenate 10mg)	Approved with condition to change indication as 'in the deficiency state of pantothenic acid' only.
<u>Asiatic Lab., Dhaka</u> Syrup Pot. Guaiacol Sulph. 2.5%	Approved with condition to give name in generic only, deletion of liquorice liquid extract, and change indication as 'anti-tussive' only,
Syrup Pholcodine 0.1%	Kept pending because the firm has been allowed another cough preparation.

5. The following recipes for import registration, which are included in the essential/specialised drug list, were placed and decisions taken are described below:

<u>Lek, Yugoslavia</u> Genta-Lek ophthalmic drop (gentamicin) 0.3%	Approved.
<u>Unique Pharma, India</u> Nicardia cap (nifedipine) 3/4	Rejected, registration has been given to local companies for nifedipine.
<u>Serotherapeutics Inst., Austria</u> Immun serum globulin 16%	Approved.
Tetanus vaccine	Rejected, locally available
Diphtheria & Tetanus vaccine	Rejected, not required. approved 16/10/75
Diphtheria, Tetanus & Pertusis vaccine	Approved.
<u>Shanghai Surg. Dressing Fact., China</u> Snowflake brand Plaster of Paris bandage	Sample to be referred to Prof. Anisuddin Ahmed, Professor of Surgery, Mitford Hospital, Dhaka for opinion.
<u>Sanghai Sanitary Mat. Fact., China</u> Snowflake brand Zinc oxide adhesive plaster	-do-
<u>Jhonson &amp; Jhonson, India</u> Velroc brand Plaster of Paris bandage BPC	-do-
<u>Renmin Pharma, China</u> Streptomycin sulphate inj 1g/vial	Rejected, local brands available
2% Dextrose inj	Rejected,
<u>Shanghai Pharma, China</u> 25% Dextrose inj	Rejected, enough available
<u>Pharmachemie, Holland</u> Inj Metypresol (methyl prednisolone sodium succinate) 125mg, 500mg, 1000mg, & 2000mg	Approved,
Inj Hydrocortisone 100mg & 500mg	Approved.
Inj Curalest 50mg/ml (suxamethonium chloride)	Approved.
<u>Shanghai Pharma, China</u> Vincristine sulphate inj	Approved.
Amnophylline inj 250mg	Approved.
Fluorouracil inj 250mg	Approved.

*Wahid*  
16/10/75

Tubilux Pharma, Italy  
Omatropina 2% eye drop  
(homatropine HCl)

Approved.

ICI, UK  
Tenormin Inj 0.5mg/ml  
(atenolol)

Approved. In this connection it was decided that M/s ICI Bangladesh Manufacturers and M/s Squibb of Bangladesh Ltd. be requested to develop manufacturing facilities for parenteral preparations within one year.

Krka, Yugoslavia  
Tetracycline skin oint 3%

Rejected. *Locally available*

Boehringer C.H., West Germany  
Persantin tab 100mg  
(dipyridamole)

Approved.

6. Miscellaneous:

- a) In the 105th meeting of the DCC held on 21.8.85 the recipe of Sulphanilamide Powder BPC of Standard Chemical, Dhaka was rejected with reason that such drug is not required. It was further decided that registration of all similar existing items be cancelled as well. It was observed that Sulphanilamide powder is included in the approved essential drug list. Therefore, <sup>actions under</sup> the earlier decisions were kept pending.
- b) In the 40th meeting of the DCC held on 2.10.83, Gentamicin inj of Unique Pharma, India was recommended to be registered for import, which is now under process of registration. DCC reviewed the said decision on the ground that Gentamicin inj is adequately manufactured locally, and decided that new import registration is not necessary any more. Their earlier decision of approving Gentamicin inj of Unique Pharma, India was revoked.
- c) TungHai Brand Fish Liver Oil emulsion and Dashui brand Fish Liver Oil emulsion of China were earlier recommended by the DCC for import registration. While processing their registration it was found that the label & carton of both the products have similar design and colour with difference in the name and monogram only. The matter was placed before the DCC for opinion and <sup>The DCC observed</sup> that registration of the items may be given with the <sup>existing</sup> ~~applied~~ label and carton.
- d) It was observed that Ancoloxin tab of Glaxo contain ~~M~~eclozine HCl and Pyridoxine HCl as active ingredients, ~~and~~ in general, combinations are discouraged under the National Drug Policy. The matter was referred to the DCC for opinion. DCC referred the case to Prof. Syeda Feroza Begum for opinion as to whether Pyridoxine HCl is required in this product.

contd.... p/4

*Waller*  
*16/8/85*

- ✓ e) The Committee decided to advise all manufacturers to produce locally <sup>by 2008</sup> all those items which are being imported in finished form <sup>has</sup> in spite of the same company having a factory and facilities <sup>manufacturing</sup> in Bangladesh. This decision was made in the light of representation for S.K.F. Employees. ~~by failing to~~ <sup>which</sup> ~~was~~ <sup>may</sup> ~~the~~ <sup>be</sup> ~~registration~~ <sup>can</sup> ~~of the~~ <sup>collected</sup> ~~products~~ <sup>may</sup> ~~may~~ <sup>be</sup> ~~be~~ <sup>collected</sup>.
- ✓ f) A report of the action taken about sub-standard market samples <sup>was</sup> during the months of July, August & September, 1985 was placed before the committee for information.

The meeting ended with a vote of thanks to the chair.

*Walla*  
16.10.85

Working Papers

Miscellaneous

Agenda 6 (a) ✓

In the 105th meeting of Drug Control Committee held on 21-8-85 recipe of ' Sulphanilamide powder BPC' of Standard Chemical, Dhaka was cancelled with reason that such drug is not required. It was further decided that all existing similar items to be cancelled.

But it is observed that the drug is included in our essential drug list, Submitted for review of the decision.

*may panel  
22.10.85*

Agenda 6 (b) ✓

In the 40th meeting of Drug Control Committee held on 2/10/83, Cortinid inj. of Unique Pharma, India was recommended to be registered for import. The item is now under process of registration. Submitted for review of the earlier decision in light that now we have adequate local substitute of the item.

*on further consideration  
is decided that the  
product is not necessary  
22.10.85*

Minutes of the 112th meeting of the Drug Control Committee held on 16.10.85

The 112th meeting of the Drug Control Committee was held on 16.10.85 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Professor Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Prof. A. Jabbar  
Prof. Mofazzal Hossain  
Brig. Anis Waiz  
Prof. M.Q.K. Talukder  
Dr. Humayun K.M.A. Hye

Dr. Md. Jahangir, Dy. Director, Drug Administration attended the meeting as an observer.

Proceedings & Decisions

1. The minutes of the 111th meeting were confirmed.
2. The following resubmitted recipes were placed and decision taken are described below:

<u>Firms/ Brands</u>	<u>Decision</u>
<u>Pharmadesh, Dhaka</u> Pholcodine syrup 0.1%	Approved with condition to delete children dosage, overage, and excipients such as, colour Supra Tartrazine, Supra Amaranth & Chloroform Spirit. Allowed to market in 100ml pack size with indication as 'antitussive' and contra-indication as 'not for children's use'.
<u>Pfizer, Dhaka</u> Combantrin chewable tablet 125mg & 250mg (pyrantel pamoate)	Approved in place of existing tablet form.
<u>Pacific, Dhaka</u> Dextromethorphan HBr syrup 0.2%	Approved.

3. The following recipes of import substituted drugs were placed and decisions taken are as follows:

<u>Seema, Dhaka</u> Rantin tablet (ranitidine HCl 150mg)	Approved.
<u>Opsonin, Barisal</u> Opsodrin tablet (procyclidine HCl 5mg)	Approved.

contd...../2

Approved  
Waliullah  
6/10/85

K.D.H. Lab., Dhaka

- a) Sinozol nasal drop (xylometazoline HCl 0.1%) Approved with condition to market in sealed semi-sterile container.
- b) Diofen tablet (diclofenac sodium 25mg) Approved.

Jayson, Dhaka

- Dixicon capsule (nalidixic acid 500mg) Approved.

Sheba Chemical, Dhaka

- a) Sacarin tablet (saccharin sodium 12.5mg) Approved with condition to change name as generic.
- b) Cardinate tablet (verapamil HCl 40mg) Approved.
- c) Cardinate tablet (verapamil HCl 80mg) Approved.
- d) Cardinate tablet (verapamil HCl 120mg) Rejected because such strength is not necessary.

Opsonin, Barisal

- a) Verine tablet (verapamil HCl 40mg) Approved.
- b) Verine tablet (verapamil HCl 80mg) Approved.
- c) Verine injection (verapamil HCl 5mg/2ml ampoule) Approved.

name may be changed  
W

The meeting ended with a vote of thanks to the chair.

approved,  
Wallas  
4/11/85

Minutes of the 113th meeting of the Drug Control  
Committee held on 6.11.85

The 113th meeting of the Drug Control Committee was held on 6.11.85 at 10.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Professor Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Prof. A. Jabbar  
Prof. Syeda Feroza Begum  
Prof. A.T. Siddique  
Prof. Mofazzal Hossain  
Brig. Anis Waiz  
Prof. M.Q.K. Talukder  
Dr. Humayun K.M.A. Hye

Dr. Md. Jahangir, Dy. Director, Drug Administration attended the meeting as an observer.

Proceeding & Decisions

1. The minutes of the 112th meeting were confirmed.

2. Matters arising out of the minutes of the last meeting.

While confirming the minutes regarding the approval of the recipes of Cardinate tablet (verapamil) 40 & 80mg of M/s. Sheba Chemical, Dhaka, it was decided that the firm may be asked to change the brand name of the product.

3. The following recipes which were kept pending for inspection report were placed and decision taken are as described below:

Firms/Brands

Decisions

Bengal Research, Barisal

DcRex cap  
(doxycycline 100mg)

Rejected because the firm does not have biological licence.

Cimedine tab  
(cimetidine 200mg)

Approved.

Ilozyme cap  
(pancreatin 325mg)

Rejected because inspection report does not support availability of facilities for production & quality control of the item in the firm.

4. The following other recipes were placed and decisions taken are described below:

Skylab, Comilla

Hydrotalcite tab

Rejected because not considered necessary.

Hydrotalcite susp

-do-

Amoxycillin cap 250mg

Approved.

Riboflavine tab 5mg

Approved.

Therapeutics, Chittagong

Riboflavine tab 5mg

Approved.

Furantin tab  
(nitrofurantoin 100mg)

Rejected because not required anymore.

contd....2

*Waliullah*  
*13/11/85*

Wee Pharma, Dhaka

Amoxin/Amoxil dry syrup  
(amoxycillin 2.5g/100ml)

Approved with condition to change name, delete colour amaranth, give proper specification for orange flavour, and change indication as per BNF.

Ibne Sina, Dhaka

Sinamide cap  
(loperamide 2mg)

Kept pending till manufacturing licence is issued to the firm.

Beximco, Dhaka

Stopain inj  
(pentazocine 3%)

Approved.

Vitamin B-complex inj  
10ml vial

Approved with condition to justify the use and dosage of lignocaine. *Wahid*

Albert David, Dhaka

Aldalin inj  
(amoxycillin 500mg)

Kept pending for inspection report.

Fisons, Dhaka

Pilactazide tab  
(spironolactone 25mg +  
chlorthiazide 25mg)

Kept pending for papers regarding justification of the combination and evidence about availability of the drug in other countries.

Pancreatin tab 325mg

Approved provided coating is done locally and specification of the excipients is adjusted as per BP/USP.

5. The committee reviewed the following recipe which was rejected earlier on the ground of adequate availability and approved the same observing that at present only one syrup & two drops form of the drug are available.

Delta Pharma, Dinajpur

Kidicee drops 15ml  
(ascorbic acid 50mg/ml)

Approved with condition to change name.

6. The committee considered the review application of Acme, Dhaka for the recipe of Acmezyme cap (pancrelipase) and decided as given below.

Acme, Dhaka

Acmezyme cap  
(pancrelipase 300mg)

*x recommended because of low potency the BP*

The active ingredient 'pancrelipase' is not acceptable. However, the firm may resubmit the recipe after changing the active ingredient to Pancreatin BP80 325mg. *WV*

7. The committee revalidated the following recipe which was approved before the National Drug Policy.

Zaman Pharm., Dhaka

Calciate tab  
(calcium pantothenate)  
*50mg*

Approved with condition to change indication as 'in pantothenic acid deficiency only'.

8. Prayer for import registration of the following recipes were placed and discussed. Decisions taken are as mentioned below.

Les Lab. Servier, France

Diamicron tab (gliclazide 0.08g)

Approved.

Natrilix tab (indapamide 2.5mg)

Rejected because not considered necessary.

LEK, Yugoslavia

Dexa-Lek ophthalmic soln  
(dexamethasone 1mg/ml)

Rejected because locally manufactured substitute available.

*Wahid*  
*12/11/95*

Ashford Lab., Hongkong

Rif cap (rifampicin 150mg) Rejected because locally manufactured substitute available.

Rif cap ( -do- 300mg) -do-

Cloxacillin inj 500mg -do-

Neocillin inj (ampicillin 250mg & 500mg) -do-

Continental Pharma, Belgium

Bufexine inj (bufexamac) Rejected because not considered necessary.

Industria Farmaceutica, Italy

Profasi inj (chorionic gonadotrophin) Approved.  
500 i.u., 1000 i.u., 2000 i.u., 5000 i.u.

Tsingtao Factory, China

Double whale brand fish liver oil emulsion Rejected because not considered necessary

Double whale brand fish liver oil cap -do- *any more W?*  
(vit A 4500 i.u. + vit D 450 i.u.)

Smith & Nephew, UK

Flamazine cream The committee reviewed their earlier decision of cancellation of registration of this item and approved re-registration of the same.  
(silver sulphadiazine 1%w/w)

Medimpex, Hungary

Isolanid tab (lanatosidum 0.25mg) Rejected because such drug may be prepared by the firm in their local factory. May apply for local prodn.

Isolanid inj (deslanatoside) -do-

Hormofort inj (hydroxy progesterone caproate 250mg/2ml) Referred to Prof. Syeda Feroza Begum for opinion.

Norcolut tab (norethisterone 5mg) -do-

Johnson & Johnson, India

Band Aid brand medicated dressing Approved.  
mercurochrome adhesive bandage

Johnsonplast brand adhesive bandage Approved.  
Zinc oxide adhesive bandage USP

May & Baker, UK

Anaesthetic ether BP 100% Approved.

Pharmachemie, Holland

Tamoplex tab (tamoxifen 10mg) Approved.

Basolest tab (carbimazole 5mg) Approved.

Cebralest tab (dihydroergotoxin mesylate 1.5mg) Referred to Prof. Syeda Feroza Begum for opinion.

Ciba-Geigy, Switzerland

Rengasil cap 200mg & 400mg (pirprofen) Approved.

Rengasil inj 400mg/4ml (pirprofen) Approved.

Krka, Yugoslavia

Oracef susp (cephalexin) Rejected because locally manufactured substitute available.

Oracef cap 250mg & 500mg -do-

Diazepam inj 10mg/2ml -do-

Erazon cap (piroxicam 10mg) -do-

contd....4

*W. S. 13/11*

Asta Werke, West Germany

Uromitexan inj 100mg, 200mg & 400mg Approved.  
(oxazophosporial)

LEK, Yugoslavia

Nelit (ORS) powder Rejected because local substitute available.

Hoechst, West Germany

Claforan inj 0.25g, 0.5g, 1.0g & 2.0g (cefatoxime) Rejected because the firm has facilities to manufacture the items locally. May apply for local production.

R.P. Scherer, Australia

Vitamin E 100mg cap Rejected because not considered necessary. *any*

Vitamin A cap 50000 iu Rejected because local substitute available. *not considered necessary*

Burroughs Wellcome, UK

Zovirax cream (acyclovir 5%) Approved. *any more*

Leo, Denmark

Selexid inj 400mg (pivmecillinum) Approved.

Heparin inj 5000 iu/ml Approved.

Otsuka, Japan

Potassium chloride inj 7.46% w/v Approved.

Arteoptic eye drops 1% & 2% in 5ml Referred to Prof. A.Q.M.S. Harun for opinion.  
(carteolol HCl)

Smith & Nephew, UK

Airstrep post operative & casualty dressing sterile non adherant pad Referred to Prof. A.T. Siddique for opinion.

Jelonet guaze dressing (white soft paraffin sterile) -do-

Bactigras guage dressing (chlorhexidine 0.5% sterile) -do-

Melolin dry non adherant dressing -do-

Opsite spray dressing -do-

Opsite dressing (polyurethane membrane) -do-

9. Miscellaneous.

a) The representation of Bangladesh Aushad Shilpa Samity dated 23.9.85 addressed to the Chairman, Drug Control Committee was discussed. The committee gave a sympathetic consideration to the prayer and observed that due care is always given while evaluating the recipes for approval, and only unnecessary ingredients are deleted from the composition. It was further observed that in specific cases, the concerned firm is quite at liberty to send their pharmacist to defend their composition. It was decided that a reply to this context may be sent to them.

b) The committee observed that reversible mental confusion <sup>adverse effect of</sup> has been reported as an adverse effect in different countries. In view of this, it was decided that similar warning may be included in the inserts & literatures of locally available ranitidine preparations. *WZ*

c) It has been reported in different countries that caution is needed in patients with adrenocortical insufficiency during rifampicin treatment because an adrenal crisis may be induced. In view of this, the committee decided that such caution should appear in the inserts & literatures of locally available rifampicin preparations.

contd....5

*Walls*  
*13/11/85*

The committee observed that US FDA and several other countries have revised the data sheet of Pyrimethamine plus sulphadoxine tablet because of reports of severe cutaneous reactions associated in some cases with fatalities and other adverse reactions including serum sickness, exfoliative dermatitis, urticaria and hepatitis. In view of this, the committee decided that the following information should be included in the inserts & literatures of locally available pyrimethamine-sulphadoxine preparations.

Warnings: Fatalities associated with the administration of Pyrimethamine plus sulphadoxine preparations may occur due to severe reactions, including Stevens-Johnson syndrome and toxic epidermal necrosis. The prophylactic use of the drug should be discontinued at the first appearance of skin rash, if a significant reduction in the count of any formed blood elements is noted, or upon the occurrence of active bacterial or fungal infections of skin.

Contra-indications: Prophylactic (repeated) use of the drug is contra-indicated in patients with severe renal insufficiency, marked liver parenchymal damage or blood dyscrasias.

Precautions: Drug interactions: There have been reports which may indicate an increase in incidence and severity of adverse reactions when chloroquine is used with the drug as compared to the use of the drug alone."

It was observed that Drug International, Dhaka was earlier allowed the brand name 'VeeCe' for their vitamin C tablet which was very similar to that of 'Veecee' tablet of Squibb, Dhaka and which has been banned under the National Drug Policy. It was decided by the committee that Drug International, Dhaka will be asked to change the brand name.

Recipe of Inflamm 400 (ibuprofen 400mg) tablet was earlier allowed to Fisons, Dhaka. The matter was placed before the committee for opinion as to the requirement of such strength. After discussion it was opined by the committee that the 400mg strength of the drug ibuprofen may continue.

The Director, Drug Administration sent a proposal to the Ministry of Health & Population Control for the revision/modification of the approved Essential Drug List. The Ministry through their memo S-DA/D-37/85/726 dated 10.10.85 has referred the matter to the Drug Control Committee for their examination of the List and send their decision to the Ministry for taking further necessary action in the matter. The committee decided that the matter will be discussed in a special meeting to be held in some convenient time during the middle of December 1985.

Medimpex, Hungary was asked to show cause for importing ATS injection (tetanus antitoxin) 1500 i.u. which has been banned under the Drug Policy as determined from certain evidence. A reply to this effect was received from the Hungarian Embassy denying any such import of Tetanus antitoxin 1500 i.u. This was placed before the committee for information and opinion.

The committee advised to ask Medimpex to explain under what circumstances they have taken up the case at a diplomatic level.

The meeting ended with a vote of thanks to the chair.

*Waller*  
17/11/85

Square, Babna

Doxacil-50 cap  
(doxycycline)

Rejected because not required in this strength.

B-50 Forte High Potency inj

Approved with condition to omit the word 'High Potency'.

Betameson oint  
(betamethasone dipropionate 0.1%)

Approved with condition to delete indication other than 'Inflammation of corticosteroid responsive dermatoses.'

Betameson cream 0.1%

-do-

Betameson tab 0.5mg  
(betamethasone sodium phosphate)

Approved with condition to mention indication as per BNF.

Beximco, Dhaka

Cephalen powder for susp  
(cephalexin 2.5%)

Approved with condition to delete sodium benzoate and FDC Yellow No. 6 from excipients. Alternate colour may be approved by DDA.

Opsonin, Barisal

Trimin inj 100mg/~~m~~5ml  
(trimethoprim)

Rejected because not considered required and essential for our country.

Trimin inj 200mg/2ml

-do-

Purbadesh, Comilla

Milk of Magnesia

Rejected because the formula is not as per BPC.

Fisons, Dhaka

Tolectin DS 400 cap  
(tolmetin)

Approved.

Drug Intl., Dhaka

Theovent cap 300mg  
(theophylline enteric granules)

Approved with condition to use theophylline in sustained release granular form. There is no justification in using the drug in enteric coated form. Indication to be 'in bronchial asthma and as broncho-dilator'.

National, Dhaka

Minocin cap 100mg  
(minocycline)

Rejected because not considered required and essential for our country.

Acme, Dhaka

Chendole cap 250mg  
(chenodeoxycholic acid)

Rejected because not considered required and essential for our country.

Pharmachemie, Dhaka

Manorub oint  
(vaporub)

Approved with condition to change name and indication to be 'as counter irritant in aches and pains' only.

Therapeutics, Ctg.

Dextromethorphan syrup

Approved with condition to change strength to 0.2%.

Pholcodine syrup 0.1%

Rejected because only one cough syrup will be allowed to a firm.

Isoaminile syrup 0.3%

-do-

Potassium guaicol sulphonate syrup

-do-

Chloramex susp 2.5%  
(chloramphenicol)

Approved with condition to change name and deletion of 'chronic infection of urinary tract' from indication.

contd....3

Approved  
Walla  
28/11/85

Peoples Pharma, Dhaka

Diloxon tab 500mg  
(diloxanide furoate)  
Diloxon susp 200mg/5ml

Approved.

Hyponol tab 50mg  
(alenoalol)

Approved with condition to give Purified Water ~~BP~~ to 100ml as diluent.

Nitrocin oint 0.2%  
(nitrofurazone)

Rejected because no such drug is known.

Approved.

Fisons, Dhaka

Gyno-Pevaryl 150  
vaginal tab  
(econazole nitrate 150mg)

Approved. The firm to clarify the use of Cilag brand as own product. *before licensing.*

Standard Chem., Dhaka

Scidex oint  
(iodine 4% + Methyl salicylate 5%)

Approved with condition to delete oleic acid & white soft paraffin from excipients; and to give indication as 'counter-irritant for aches and pains' only.

Rubex oint  
(vaporub)

Approved with condition to delete oil nutmeg and methyl salicylate from active ingredients and change indication as 'counter-irritant for aches and pains' only.

Cipla, Bogra

Dextromethorphan syrup  
0.2%

Approved with condition to replace sodium benzoate by propylparaben and adjust the quantity of preservatives and change indication as 'antitussive' only.

Standard Chem., Dhaka

Ephital liq  
(prednisolone + chloro-carvacrol + acid salicylic)

Rejected because *combination of prednisolone* ~~not permissible under National Drug Policy as combination drug.~~ *with acid salicylic is not justified.*

Ezensa oint  
(prednisolone + cincoaine + hexachlorophene + clemizole)

Rejected because not considered acceptable

Rx

3. Prayers for import registration of the following recipes were placed and discussed. Decisions taken are as follows.

Radiumfarma, Italy

Cefrasol tab 1g  
(cephradine)  
Cefrasol inj 1g  
Cefrasol inj 500mg  
Cefarad inj 1g  
(cephazoline)  
Cefarad inj 500mg  
Naprium cap 250mg  
(naproxen)

Rejected because adequate locally manufactured substitute available.

Approved.

Rejected because not considered necessary.

Approved. *in this case.*

Rejected because not considered necessary. *in this case.*

Rejected because not required any more.

Ifiunik Pharma, India

Povidone Iodide 1%

Rejected because not considered necessary.

Medimpex, Hungary

Kalnormin tab 1g  
(potassium chloride)

Rejected because locally manufactured substitute available.

*Approved*  
*W. S. M.*  
*28/11/95*

May & Baker, UK

Strypen Forte Rapid (vet) inj Approved.  
(procaine penicillin 300mg+  
dihydro streptomycin 250mg/5ml)

Ranbaxy, India

Gramoneg tab 500mg Rejected because locally manufactured  
(nalidixic acid) substitute being available.

Boehringer Mannheim, W. Germany

Ismo 20mg tab Rejected because locally manufactured  
(isosorbide-5-mononitrate) substitute are being registered.

Ismo 40mg tab -do

Ciba-Geigy, Switzerland

Sicorten-plus cream Rejected because not considered necessary.  
(halometason + triclosan)

Krka, Yugoslavia

Benaquin inj 200mg/5ml Prayer to extend the validity of the regis-  
(chloroquine) tration which expired on 24.8.85 was rejected  
Reg. no. 188-2052-85 because not considered necessary any more.

Lek, Yugoslavia

Aminophylline tab 100mg Rejected because locally manufactured  
substitute available.

Aminophylline retard tab 350mg Approved.

Aminophylline inj 250mg/5ml <sup>10ml</sup> Approved.

Serobiotics Inc., Canada

Inj Stero-Bemicillin 1200LA Rejected because locally manufactured  
(penicillin G benzathine) substitute available.

Rowa Ltd., Ireland

Rowachol cap Rejected because the therapeutic benefit  
(menthol+menthone+pinene is doubtful.  
+borneol+cineol)

Rowachol liq -do-  
(menthol+menthone+pinene+borneol+  
cineol+canphene)

Rowalnex cap -do-  
(pinene+camphene+cineol+  
fenchone+borneol+anethol)

Pliva, Yugoslavia

Ampicillin inj 250mg Rejected because local substitute available.

Ampicillin inj 500mg -do-

Medimpex, Hungary

Polybe S inj Rejected because local substitute available.  
(vitamin B complex)

Krka, Yugoslavia

Vitamin B12 inj Prayer to extend the validity of the regis-  
Reg.No. 101-2030-84 tration which expired on 1.11.85 was rejected  
because local manufactured substitute  
available ~~is~~ adequately.

Medimpex, Hungary

Vitamin B12 inj Prayer to extend the validity of the regis-  
RegNo. 63-2021-84 tration which expired on 13.10.85 was  
rejected because adequate locally manufactured  
substitute available.

*Approved  
Walla  
20/11/85*

- 2 Ciba-Geigy, Switzerland ✓  
Fasinex bolus for cattle 900mg (vet) Approved.  
Fasinex bolus for sheep & goat 250mg Approved.  
Serotherapeutics, Austria  
Anti-Rho(D) Immuno serum globulin 250mg Approved.  
F.T. Otsuka, Indonesia  
Plas-amin inj 500ml Approved.  
(amino acid inj with glucose)  
Tientsin Ren Min Pharm, China  
Dextrose inj 25% Review petition rejected.  
Vitamin C inj 500mg Rejected because local substitute available.  
MSD, USA  
Dolobid tab 250mg & 500mg Kept pending for further study by Prof A K Azad  
(disflunisal) Kh  
Ciba-Geigy, Switzerland  
Disferal inj ~~0.5mg~~ 0.5g Approved.  
(desferrioxamine mesylate)

4. Miscellaneous.

- a) It was decided by the Drug Control Committee that the Ministry of Health & Population Control be requested to co-opt the Superintendent, of Laboratories, Drug Testing Laboratory, Institute of Public Health, Mohakhali, Dhaka as a member of the Drug Control Committee.
- b) It was decided that the existing lists of Essential Drugs and Specialised Drugs be distributed amongst the members of the Drug Control Committee for their study and opinion about any deletion, replacement, etc for revision of the lists.

The meeting ended with a vote of thanks to the chair.

*Waller*  
*ref. 1/85*

Minutes of the 115th meeting of the Drug Control  
Committee held on 20.11.85

The 115th meeting of the Drug Control Committee was held on 20.11.85 at 11.00 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Professor Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting.

Prof. A. Jabbar  
Prof. Mofazzal Bssain  
Brig. Anis Waiz  
Prof. M.Q.K. Talukder  
Mr. Kazi Abdul Kattah  
Dr. Humayun K.M.A. Hye

Dr. Md. Jahangir, Dy. Director, Drug Administration attended the meeting as an observer.

Proceedings & Decisions

1. The minutes of the 114th meeting were confirmed.
2. The following recipes were placed and decisions taken are as described below.

Firms/Brands

Robinsons, Chittagong

Mortein liquid  
insecticide  
(d-allethrin 0.3%+  
bio-resmethrin 0.03%)

Chemico, Rajshahi

Wormin-K susp  
(mebendazole 2%)

Gonoshasthaya, Dhaka

G-Benoxinate eye drops  
0.4%

Skylab, Comilla

Skycid powder  
(dried aluminium hydroxide gel 49%+ magnesium hydroxide dried 49%)

Jams, Dhaka

Riopan susp  
(magaldrate paste)

Riopan tab

Seema, Dhaka

Seemaldrat  
(magaldrate paste)

Pholcodine linctus 0.1%

Tenol tab  
(atenolol 50mg)

Decisions

The reformulated recipe of the product in higher strength was approved in place of the existing one with condition to specify the name & specification of the deodorant to be used.

Rejected because formula is defective due to absence of excipients like, preservative, colour, flavour, sweetening agent, etc.

Referred to Prof. A.Q.M.S. Harun of Ophthalmological Instt. and Prof. Fazlul Haq of Dhaka Medical College for opinion.

Approved with condition to declare the aluminium and magnesium oxide content and specification of lemon juice flavour.

Rejected because not essential and no more required.

-do-

Rejected because not essential and no more required.

The recipe to be resubmitted after deletion of chloroform, amaranth & tartrazine from excipients and reformulating properly.

Approved with condition to give indication and dosage as per BNF.

contd....2

*Waliullah*  
*21/11/85*

Square, Pabna

Esfulvin susp  
(griseofulvin 2.5%)

Approved with condition to delete tylose C, macrogol 4000, tween 80, sodium saccharin, glycerine & tartrazine from excipients. Alternative colour may be approved by DDA.

City Pharma, Ctg.

Cetol soln  
(benzethonium chloride  
0.2%)

Approved with condition to change name and deletion of tartrazine. Alternate colour may be approved by DDA.

Isoaminile syrup 0.8%

Approved with condition to replace benzoic acid by sodium benzoate; to give indication as 'antitussive' only; and specify dose 40mg 3-5 times daily.

Phocodine syrup

Rejected because only one cough syrup will be allowed to a firm.

Pot. guaicol sulfonate syrup

-do-

Dextromethorphan syrup

-do-

C-Glucose powder

Approved with condition to mention active ingredient as 'dextrose monohydrate BP' and change indication as 'for nutritional supplement and debility state'. *change name*

Beximco, Dhaka

Magaldrate tab

Rejected because not essential and no more required.

Magaldrate susp

-do-

3. Miscellaneous.

It was again confirmed by the Drug Control Committee that the Director, Drug Administration may approve any appropriate amendment of an approved recipe in respect of excipients only, (when applied for.) *WZ*

The meeting ended with a vote of thanks to the chair.

*WZ*  
*27.11.55*

Minutes of the 116th meeting of the Drug Control Committee  
held on 27.11.85

The 116th meeting of the Drug Control Committee was held on 27.11.85 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Professor Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Prof. A. Jabbar  
Dr. Munawara Binte Rahman  
Brig. Anis Waiz  
Dr. Humayun K.M.A. Hye

Proceedings & Decisions

1. The minutes of the 115th meeting were confirmed.
2. The following recipes were placed and decisions taken are as described below:

Firms/Brands

Decisions

Hoechst, Ctg.

Amblosin drops  
(ampicillin 100mg/ml  
in 15ml. bottle with  
dropper)

Approved with condition to correct the dosage for 6 hourly interval.

Bengal Chemical, Dhaka

Ulcerin tab  
(sucralfate 500mg)

Approved.

Sheba, Dhaka

Quickstop cap  
(loperamide 2mg)

Approved with condition to change name and indication to be as per BNF.

Bengal Techno, Dinajpur

Chloramphenicol cap 250mg

Kept pending for inspection report.

Asmatex syrup  
(theophylline  
sodium glycinate)

Approved with condition to change strength as 2.4%, give proper specification of essences and correct dosage as per BNF.

Rephco, Barisal

Refalex cap  
(cephalexin 250mg)

Approved.

Apollo, Dhaka

Zantin tab  
(ranitidine 150mg)

Approved.

Aminol tab  
(atenolol 50mg)

Approved with condition to change name.

Opsonin, Barisal

Orflex inj  
(orphenadrine 60mg)

Approved.

Orflex tab 100mg  
(sugar coated)

Approved with condition to delete tartrazine. Alternate colour may be approved by DDA.

Ali's Lab, Dhaka

Diazine tab  
(sulfadiazine)

Rejected for non-availability of Manufacturing facilities.

contd.....2

*Approved  
Waliullah  
27/11/85*

Cosmic, Dhaka

Cosmic vaporub

May be resubmitted after correction of formula, indication, dosage, etc.

-do-

Iodol oint

Oasis, Serajganj

Riboflavin tab 5mg

Kept pending for inspection report.

Cimetidine tab

-do-

UCPL, Ctg.

Dextromethorphan  
syrup 0.2%

Approved with condition to delete sodium chloride, sodium saccharin, and amaranth red from the excipients; and to give specification of flavours and diluent.

Hemaplus syrup  
(ferrous gluconate 6%)

To resubmit the recipe with a changed name and correction of formula with proper sweetening agent, antioxidant, etc.

Microbe Lab, Bogra

Riboflavin tab 5mg

Rejected because the formula is wrong.

Opsonin, Barisal

Pholex linctus  
(pholcodine)

Rejected because only one cough syrup will be allowed to a firm and the firm has already been allowed noscapine syrup/ta b.

Orex cap  
(potassium guaiacol sulfonate)

-do-

Janata Lab, Dhaka

Mucon susp  
(magaldrate)

Rejected because no more required.

Skylab, Comilla

Tab ergotamine with  
caffeine (1mg + 100mg)

Approved with condition to change name and give dosage as per BNF.

ICI, Dhaka

Vivalan 50mg tab  
(viloxazine HCl)

Referred to Prof. Nazimuddowla Chowdhur of IPGMR and Col. A.F.M. Aziz of CMH for opinion.

Vivalan tab 100mg

-do-

Fisons, Dhaka

Dilamen tab  
(oxyfedrine HCl)

Rejected because not essential and considered necessary.

Fitaxon tab 25mg  
(doxepin HCl)

Approved.

✓ Theophylline syrup  
80mg/15ml

The recipe may be considered if sustained release preparation of the drug is manufactured by the firm.

Jayson, Dhaka

Suprazyme cap 325mg  
(pancreatin BP 80)

Approved with condition to give dosage as per BP 80/ BNF 85.

Dixicon susp  
(nalidixic acid)

Approved with condition to change the strength as 6g/100ml and justify use of ethanol, phenylethyl alcohol, and sodium bicarbonate; and give proper specification for carageenan sodium & food colour brown.

Vitafort inj  
(thiamine 100mg+  
riboflavin 10mg+  
pyridoxine 100mg/2ml ampoule)

To resubmit the recipe with standard formula for B-complex injection.

contd.....3

*Approved*  
*4/12*

Opsonin, Barisal

B vit 6 tab  
(pyridoxine HCl)

Approved with condition to change strength as 50mg/tab and give indication and dosage as per BNF.

3. Prayer for import registration of the following recipes were placed and discussed. Decision taken are as follows:

Krka, Yugoslavia

Vitamin B<sub>12</sub> inj

Prayer for revalidation of the provisional registration (101-2030-82) was approved.

Eflaron soln for i.v. infusion  
(metronidazole 500mg/100ml bottle)

Approved.

Pimidel cap  
(pipemidic acid 200mg)

Rejected because not essential and considered necessary.

Medimpex, Hungary

Vitamin B<sub>12</sub> inj

Prayer for revalidation of the provisional registration (63-2021-84) was approved.

Gentamicin inj  
20mg/ml in 2ml amp.

Rejected because such strength is not required.

4. Miscellaneous.

- a) It was observed that Pfizer has asked for import of bacampicillin (for their product Bacacil), which is converted to ampicillin after absorption, at a price of US\$ 352/kg (Tk 10582/-) against US\$70/kg of ampicillin. There is no special therapeutic advantage that justifies the exorbitant price of bacampicillin raw materials which leads to higher MRP of the product.

It was also observed that they have applied for import of tiocona zole, an antifungal imidazole derivative for their Trotyd cream at a price of Tk 81525/- per kg (US\$ 2717) which is 50-60% more than the existing imidazole derivative available in the market. There is no therapeutic advantage that justify such high price of tioconazole raw materials which lead to higher MRP.

The committee reviewed the approval of Bagacil and Trotyd with the above viewpoints and decided that these drugs may be allowed in restricted quantity to be determined by the DDA for specialised use only and the firm may be asked to reduce the price of raw materials of these products.

- b) The decision about discontinuation of dicyclomine syrup/drops was kept pending for next meeting.
- c) As observed that ampicillin preparations may cause pseudomembranous colitis, the committee recommended that such warning be incorporated in the inserts of ampicillin preparations of the country.
- d) A prayer of Bangladesh Chemists & Druggist Samity dated 25.11.85 requesting to reconsider the approval for registration of Vitamin B<sub>12</sub> inj, Vitamin B-complex inj, and Benaquin inj was considered. The committee recommended for revalidation of registration of Vitamin B<sub>12</sub> inj of Krka, Yugoslavia and Medimpex, Hungary. However, for Benaquin inj and Vitamin B-complex inj, the committee upheld their earlier decision.

The meeting ended with a vote of thanks to the chair.

*Approved  
W. S. R. / 11/1/85*

Minutes of the 117th meeting of the Drug Control Committee held on 4.12.85

The 117th meeting of the Drug Control Committee was held on 4.12.85 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Professor Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Dr. Munawara Binte Rahman  
Prof. Mofazzal Hossain  
Brig. Anis Waiz  
Prof. M.Q.K. Talukder  
Dr. Humayun K.M.A. Hye

Proceedings & Decisions

1. The minutes of the 116th meeting of DCC were confirmed.
2. The following recipes were placed and decisions taken are as described below.

<u>Firms/Brands</u>	<u>Decisions</u>
<u>Janata, Dhaka</u>	
Dexophan liquid (dextromethorphan HBr)	Rejected because the formulation is wrong and does not fulfil the criteria fixed for antitussive syrups.
<u>Opsonin, Barisal</u>	
Gentin inj (gentamicin 20mg/2ml amp)	Approved.
<u>Orion, Dhaka</u>	
Ascorin liquid (ascorbic acid 100mg/5ml)	Approved with condition to delete sodium metabisulphite.
Magaldrate susp	Rejected because not essential and no more required.
Noscapine linctus	Approved with condition to replace 'linctus' by 'syrup' from name; give strength noscapine hydrochloride 300mg/100ml as salt; give indication as 'antitussive' only; give the warning 'not recommended for children'; and delete chloroform water from excipients.
<u>Chemico, Rajshahi</u>	
Noscapine syrup	Rejected because the formulation is wrong and does not fulfil the criteria fixed for antitussive syrups.
<u>City Pharma, Ctg</u>	
Gluconate syrup	The recipe may be resubmitted with a changed name, strength as 6% and preservative in sodium salt form.
<u>Niramoy, Dhaka</u>	
Neozyme cap 325mg (pancreatin BP 80 enteric coated granules)	Approved with condition to give dose as per BNF (2-4g per day)
<u>Square, Pabna</u>	
Esrufen 400 coated tablet (ibuprofen 400mg)	Approved with condition to delete Povidone and Primojel from the excipient and overage of the active ingredient.
Esrufen 600 coated tab (ibuprofen 600mg)	Rejected because such strength is not necessary.

contd.....2

*Waliullah*  
*15/12/85*

3. Prayer for import registration of the following recipes were placed and discussed. Decisions taken are as follows.

Korea Green Cross, Korea

Hepavax-B vaccine Approved.  
(Hepatitis B surface antigen  
inactivated, 20mcg/ml)

Lek, Yugoslavia

Palin cap 200mg Rejected because not essential and  
(pipemidic acid) not required.

Pharmachim, Bulgaria

Avimycin oral powder (vet) Kept pending for further study.  
(oxytetracycline + neomycin)

Analgin 30% vial (vet) (dipyrone) -do-

Ampicillin i.m. inj (vet) -do-

Hoxol aerosol (vet) (chloramphenicol) -do-

Gentamicin inj (vet) -do-

Tetracycline oral powder (vet) -do-

Bioxacycline depot cap (vet) -do-

Medimpex, Hungary

Jumex tab Rejected because not essential and  
(selegiline 5mg) not required.

Squibb, UK

Kenalog in orabase Rejected; may apply for local manufacture.  
(triamcinolone)

4. Miscellaneous

- a) It was observed that in UK, dicyclomine syrup and drops has been contra-indicated in infants under six months of age and has recommended to delete the indication for its use in infant colic.

In Bangladesh, dicyclomine is mostly used in infant colic for children below six months of age. Also, the drug in syrup and drops form is highly misused as a different form of gripe water.

As the drug may cause apnoea and other sign of respiratory distress in infants, the availability of the drug in syrup and drop form was reviewed by the committee and it was decided that all brands of the drug is to be withdrawn and registrations be cancelled within one year. No new recipes will also be considered.

- b) It was observed that Squibb has applied for import of 'halcinonide', for their Halog cream at an exorbitantly high price of Tk 11 lacs per kg, which is 3000% higher than that of other available topical steroids.

The committee reviewed the approval for Halog cream with the above view point and decided that the drug may be allowed in a restricted quantity to be determined by the DDA for specialised use only and the firm may be asked to reduce the price of the raw material.

The meeting ended with a vote of thanks to the chair.

Approved  
A. S. Akbar  
19/12/55

Minutes of the 118th meeting of the Drug Control  
Committee held on 18.12.85

The 118th meeting of the Drug Control Committee was held on 18.12.85 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Prof. Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Brig. Anis Waiz  
Dr. Humayun K.M.A. Hye

Proceeding & Decisions

1. The minutes of the 117th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting.

While discussing about the exorbitantly high price of raw materials, such as tioconazole, bacampicillin and halcinonide, it was desired by the Drug Control Committee that from now on, while applying for approval of a recipe of non-pharmacopoeal drugs the manufacturer has to justify the introduction of a new drug in a summarized form not exceeding 20 lines and also inform the probable retail price of the product when marketed.

3. The following recipes were placed and decisions taken are as described below.

Firms/Brands

Decisions

Glaxo, Chittagong

Pholcodine syrup 0.1%

The recipe to be resubmitted with proper specification for flavour, preservative & solvent; and indication as 'antitussive' only.

Globe Research, Feni

Iogex oint  
(iodine oint)

Approved with condition to change name and give indication as 'counter irritant for external application'.

Potassium guaiacol  
sulphonate syrup 2.5%

Approved with condition to give proper specification for Raspberry Red.

G.M. Laboratory, N'ganj

Tincture Belladonna

Rejected because not essential and not required any more.

Health Lab, Dhaka

Cap Superzyme  
(pancreatin 325mg)

Approved with condition to change name, give specification of Pancreatin as BP 1980, replace lactose by starch in excipients, give indication as 'pancreatic deficiency' only, and dosage as 2-4g daily.

Coughryl syrup  
(dextromethorphan  
syrup 0.2%)

The recipe may be resubmitted with name in generic form, indication as 'antitussive'; using methyl paraben in sodium salt form to make it water soluble, and ~~replement~~ <sup>of FD&C Red No. 40 with suitable colour.</sup> *Wc*

Cipla Ltd, Bogra

Comfrte rub  
(vapcrub)

The recipe to be resubmitted as per the standard formula and change of name. The standard formula include, per 100g, menthol 0.5-2%, camphor 1-3%, oil eucalyptus 1-4%, oil clove 1-3%, & oil terpenine 5%. In the excipient olive oil to be replaced by arachis oil or coconut oil.

contd.... 2

*Approved  
Waliullah  
1.1.86*

Square, Pabna

Rifazid 300 coated tab  
(rifampicin 300mg+  
isoniazid 150mg)

Approved with condition to change name.

Albert David, Dhaka

Nalidixic acid cap  
500mg

Approved with condition to give  
indication and dosage as per BNF.

Square, Pabna

Neotack 300 scored tab  
(ranitidine 300mg)

Approved.

Rifazid 225 coated tab  
(rifampicin 225mg+  
isoniazid 150mg)

The recipe to be resubmitted with  
rifampicin 150mg and isoniazid 100mg  
per tablet, dosage as per BNF, colour  
different from that of Rifazid 300 coated  
tablet, and a changed name.

Bengal Techno, Dinajpur

Pholcodine syrup 0.1%

Approved with condition to delete colour  
tartrazine, give indication as 'antitussive'  
only, give warning 'not for children' on  
label, carton & leaflet, and give proper  
specification for flavour. Alternate  
colour may be approved by DDA.

B-Zyme cap  
(pancreatin BP'80 325mg)

The recipe to be resubmitted with changed  
name, correct indication and dosage as per  
BNF, 15% overage, and mentioning the  
active ingredient as enteric coated  
granules of pancreatin.

Medicon, Dhaka

Entazyme cap  
(pancreatin enteric  
coated granules 325mg)

Approved with condition to give indication  
and dosage as per BNF, replace lactose  
by starch in excipients, and give speci-  
fication of pancreatin as BP 1980.

Skylab, Comilla

Noscapine cough syrup  
0.3%

The recipe to be resubmitted after  
deleting 'cough' from the name, replacing  
tartrazine with a suitable colour, giving  
pack size as 100ml only, and with proper  
specification for flavours. Also indication  
as 'antitussive' only and the warning  
'not for children' to be mentioned.

Vitamin C drops

Approved with condition to reduce strength  
to 5g ascorbic acid per 100ml, replace  
benzoic acid by methyl paraben sodium,  
give quantity of syrup simple<sup>as</sup> 60ml,  
and give proper specification for flavours.

Vitamin C syrup

Rejected because vitamin C <sup>drops</sup> has been  
allowed to the firm.

Hoechst, Chittagong

Bactamox tab  
(amoxicillin 500mg)

Rejected because not required in this  
strength.

City Pharm, Ctg.

Cyodex oint  
(iodine oint)

Approved with condition to specify type  
of vaseline to be used (yellow or white),  
and give indication as 'counter irritant  
for external application' only.

Civicks oint  
(vaporub)

Approved with condition to change name and  
give indication as 'counter irritant for  
external application' only.

Cimicillin syrup  
(dicyclomine HCl)

Rejected because the DCC has recommended  
for cancellation of registration of  
such preparations.

Approved  
Walt  
11/56

contd.... 3

Gonoshasthaya, Dhaka

G-Cimetidine inj                      Approved.  
200mg per 2ml ampoule

Fisons, Dhaka

Pevisone oint                              Approved.  
(econazole nitrate 1%+  
triamcinolone acetoneide 0.1%)

Seeme, Dhaka

Pot. guaiacol syrup                      Approved with condition to give indication  
2.5% (potassium                              as 'antitussive' only, delete colour  
guaiacol sulphonate                              amaranth, give warning 'not for children'  
syrup)    in label, carton & leaflets & give preser-  
vatives in sodium salt form. Alternate  
colour may be allowed by DDA.

Central, Dhaka

Magacid tab                                      Rejected because not essential and not  
(magaldrate)                                      required any more.

Magacid susp                                      -do-

Seema, Dhaka

Seemacillin drops                              Approved with condition to give calibrated  
(ampicillin 100mg/ml                              droppers to measure 1.25ml, 0.62ml etc.  
in 15ml bottles)                                      and give indication as per BNF.

Seemodium cap                                      Approved.  
(loperamide HCl 2mg)

Bengal Research, Barisal

Tab Oxyphen                                      Approved.  
(oxyphenonium bromide 5mg)

4. Miscellaneous.

- a) While reviewing the objectives and activities of the Drug Control Committee it was observed that the Committee meets as frequently as every week regularly in order to carry out the important responsibilities entrusted. And each of these meeting continues for long hours.

To carry out the work of the Committee much administrative and secretarial jobs are involved. But no fund has yet been allocated for this purpose.

In the circumstances, the Committee suggested that a special fund be created to be operated by the Member-secretary of the Committee who is also the Licensing Authority (Drugs) to bear the expenses incurred while carrying out the functions of the Drug Control Committee. Thus it was suggested that while applying for approval of a recipe the manufacturers may submit an amount of Taka 100.00 per recipe by cash or crossed cheque along with the usual chalan of the recipe evaluation fee of Taka 300.00.

The Committee decided to put forward the above suggestion for consideration of the Secretary, Ministry of Health & Population Control for approval.

*Approved*  
*W. S. S.*  
*1.1.88*

-: 5 :-

The committee decided to obtain opinion of Celm. Mchaimen and Celm. Minaj before considering of registration of the following items.

Name of the items.

Name of Manufacturer.

1. Marcaine soln. for inj.

M/s. Astra Chemicals, West  
Germany.

2. Marcaine adrenaline soln. for inj.

-de-

The meeting ended with vote of thanks to the chair.

Approved  
Walter  
1.1.55

Minutes of the 119th meeting of the Drug Control Committee held on 1.1.86

The 119th meeting of the Drug Control Committee was held on 1.1.86 at 11.30 a.m. in the chamber of the Director, Drug Administration under the chairmanship of Prof. Waliullah, the Chairman of the Drug Control Committee.

The following members attended the meeting:

Prof. A. Jabbar  
Prof. Mofazzal Hossain  
Brig. Anis Waiz  
Prof. M.Q.K. Talukder  
Dr. Humayun K.M.A. Hye

Proceeding/Decisions

1. The minutes of the 118th meeting were confirmed.
2. The following recipes of import substitute drugs were placed and decisions taken are as described below:

Firms/Brands

Decisions

Pacific, Dhaka

Olive oil (emollient)

Approved with condition to delete -  
'It is applied to the skin to remove  
in crustations in eczema and psoriasis,  
and used as a lubricant in massage',  
from indication.

Gonoshasthaya, Dhaka

G-B-Complex injection

Approved with condition to manufacture  
in pack size of 2 ml ampoule only.

In this connection it was also decided  
that the other companies who are now  
manufacturing Vitamin B-Complex  
injection in 10 ml multidose vial  
packing will have to convert the packing  
to 2 ml ampoule within one year.

Opsonin, Barisal

Metryl-D injection  
(metronidazole 1 g +  
dextrose 25 g/100 ml)

Rejected because this pack size is  
not necessary.

Organ, Dhaka

Mousumi Cod Liver oil

Approved.

Mousumi Cod Liver Oil  
emulsion (vitamin A 24000 i.u.  
+ vitamin D 2400 i.u./100 ml)

Approved.

- The following resubmitted recipes were placed and decision taken are as described below:

Opsonin, Barisal

Nifedin soft gelatin capsule  
(nifedipine 10 mg)

Approved.

Peoples Pharma, Dhaka

P-Dextromethorphan  
syrup 0.2%

Approved with condition to delete  
'P' from name; change indication as  
'antitussive' only; and delete sodium  
citrate, glycerine & custard flavour  
from excipients.

contd..... 2

*Approved,  
Waliullah,  
15.1.86*

Bengal Chemical, Dhaka

Dextromethorphan syrup 0.2% Approved with condition to give indication as 'antitussive' only and delete glycerine from excipients.

Sheba, Dhaka

Dextromethorphan syrup 0.2% Approved with condition to delete amaranth colour from excipients. Alternate colour may be approved by DDA.

Chemico, Rajshahi

Noscapine syrup 0.3% Approved with condition to delete carboxymethylcellulose from excipients.

Nipa, Dhaka

Pencin 'V' drop (dry)  
(penicillin V) Rejected because not required.

Moxapen drop (dry)  
(amoxycillin 20.833 g/100 ml) The recipe may be resubmitted with strength equivalent to 100 mg amoxycillin base per one ml, packing 15 ml with calibrated dropper to measure 1.25 ml, 1 ml & 0.625 ml; and correction of excipients.

Ioxcin drop (dry)  
(cloxacillin 20.83 g/100 ml)

-do-

4. Miscellaneous.

The committee decided that the meeting to review the Lists of Essential and Specialised Drugs will be held on 12th February 1986 at 11.30 a.m.

The meeting ended with a vote of thanks to the chair.

For approved  
Atallah  
15.1.86