

Minutes of the 120th meeting of the Drug Control Committee held on 15.1.86

The 120th meeting of the Drug Control Committee was held on 5.1.86 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 other members attended the meeting:

Prof. A. Jabbar  
Mr. Kazi Abdul Fattah  
Dr. Md. Jahangir  
Dr. Humayun K.M.A. Hye

Proceedings & Decisions

1. The minutes of the 119th meeting of the Drug Control Committee were confirmed.
2. The following recipes of import substitute drugs were placed and decisions taken are as described below:

Firms/Brands

Decisions

GACO, Dhaka

Unitac tab 150 mg  
(ranitidine HCl)

Approved with condition to change indication as, 'A histamine H<sub>2</sub>-receptor antagonist indicated in the treatment of benign gastric ulcer, Zollinger-Ellison syndrome and reflux oesophagitis.'

Acme, Dhaka

Nalidix cap 500mg  
(nalidixic acid)

Approved.

Skylab, Comilla

Verapamil HCl tab 80mg

Approved with condition to give indication as per BNF.

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

Ibne Sina, Dhaka

Sinaphyllin tab 120mg

Approved with condition to change adult dose as '1/2 to 3 tablets every 6 hours;' delete 'broncho pneumonia, pulmonary, renal oedema and angina pectoris' from indication and add 'reversible airways obstruction' in the same; and delete overage.

Gastrosin tab 200mg  
(cimetidine)

Approved with condition to delete overage and change dosage  $\frac{1}{2}$  per BNF.

Sinamide cap 2mg  
(loperamide HCl)

Approved with condition to delete overage.

Sinamox cap 250mg  
(amoxycillin)

Approved with condition to change dosage as 1 - 2 capsules 8 hourly.

Sulphasina tab 500mg  
(sulphadiazine BP)

Approved with condition to supply in bulk packing without strip.

contd.... 2

*Waliullah*  
19.2.86

Sinazyme cap 325mg (pancreatin BP80) Approved with condition to change dosage as ~~12~~ '2-4 capsules 3 times daily'.

Magsina tab (magaldrate) Rejected because not required any more.

Fisons, Dhaka

Pevaryl skin lotion Approved with condition to amend indication. (econazole nitrate 1%)

Pevaryl p.v. foaming solution (econazole 1%) Rejected because not required in this form.

*Referred to Prof. Hasan Ali Khan for the Govt. Eastern Sindh CMH*

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

Medimpex, Hungary

Hormofort inj (hydroxyprogesterone caproate) Approved.

Norcolut tab (norethisterone) Rejected because not required.

Pharmachem, Bulgaria

Avimycin oral powder (vet) (oxytetracycline + neomycin) Rejected because not required.

Analgin 30% vial (vet) (dipyrrone) Rejected because not permitted under National Drug Policy.

Ampicillin <sup>intra-mammary</sup> IM inj (vet) Approved.

Syringe of 0.58823 g (500iu) / syringe of 10g

Ampicillin inj 0.1666g (150iu) Approved.

Hosol 140g aerosol (vet) (chloramphenicol) Rejected because not required.

Gentamycin inj 400mg (vet) APPROVED.

Tetracycline + Vitamin B-complex powder Rejected because not required.

Bioxacycline depot cap (vet) (bioxacillin) Rejected because not required.

Pliva, Yugoslavia

Chloramphenicol 5% ear drops Rejected because not required.

Diplivan nasal drops 10ml (diphenhydramine + naphazoline) Rejected because not required.

Helkamen tab (oxyphenium Br) Rejected because not required.

Mixed Gas gangrene Antitoxin Rejected because not permissible under National Drug Policy.

Nystatin powder for oral susp 24ml (100000 units/ml) (35 drops) Approved.

Bio Lab Co, Thailand

Cimulcer tab (cimetidine) Rejected because not required any more.

Inflanac tab (diclofenac) Rejected because not required any more.

Oxo-Chemic, W.Germany

Oxoferin soln. for local treatment of wounds (tetrachlordioxide) Rejected because of doubtful efficacy.

TCDE

contd.... 3

*W.ullah  
19/2/56*

5. Miscellaneous.

a) Recipes of essential drugs:

It was raised by Prof. A. Jabbar that all recipes belonging to the List of Essential Drugs should be placed before the Drug Control Committee from now on.

It may be mentioned here that approval of recipes belonging to the Essential Drug List was previously delegated by the Drug Control Committee to the Director, Drug Administration to clear up the backlog and shorten the registration time of essential drugs.

It was decided by the Committee that from now on, all recipes of essential drugs as well as other drugs will be considered for approval by the Drug Control Committee. It was also decided that all such recipes of essential drugs and recipes of import substitute drugs will be considered on a priority basis in every two consecutive meetings and the other recipes will be considered in every third meeting. This decision will be applicable for both recipes of local manufacture and import registration.

However, the Director, Drug Administration observed that this procedure may cause delay in disposing the recipes of essential drugs.

b) Expiry dating of Pancreatin preparations:

It was observed by the Committee that Pancreatin is highly sensitive to temperature and moisture and deteriorates rapidly in a short period when exposed above 20°C.

Therefore in order to ensure the potency of Pancreatin preparations, it was decided that all Pancreatin preparations should bear an expiry date not exceeding one year. Also it was decided that all manufacturers of such preparations should submit one year's stability data after completion of one year of marketing of the product.

c) Cancellation of registration of some products of Alcon, USA:

The Committee recommended for the cancellation of registration of the following products of Alcon, USA as similar products belonging to Alcon, Belgian are under the process of registration, which has been permitted to keep the price unchanged.

The products are i) Isopto Homatropine 2% ophth soln; ii) Maxidex ophth soln; iii) Mydriacyl 1% ophth soln; iv) Oratrol tab; v) Statrol ophth soln; vi) Zincfrin ophth soln; and vii) Maxitral ophth soln.

d) Letter of M/s Square dated 12.12.85 on Esfulvin syrup:

The Committee considered a letter of M/s Square dated 12.12.85 about the deletion of some excipients from the recipe of Esfulvin syrup and further decided that the firm may be requested to justify the use of the deleted excipients on an itemwise basis.

e) While considering the application dated 14.12.85 of the local agent of M/s Otsuka the Committee allowed the amendment of the name of the manufacturer as P.T. Otsuka, Indonesia instead of Otsuka, Japan for the product Potassium Chloride inj which was approved earlier.

The Committee further decided that all products registered under Otsuka, Japan be cancelled as similar products are registered and imported from P.T. Otsuka, Indonesia.

contd.... 4

*Wulla*  
*19/12/85*

- f) The Committee considered the replies of M/s Squibb and M/s Ambee about local manufacture of their imported products. As both the firms indicated positive attitudes, the Committee decided to review the progress from time to time and take necessary action if progress is not substantiated in future.
- g) The Committee took note of the clarification (dated 21.12.85) of M/s Medimpex about the letter of the Commercial Secretary of Hungarian embassy regarding their import of a banned drug, Teátanus Antitoxin 1500i.u.

The Committee warned that in future any correspondence with Medimpex must not be taken at a diplomatic level, and the Commercial Secretary should write on behalf of Medimpex only and not as an embassy person.

- h) The Committee considered the review application of M/s Hoechst for import registration of Claforan inj (cefotaxime), which was rejected earlier with suggestion to apply for local manufacture.
- The firm claimed that local manufacture of Claforan inj will not be possible due to high technological skills and stringent manufacturing control parameters involved in the production process.
- Decision regarding the prayer has been kept pending for further study.

- i) The committee considered the prayer dated 24.12.85 of the local agent of M/s Astra, UK and allowed the amendment of the registration of Bricanyl as a 'Misthaler' instead of 'Inhaler', both having the same composition.
- j) The Committee decided to withheld the registration of Gordox inj (aprotinin) of M/s Medimpex, Hungary as BNF observes that the effectiveness of the drug has not been substantiated.

- k) While processing the registration of Bricanyl tab 2.5mg (terbutaline) of M/s Astra, UK it was observed that no such strength exist in the BNF or the Extra Pharmacopoeia.

The committee revoked the approval of Bricanyl 2.5mg tab and observed that the firm may apply for the registration of Bricanyl 5mg tab.

- l) While processing the registration of Zitazonium tab (tamoxifen) of M/s Medimpex, it was observed that the firm have facilities to manufacture the item in their local factory.

Therefore the Committee recommended that the registration of the drug be withheld and the firm be advised to manufacture the drug locally.

*Temporary registration for one year with an  
under the firm should manufacture it locally.*

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

*W. S. S. S.*  
*18/2/80*

Minutes of the 12<sup>th</sup> meeting of the Drug Control Committee.

The 12<sup>th</sup> meeting of the Drug Control Committee was held on 19.8.50 at 10:30 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:

1. Prof. A. Jabbar
2. Prof. Sayeda Firoza Begum,
3. Prof. M.R.K. Talukder
4. Prof. Mofazzal Hossain
5. Brig. Anis Uddin.
6. Dr. Md. Jabangir,
7. Dr. Hamayun K.M.A. Hye.

Proceedings/Decisions.

1. The minutes of the 12<sup>th</sup> meeting were confirmed.
2. The following recipes of import substitute drugs were placed and decisions taken are as described below: *essential*

Trims/Brands

Decisions.

Greenland, Dhaka

Aspirin tab.  
(aspirin B.P. 300mg)

Approved with condition to change name.

G-Oxyper cap.  
(Oxytetracycline HCL BP 250mg)

Approved with condition to change name.

Givit tab.  
(vitamin B-Complex)

Approved with condition to change name and change name.

Sulphadiazine tab. 500mg

Approved with condition to change indication as per BNF & Data sheet *compendium*

Vernin tab.  
(levamisole HCL, BP 4mg)

Approved with condition to change name.

Gastronex tab.  
(dried aluminium hydroxide  
BP 250mg + Magnesium  
trisilicate BP 500mg)

Approved with condition to change name.

Paralgin tab.  
(paracetamol BP 500mg)

Approved with condition to change name.

Relupain tab.  
(hyoscine butyl bromide  
BP 10mg)

Approved.

Siron cap.  
(dried ferrous <sup>0</sup> 4 BP 200mg  
+ folic acid 0.3mg)

Rejected, may resubmit in tablet form.

Greenod tab.  
(metronidazole BP 400mg)

Approved.

Greenod tab.  
(metronidazole BP 200mg)

Approved.

*WZ*

*W*

Givite-C tab.  
(ascorbic acid USP).

Approved with condition to change name.

Genoprim tab.  
(cotrimoxazole 80mg +400mg)

Approved with condition to change indication as per Data Sheet compendium.

Alergin tab.  
(chlorpheniramine maleate BP 4mg)

Approved with condition to delete tartrazine. Alternate colouring agent will be approved by DDA.

Najat, Dhaka.

Fourvita cap.  
(vitamin B-complex)

Approved.

Nira, Dhaka.

Loxoin drop (Dry)  
(cloxacillin Na BP 100mg/1ml)

Approved with condition to delete 'so it is effective against mixed gram positive infections from indication.

Moxapen Drop (Dry)  
(amoxycillin trihydrate BP 100mg/1ml.)

Approved.

Peoples Pharma, Dhaka.

FPvin PP tab.  
(Griseofulvin BP 250mg)

Approved with condition to modify indication & dosage etc. as per BNF.

Opsonin, Barisal.

Oxytetracycline BP Inj. I.M. Sof  
250mg per 2ml. amp.

Approved.

Fisons, Dhaka.

Vitamin B12 inj.  
(hydroxocobalamine BP 1mg/1ml amp.)

Approved.

Bio Pharma, Dhaka.

Broncholax syrup  
(salbutamol So4 BP 40mg/100ml.

Approved with condition to change indication as per BNF.

Broncholax tab. 2mg

Approved with condition to change indication as per BNF.

Malarix tab.  
(pyrimethamine BP 25mg + sulfadoxine BP 500mg)

Approved with condition to change <sup>indication &</sup> dosage as per BNF.

Tibrin cap.  
(rifampicin BP 450mg)

Approved with condition to change <sup>Ca</sup> indication and dosage as per BNF.

Bionycin cap.  
(oxytetracycline HCL. BP 500mg)

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

Bioclox Dry Syrup.  
(cloxacillin)

Kept pending for inspection report.

Squibb, Dhaka.

Valadol CT.  
(acetaminophen USP 500mg)

Approved with condition that registration of Valadol CT 350mg will be cancelled.

Tronizel C.T.  
(metronidazole BP 200mg)

Approved.

Gonoshasthaya, Dhaka.

Approved.

G-Promethazine syrup 100mg/100ml.

K, D, H. Lab., Dhaka.

Neorine inj. IM  
(thiamine HCl BP 2.5g/100ml  
in 1 ml. amp.)

Kept pending inspection report.

Rebonic sugar coated tab.  
(vitamin B-complex)

Approved.

Ergotin tab.  
(methyl ergometrine maleate  
BP O. 125mg)

Approved.

Albert David, Dhaka.

Phenazin inj.  
(promethazine HCl BP 25mg/1ml amp.

Approved with condition to change indication  
as per BNF. <sup>ca</sup>

Phenazin inj. 50mg/2ml amp.

-do-

Indo Bangla, Barisal.

Indovit-C tab.  
(ascorbic acid BP 250mg)

Approved.

Metrol susp.  
(benzoyl metronidazole 6.4%).

The firm may resubmit the recipe after correction

Thioxin tab.  
(Thiamine HCl BP 100mg)

Approved.

Pfizer, Dhaka.

Refacap 300mg cap.  
(rifampicin USP)

Approved with condition to add 5% coverage and  
change indication and dosage as per BNF/WHO.

City Pharmaceuticals, Ctg.

Cetrimide lotion  
(cetrimide + chlorhexidine)

~~Standard for mycobacterial infection only.~~  
The firm may resubmit recipe after correction.

Promazine syrup.  
(chlorpromazine HCl BP.5%)

Approved.

Levamisol syrup.  
(levamisole HCl.BP)

The firm may resubmit the recipe after correction

Furbadesh, Comilla.

Paracetamol syrup 2.4%

Approved with condition to omit adult-dose.

Acne Lab., Dhaka.

Cloxacilin Dry Syrup.  
(Cloxacillin Na)

Approved with condition to delete 'Sunset yellow  
colour' and as amended the amount of cloxacillin  
Na.

Histalex tab.  
(chlorpheniramine maleate  
USP 4mg)

Approved.

3. Miscellaneous:

- a) The committee considered on prayer of Opsonin, Barisal requesting to expedite decision about their recipe of Opsovit inj. for which they applied on 2.1.85 and the same was kept pending by the committee for inspection. It was decided that Prof. A. Jabbar, and Brig. Anis Waiz will inspect the laboratory on 6th March 1986 and the recipe will be disposed of after the inspection report is available.

- b) The committee recommended for registration of Intraliposid 10% inj of Greek Cross Corporation of Japan. Samples of two batches (e.g. 0028GB and 00620 GI) of the drug did not conform to the claim <sup>in respect of PH</sup> (found 4.7 & 4.1 respectively, limit 6.5 to 8.5) in our Drug Testing Laboratory and as per the certificate of analysis submitted from the manufacturer the same batches conform to the claim. The committee accorded approval for the registration on the basis of the manufacturer's <sup>analytical</sup> certificate and with a conclusion that due to improper storage (storage without refrigeration) in our laboratory free fatty acid <sup>might have been</sup> liberated from the sample causing lowering of PH.
- c) The committee cancelled their recommendation (accorded in Nov. 1984) for registration of Merital (nonifensin) of Hoechst for local manufacture <sup>view of the</sup> ~~and~~ voluntary withdrawal of the product by the manufacturer due to reported side effect of haemolytic anaemia.
- d) The request for review of the application for import registration ~~of~~ <sup>claroram.</sup> (cefotaxime inj) of Hoechst, W. Germany was considered. The drug was referred to Prof. S.G.M. Chowdhury, Prof. T.A. Chowdhury, Prof. Mofazzal Hossain and <sup>Prof.</sup> M. Raman for their opinion.

The meeting ended with vote of thanks to the chair.

Confirmed

Wzy

*[Signature]*  
AWAN

26/2/86

Minutes of the 122nd meeting of the Drug Control  
Committee held on 26.2.86

The 122nd meeting of the Drug Control Committee was held on 26.2.86 in the chamber of the Director, Drug Administration. Brig. Anis Waiz presided over the meeting as Prof. Waliullah, Chairman of the Committee was abroad.

The following other members attended the meeting:

Prof. A.T. Siddique  
Prof. Mofazzal Hossain  
Mr. Kazi Abdul Fattah  
Dr. Md. Jahangir  
Dr. Humayun K.M.A. Hye

Proceedings & Decisions

1. The minutes of the 121st meeting were confirmed.
2. The following recipes of essential drugs were placed and decisions taken are as described below:

Firms/Brands

Decisions

Doms Pharma, Mymensingh

Demol liq  
(paracetamol BP 2.4%)  
  
Domaferron syr  
(ferrous sulphate BP 4%)

Approved.

Approved with condition to delete 'Amaranth red'. Alternate colour may be approved by DDA.

Promazine liq  
(promethazine HCl 0.1%)

Approved with condition to change name and delete ascorbic acid.

Epharin liq  
(ephedrine HCl 0.15%)

Rejected because not required.

Seema, Dhaka

Sevdol sol  
(chlorhexidine gluconate  
solution BP 1.5ml + cetrimide 3g/100ml)

Approved.

Doctor's, Bogra

Prssine tab  
(propranolol HCl BP 10mg)  
  
Helmin syr  
(levamisole HCl BP 0.8%)

The firm may resubmit the recipe with indication and dosage as per BNF.

Approved with condition to delete sodium calcium edetate from excipient, use sodium salt form of methyl and propyl paraben, and change indication as per BNF.

D-Butamol tab  
(salbutamol 2mg)

Approved with condition to change indication as per BNF.

Dactone tab  
(spironolactone BP 25mg)

The firm may resubmit the recipe after reformulation for a smaller size tablet.

Refambin cap  
(rifampicin 450mg)

Approved with condition to add 2.5% overage and give indication and dosage as per WHO recommendation.

Halmodin liq  
(ferrous fumarate BP 4%)

The firm may resubmit the recipe deleting unnecessary excipients.

Denol liq  
(chlorxylenol 5%)

Approved with condition to change name.

Dexone tab  
(dexamethasone BP 0.5mg)

Approved with condition to change indication as per BNF.

contd.... 2

Robinsons, Chittagong

Disprol dispersible  
paracetamol tab 500mg

Rejected because dispersible form of  
this drug is not required.

Junior Disprol tab 120mg

-do-

Albert David, Dhaka

Ramex eye drops  
(chloramphenicol BP 0.5%)

Approved with condition to give warning  
about hypersensitivity reaction and  
side-effects of the drug.

Ramex ear drops  
(chloramphenicol BP 5%)

-do-

Ramex eye oint 1%

Kept pending to check facilities for  
sterile ointment preparations.

Iopanoic acid BP tab 500mg

Kept pending for information about  
source of raw material, price and  
facilities for manufacture.

Tab Allopurinol BP 100mg

Approved with condition to change indica-  
tion and dosage as per BNF.

Dexamethasone tab 0.5mg

Approved with condition to amend indica-  
tion as 'in all conditions responding  
to steroid therapy.'

Dexamethasone inj  
4mg/1ml amp

Approved with condition to amend strength  
as 'dexamethasone sodium phosphate 5.2mg  
equivalent to 4 mg dexamethasone base  
per 1ml ampoule'; delete overage; and  
change indication and dosage as per BNF.

Azad, Dhaka

Whitfield oint  
(salicylic acid 3%+benzoic acid 6%)

Approved.

Seema, Dhaka

Salbron syr  
(salbutamol 40mg/100ml)

Approved with condition to delete  
'Amaranth red' colour; use sodium salt  
form of methyl and propyl paraben; and  
change indication and dosage as per BNF.  
Alternate colour may be approved by DDA.

Methoxin tab  
(sulfadoxine 500mg+pyrimethamine 25mg)

Approved.

Sedral tab  
(propranolol HCl BP 10mg)

Approved with condition to change name.

Skylab, Comilla

Saftol liq  
(chlorxylenol BP 5%)

Approved.

Robinsons, Ctg.

Dettoline liq (mouthwash)  
(chlorxylenol BP)

Approved.

Dettol antiseptic cream  
(chlorxylenol+triclosan)

Approved.

Agrani, Dhaka

Agraplex cap (vit B-complex) Kept pending for inspection report.

Agraferron cap (ferrous fumarate+folic acid)

-do-

Adizole tab (metronidazole)

-do-

Agramol tab (paracetamol)

-do-

Agtrim liq (co-trimoxazole)

-do-

contd.... 3

13

Would  
5/3

advised to ~~approve~~ manufacture  
to apply for manufacture  
of actual obstetric cream

*Approved*

Rephco, Dhaka

Vitamin B<sub>1</sub> inj  
(thiamine HCl 25mg/1ml)

Kept pending for inspection report. *Other*  
- dose to be uniform as *Barisal*

Thianomin tab  
(thiamine HCl)

Approved with amendment of strength as 10mg and deletion of lactose.

Cosmic, Dhaka

Cosmogon syr  
(promethazine HCl)

Approved with condition to delete indication and dosage as sedative.

Prayer for import registration of the following essential recipes were placed and discussed. Decision taken are as mentioned below:

Faran Lab, Greece

Allopurinol tab 300mg

Rejected because not required as local substitute available.

Alvetra GmbH, W.Germany

Veterinary products (44 items)

Kept pending for the opinion of Mr Kazi Abdul Fattah.

P.T. Otsuka, Indonesia

Peri soln. 1000ml  
(peritoneal dialysis soln.)

Referred to Prof. Motiur Rahman for opinion whether import of such bulk product is required/economic.

Green Cross, Japan

HB-Vaccine  
(precipitated hepatitis B vaccine;  
200mcg/0.5ml vial of HBs Aq protein)

Approved.

Hoechst, W. Germany

Anti Rabies vaccine from purified chick embryo.

Approved.

Zdravlje-Leseovac, Yugoslavia

Sterile Disposable syringe & needle

Approved.

4. Miscellaneous:

*Rd* i) It was observed that M/s Chemist Lab, Barisal and M/s Oponin Lab, Barisal are marketing Hyoscine Butylbromide injection in ampoules of 5ml having strength as 20mg/ml. In view of the fact that the only recommended packsize of the product is 20mg/ml in ampoule of 1ml, and no higher packsize is mentioned on any pharmacopoeia or reference books, the Committee recommended for the cancellation of the permission to manufacture and market the 5ml ampoule packsize of the drug as such high amount in a single dose may lead to toxicity and overdose. However the firms may only sell the existing finished product stock to hospital and clinics only.

ii) M/s Jayson Pharmaceutical applied for reconsideration of the recipe of Vitafort inj (thiamine HCl 100mg+riboflavine 5-phosphate +pyridoxine HCl 100mg/2ml ampoule). The Committee reviewed their prayer and approved the recipe as similar formulation is available in the market. *10 mgm*

contd.... 4

*b*

*Ward*  
*5/20/80*

i) The Committee recommended for restriction of import of the raw materials - tioconazole and bacampicillin of M/s Pfizer, due to their high price in comparison to similar available raw materials.

In view of the firm's prayer for review of the decision stating that bulk cost of these products will be less than that of similar available products, the Committee recommended that tioconazole may be allowed to be imported upto 15kg per year in the present circumstances and bacampicillin may be allowed to be imported upto 100kg per year.

iv) As reported by the WHO, the FDA (USA) has withdrawn various brands of Cyclocladate and pentaerythritol tetranitrate (PETN) due to lack of substantial evidence of effectiveness. In view of the information the Committee recommended for cancellation of registration of the following brands of Cyclocladate:

Brand	Manufacture
Cyclobral cap	Norgine Ltd, UK
Venala cap	Mochida, Japan.

As for PETN, the matter was referred for opinion to Prof. S.G.M. Chowdhury, Brig. Malek, and Prof. Abu Zafar for their opinion.

*Prof. M.A. Rashid*  
*Prof. N.A. Manna*  
*DR Nabr Alam*

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

*Alam*

*Walla*  
*5/2/86*

Minutes of the 123rd meeting of the Drug Control  
Committee held on 5.3.1986.

The 123rd meeting of the Drug Control Committee was held on 5.3.86 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.

1. Prof. Mofazzal Hossain,
2. Brigadier Anis Waliz,
3. Mr. Kazi Abdul Fattah,
4. Dr. Humayun K.M.A. Hye

Proceedings & decisions.

1. The minutes of the 122nd meeting were confirmed.
2. Matters arising out of the minutes of the last meeting:  
The prayer about registration of Alveita GmbH, West Germany which were referred to Mr. Kazi Abdul Fattah for opinion was discussed. In this connection a representation of Bangladesh Aushad Shilpa Samity was also discussed. It was decided that opinion of the Director, Directorate of Livestocks Services should also be obtained about the products (itemwise) for confirmation as to whether such drugs are really needed by their Directorate. Decision about these drugs were deferred till such opinion was received and checking of all papers completed by the concerned member.
3. The following recipes of import substitute drugs were placed and decisions taken are as described below:

Opsonin, Barisal.

Orisol Infusion  
(Dextran 40 + Sodium  
Chloride + Potassium  
Chloride + Sodium lactate)

Kept pending for inspection report  
and marketing of ordinary I.V. fluids.

Plasma substitute  
(polygeline + sodium  
chloride + Potassium  
chloride + calcium).

-do-

Dextrose Intravenous infusion 5%

Approved with condition to give  
indication as per BNF & use Dextrose  
injectable grade.

Normal Saline

Approved with condition to use sodium  
chloride injectable grade.

Sodium Chloride and  
Dextrose  
(intravenous infusion) 9% + 5%.

Approved with condition to use the  
active ingredients of injectable grade  
and give indication as per BNF.

Contd.....F/2.

*[Handwritten signatures and initials]*

4. The following other recipes were placed and decision taken are as described below:-

Mukti, Dhaka.

Amocil cap. Rejected for lack of facilities.  
(amoxycillin)  
Vitanol cap. Rejected for lack of facilities.  
M-Phenical cap. Rejected for lack of facilities.  
(chloramphenicol)

Oasis, Serajgonj.

Reboflavin tab. 5mg Approved.  
Oasidine tab. The recipe may be resubmitted as film  
(cimetidine) coated tablet after Creating film  
coating facilities.  
Amoxcis cap. The recipes may be resubmitted after  
(amoxycillin 250mg) creating proper facilities for quality  
control and production.  
Chloramasis cap. -do-  
(chloramphenicol 150mg)

Standard Chemical, Dhaka.

Inj. Calcium Gluconate 10% Approved with condition to ensure  
pyrogen testing before licensing.

National, Dhaka.

Rompazid-300mg Cap. With-held pending implementation of  
(refampicin 300mg the recommendation of the inspection  
+ isoniazid 150mg) team.  
Bacampicillin tab. 400mg -do-

5. Prayer for import registration of the following recipe was placed and discussed. Decision taken are as below:-

Ciba-Geigy, Switzerland.

Sicorten Plus Cream Approved.  
(halometason  
+ triclosan)

6. Miscellaneous.

- a) The Committee agreed to the suggestion that from now on ~~and~~ information like "date of manufacture" and "date of expiry" to be specified on the packing materials of all registered biological products. The expiry date for each product may be determined on the basis of the stability study performed by the manufacturer in their own quality control laboratory. The firms will be allowed one year time (upto March 1987) to meet this requirement for all their existing biological products.

Contd....E/3.

*M. J. Khan*  
12/10/86

*BY*

6. (b) Recipes of warmin tab. (levamisole), <sup>(antacid) & Paralyjin tab. of</sup> Gastromex tab (paracetamol) of Greenland, Dhaka were approved by the committee on 19.2.86 with condition to change name. In view of the fact that the firm is already marketing the liquid form of these products under the brand names as <sup>proposed</sup> the committee reviewed their earlier decision and allowed the same names for their similar tablet products to keep uniformity.

The meeting ended with vote of thanks to the chair.

Read and Confirmed  
M. J. Islam  
12/2/86

WZ

Minutes of the 124th meeting of the Drug Control Committee.

The 124th meeting of the Drug Control Committee was held on 12.3.1966 at 11.30 a.m. in the chamber of the Director, Drug Administration. As Prof. Waliullah, the chairman of the committee was busy with some urgent work, Prof. A. Jabbar presided over the meeting.

The following other members attended the meeting.

1. Prof. Mofazzal Hossain
2. Brigadier Anis Wajid
3. Dr. Imayun K.M.A. Iye.

Proceedings and decisions.

1. The minutes of the 123rd meeting were confirmed.
2. The following recipes of essential drugs which were kept pending earlier for inspection report were placed and decision taken are as follows:-

Firms/Brands.

Decisions.

General Pharmacy, Dhaka.

Ganabiol emulsion  
(benzyl benzoate 25%)

Approved.

✓Virofol capsule  
✓Ferrous fumarate 200mg  
+ folic acid 200mcg

Approved ✓

Metrion liquid  
(benzoyl metronidazole  
6.4g/100ml)

Approved with condition to delete tartrazine colour and mention veegum, hipagin and hipacol in generic form. Alternate colour may be approved by DDA.

Orion, Dhaka.

Water for inj. BF, 5ml.

Approved with condition to procure a milli-pore filter, ensure proper pyrogen testing facilities and reconfirm the entire facilities by another inspection before licensing.

C. sis, Sirajganj.

Casipam tablet  
(diazepam 5mg)

Approved with condition to give indication as per BNF.

Casipam tablet 5mg  
(diazepam 5mg)

Approved with condition to give indication as per BNF.

Propacis tab.  
(propranolol Hcl 40mg)

Approved with condition to give indication as per BNF.

Propacis tab.  
(propranolol Hcl 10mg)

-do-

Metrocic tab.  
(metronidazole 400mg)

Approved ✓

Contd.....1/3.

Waliullah  
2/17

A. Jabbar  
2/17

Firms/Brands.Decisions.Gasis, Sirajgonq.

Approved.

Oastrin tablet.  
(cotrimoxazole 80mg&400mg)Parasis tablet  
(paracetamol 500mg)Approved with condition to change name to  
'Paracetamol tablet'Diassis tablet  
(glibenclamide 5mg)

Approved.

Griosis tablet  
(griseofulvin 125mg)Kept pending till marketing of the other  
approved tablet and capsule products.Oasipan tablet  
(hyoscine butyl bromide 10mg)

Approved.

Decasis tab.  
(dexamethasone 0.5mg).Kept pending till marketing of the other  
approved tablet & capsule products.Alusis tab.  
(Antacid)Approved with condition to change strength as  
aluminium hydroxide dried gel 500mg + magnesium  
hydroxide 250mg per tab. and conform to the USP  
specification in respect of microbial test.Standard Chemical, Dhaka:Injection Atropine Sulphate  
0.1%, 1ml.  
Water for injection B.P., 5ml.

Approved.

Approved with condition to procure a millipore  
filter, ensure better pyrogen testing facilities  
and reconfirmation of the entire facilities <sup>by</sup>  
an/ inspection before licensing.Skylab, Comilla.Methyl Ergometrine Maleate  
Sugar Coated tablet, 0.2mg.The recipe may be resubmitted with proper formula,  
for sugar coated tablet after creating sugar  
coating facilitiesMukti, Dhaka.Diazepam-M tablet  
(diazepam 5mg)Approved with condition to omit lactose and  
adjust quantity of starch.Riboflavin-M tab.  
(riboflavin 5mg)Approved with condition to delete lactose and  
adjust quantity of starch.Histamin tablet  
(Chlorpheniramine maleate 4mg)Approved with condition to omit lactose and  
adjust quantity of starch.Fero-F tab.  
(ferrous fumarate 200mg  
+ folic acid 200mcg.)

Approved.

Vitamin B1 tab. 100mg

Approved.

Contd.....F/3.

Walled  
24/86F. J. J. J.  
24/86

Firms/Brands.

Decisions.

3. The following other recipes of essential drugs were also placed and decisions taken are as follows:-

Gonoshasthaya, Dhaka.

G-Benzyl Penicillin Inj. (5lac)  
(0.5 million unit)

Approved with condition to delete 'five million unit'. <sup>Correct</sup> for 0.5 million unit

Unique, Dhaka.

U-Cillin cap.  
(ampicillin 250mg)

Kept pending for inspection report about suitability of the premises and proper facilities for production and quality control.

Tetracline cap.  
(tetracycline 250mg)

-do-

Cloxillin cap.  
(cloxacillin 250mg)

-do-

U-V Forte capsule

-do-

M. H. Chemical, Dhaka.

Compain syrup  
(paracetamol)

Kept pending for inspection report of the new premises.

-do-

Efergon syrup.  
(promethazine)

-do-

Iron syrup  
(ferrous sulphate)

-do-

Elizol susp.  
(benzoyl metronidazole)

-do-

Benzemul Emul.  
(benzyl benzoate)

-do-

Efercin syrup.  
(chlorpheniramine maleate)

-do-

Whitfield's oint.

Beximoc, Dhaka.

Glibenclamide tablet 5mg.

Approved with condition to mention povidone and avicel in generic form.

-do-

Glibenclamide tab. 2.5mg

Glaxo, Chittagong.

Neo-Naclex tablet  
(bendroflumazide 5mg).

Approved with condition to mention aerosil in generic form.

Bengal Research, Barisal.

Spadis tab.  
(hyoscine butyl bromide 10mg)

Approved with condition to delete lactose and adjust quantity of starch.

City Pharmaceuticals, Ctg.

Metronidazole liquid.  
(benzoyl metronidazole 6.4g/100ml)

The recipe may be resubmitted with detail information about indication and dosage and in correct form.

*Waller*  
2/4

*Shilpa*  
2/4

Firms/Brands

Decisions.

Eureka, Chittagong

Skitex oint.

Approved with condition to change name and give indication as per EMF. (skin infection due to Tinea species).

Escabigo liquid  
(benzyl benzoate 25%)

Approved.

Medicon, Dhaka.

Ironin syrup.  
(Ferrous Gluconate)

*Change name.*

The recipe may be resubmitted adding an antioxidant and reducing unnecessary excipient.

Fisons, Dhaka.

Figenta 80mg inj.  
(gentamicin So<sub>4</sub> 80mg/2ml amp.)

Approved. ✓

Figenta paediatric inj. 20mg  
(gentamicin So<sub>4</sub> 20mg/2ml amp)

Approved.

Figenta oint 0.3% w/w  
(gentamicin So<sub>4</sub>)

Approved.

Figenta Eye/Ear drops 0.3%  
(gentamicin So<sub>4</sub> 0.03g/10ml bottle.)

Approved.

Bexinco, Dhaka.

Propranolol Hydrochloride tab. 10mg

Approved.

Propranolol Hydrochloride tab. 40mg.

Approved.

Chemice, Jessore.

Multivitamin drops.  
in 15ml bottle  
(vitamins A 10 IUC unit +  
D2 11 IUC unit + B<sub>1</sub> 400mg +  
B<sub>2</sub> 200mg + B<sub>6</sub> 200mg  
+ nicotinamide 1g +  
ascorbic acid 5g per 100ml.)

Approved.

Skylab, Coimbatore

Benzyl Benzoate emulsion  
25%.

Approved.

Hoechst, Ctg.

Amblesin 500mg tab.  
(ampicillin 500mg)

Approved.

Bexinco, Dhaka.

Rifampicin cap. 450mg

Approved with condition to give indication and dosage as per WHO standard and delete trihydrate

Rifampicin cap. 150mg

-do-

Pyrazinamide tab. 500mg

Approved with condition to omit overage.

Isoniazid tab. 300mg

Approved.

Ethambutol Hydrochloride  
Tablet. 400mg

*Waller 214*

Approved with condition to delete overage and that chloroform<sup>a</sup> which will not appear in final product.

*Waller 214/86*

City Pharma, Etc.

Whitfield oint.

Approved with condition to give indication  
as per BNF.

Femoglobin liq.  
(ferrous gluconate 6,6)

Approved.

C-Antiseptic cream 1%  
(chlorhexidine gluconate solution)

Approved.

Hydrocortisone ointment 1%

Approved with condition to give indication  
as per BNF.

The meeting ended with vote of thanks to the chair.

*Waller*  
*2/4/88*

*[Signature]*  
*2/4*

Minutes of the 125th meeting of the Drug Control Committee.

The 125th meeting of the Drug Control Committee was held on 2.4.1986 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,  
Brigadier Anis Waiz  
Mr. Kazi Abdul Fattah  
Dr. Humahun K.M.A. Hye.

Proceedings and decisions.

1. The minutes of the 124th meeting were confirmed.
2. The following recipes of import substitute drugs were placed and decision taken are as follows:-

Firms/Brands

Decisions.

Opsonin, Barisal.

Opsovit Inj.  
(thiamine HCl 250mg + riboflavin sodium phosphate 27.4mg + pyridoxine HCl 30mg + nicotinamide 500mg + calcium -d-pantethenate 25mg per 10ml. vial).

Approved.

*→ in 2 ml only  
Waliullah*

Metecel inj.  
(metoclopramide hcl 10mg per 2ml. amp.)

Approved with condition to give indication as per BNF.

Orion, Dhaka.

Steritab tab.  
(sodium dichloroisocyanurate 17mg)

Approved.

K.D.H. Lab. Dhaka.

Neviron cap.  
(nalidixic acid 500mg)

Approved with condition to replace 'mannitel' by 'starch' in excipient and '8 capsules' by '2 capsuls' in dosage.

Albert David, Dhaka.

Vitamin A cap.  
(dry vitamin A acetate = 50,000 iu.)

*Composition of Cocebur*  
Approved with condition to delete lactose and disodium edetate from excipient, give indication as 'vitamin A deficiency states' and dosage as per BNF. *← granules to be*

Sorbide Nitrate tab. 5mg, Sublingual.  
(diluted isosorbide dinitrate)

Approved.

Sorbide nitrate tab.  
10mg, oral.

Approved.

Xylometazoline nasal drops

Kept pending for further checking of formulas with other similar products.

*Confidential  
Waliullah  
9.4.84*

Firms/Brands

Decisions.

Drug International, Dhaka.

Arovit Soft Capsule  
(vitamin A 50,000 i.u.)

Approved with condition to change name,  
give indication as 'vitamin A deficiency  
states and dosage as per BNF.

GeneshastraYa, Dhaka.

G-Dipyridamole inj.  
IV, 5mg/ml in 2ml-amp.

Kept pending for comments of Brigadier  
Malek of ICWD.

G-Dipyridamole tab. 25mg.

Rejected because of low strength.

G-Dipyridamole tab. 100mg

Approved.

S K & F, Dhaka.

Tagamet F/C tab.  
(cimetidine 200mg)  
*Opserin, Parisal*  
Pyrantin tab.  
(dipyridamole 100mg)

Approved.

Pyrantin tab. 25mg.

Approved with condition to give indication  
as per BNF.

Rejected because of low strength.

Fisons, Dhaka.

Amizide tab.  
(hydrochlorothiazide 50mg  
+ amiloride HCl 5mg)

Approved.

I.C.I., Dhaka.

Kemadrin tab.  
(procyclidine HCl 5mg)

Approved with condition to manufacture  
the product with their own brand name  
without any 3rd party licensing agreement.

City Pharmaceuticals, Ctg.

Metazel nasal drop  
(xylometazole HCl, 100mg)

To Resubmit with correct formula.

Fenorine nasal drop  
(phenylephrine hcl. 25mg/100mg  
in 15ml. bottle).

Approved with condition to market in  
sealed sterile pack.

Pfizer Lab., Dhaka.

Cloxiject IM/IV inj.  
(cloxacillin Na sterile 500mg/vial)

Approved

Cloxiject IM/IV inj. 250mg.

Approved.

Terramycin ~~10mg.~~ *long*  
~~Acting~~ injectable solution  
200mg/ml. vet.

Approved.

3. Miscellaneous:-

a) The Committee considered prayer of Squibb dt. 1.4.86 about their request to  
market two strengths of Valiol tab. (325mg & 500mg). It was decided not  
to approve two different strengths of paracetamol tablets to be manufactured  
by one company to avoid confusion among the consumers, especially because -

*Confirmed*  
*W. S. Ahmed*  
*9.4.86*

*Pres. Contd. .... P/3.*

it is an ~~OTC~~ OTC (over the counter) category drug. So if the firm wanted to manufacture and market the 500mg tablet of Valadol they have to withdraw their 325mg tablet.

- b) It was decided that the chairman and some members of the Committee will meet the representatives of the Bangladesh Association of Pharmaceutical Industries on 9.4.86 at 1 P.M. to discuss about matters of mutual concern as per request of the Association.

The meeting ended with <sup>a</sup>vote of thanks to the chair.

Read & Confirmed  
M. J. Akbar  
9.4.86  
Conf'd  
Walled  
9.4.86

Minutes of the 126th meeting of the Drug Control Committee

The 126th meeting of the Drug Control Committee was held on 9.4.86 at 10.30 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  
Brig. Anis Waiz  
Dr. Md. Jahangir  
Dr. Humayun K.M.A. Hye

Proceedings & Decisions

1. The minutes of the 125th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting.
- a) It was observed by the Committee that Dr. Monwara Binte Rahman, Prof. A.T. Siddique and Prof. Syeda Feroza Begum could not attend the meetings of the Drug Control Committee regularly because of their involvement in discharging other important official duties. Also Prof. Feroza Begum has recently retired from Government services.

Under the circumstances the Committee felt that the Chairman and the Member-Secretary will meet the Secretary, Ministry of Health & Family Planning for his opinion and reorganisation of the Committee for ~~getting~~ having proper representation of specialists like Surgeons and Gynaecologists & Obstetricians.

- b) In view of the request of the Bangladesh Aushad Shilpa Samity (BASS) to postpone the meeting between the Chairman, DCC and the representatives of BASS, scheduled to be held on 9.4.86, the Committee decided to fix a date later on a mutually convenient date.
3. The following resubmitted recipes were placed and decision taken are as follows.

<u>Firms/Brands</u>	<u>Decisions</u>
<u>Pharmaco, Dhaka</u>	
Benamine syrup (diphenhydramine HCl 0.2%)	Approved with condition to give indication as per BNF and amend name as 'Benamin'.
Gastrovet (vet) powder	Kept pending for Mr. K. A. Fattah.
<u>Cosmic, Dhaka</u>	
Cosmic Vaporub oint.	Approved. <i>- approved with recommendation by Mr. K.A. Fattah 16.4.</i>
Iodol oint.	Approved.
<u>Glaxo, Chittagong</u>	
Pholcodine syrup 0.1%	Approved.
<u>Skylab, Comilla</u>	
Copex syrup (noscipine 0.3%)	Approved in generic name only and if no other antitussive is given earlier.
Benzyl benzoate emulsion 25%	Approved.
<u>Cipla, Bogra</u>	
Rub oint.	Approved with condition to change name, amend indication deleting 'for nasal inhalation', and declare Eucalyptus oil & Terpene oil as active ingredients.
<u>National, Dhaka</u>	
Evinal tab 100 mg (DL-tocopherol acetate <i>solid granules</i> )	Approved. <i>Congdon 16.4.86 contd p 2.</i>

4. The following recipes which were referred for opinion earlier were placed with the opinion and decision taken are as follows:

ICI, Dhaka

Corsodyl Mouthwash 1% Approved with condition to market in 100ml pack size only and give warning to indicate short time use only not exceeding one week.

Gonoshasthaya, Dhaka

G-Benoxinate eye drops 0.4% Approved with condition to indicate for use of specialist only.

5. The following other recipes were placed and decisions taken are as follows:

Azad, Dhaka

Germox susp. (mebendazole 2%) Approved with condition to change name.

Vixorub oint. (vaporub) To resubmit as per standard formula approved.

Dithra oint. (dithranol 0.1%) Approved with condition of availability of facilities supported by inspection.

Aldrate susp. (magaldrate) Rejected because not required.

Orion, Dhaka

Chloramphenicol cap, 250mg Approved with condition to give caution, contra-indication and side-effect as per BNF.

Pancreatin cap. 325mg Approved.

Medicare, Dhaka

Cimetidine tab. 200mg Kept pending till shifting to new premises.

Opsonin, Barisal

Refanin syrup (rifampicin 2%) Approved with condition to give indication 'for tuberculosis and leprosy only', amend dosage accordingly; and show overage separately.

Metocol syrup (Metoclopramide HCl) Approved with condition to give indication as per BNF, strength as 100mg/100ml, and delete overage.

Emogel sachet (Ishapgula husk) Approved.

Flammadin cream (Silver sulphadiazine 1%) Approved with condition to give in larger pack sizes as per BNF.

Moxin paed. drops (amoxicillin 100mg/ml) Approved with condition to give calibrated droppers to measure 1.25ml, 1ml & 0.65ml.

Cetrin antiseptic soln. (cetrimide + chlorhexidine) Approved.

Cetrin Hospital concentrate Approved.

Fisons, Dhaka

Peps Mouthwash (chlorhexidine gluconate soln. 1%) Approved with condition to market in 100ml pack size only and give warning to indicate short time use only not exceeding one week.

Acme, Dhaka

Suprapen cap (bacampicillin HCl 400mg) Approved.

Suprapen dry syrup 200mg/5ml Approved.

Tenoloc cap (atenolol 50mg) Approved.

Bentum cap (benzylamine HCl) Kept pending for ~~one week~~ 1/3.

*Confidential*  
*Wadd*  
*18/11/80*

*Cap - follow up with all cap. every apply for tablet for 18/11/80*  
*Cap - not approved for 18/11/80*  
*take up with 200mg/5ml 2 oral dose from 1/3.*  
*18/11*

Temophen cap (acetaminophen 325mg) Rejected because only one strength (500mg) will be allowed.  
Temophen cap 625mg -do-  
Fluxin cap 250mg (flucloxacillin sodium) Approved.  
Fluxin dry syrup 125mg/5ml Approved.  
Oxycome-M tab (magaldrate 1000mg) Rejected because not required.

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

Alvetra gmbh, West Germany

44 veterinary products Kept pending for the opinion of Director, Livestocks and Mr. K.A. Fattah.

Schering AG, W. Germany

Ultravist 240, 300 & 370mg/ml iodine/ml inj. (iopromide) Referred to Prof, Maksudur Rahman of DMC for opinion.

Neo-Ultraproct cream (1mg fluocortolone pivalate + 20mg lidocaine HCl + 10mg chlorquinaldol per g) Approved.

Neo-Ultraproct suppository (1mg fluocortolone pivalate + 40mg lidocaine) Approved.

Chemische Fabric Rottendorf, W. Germany

Diclofenac tab 25mg & 50mg Rejected because not required *any m/c*

Squibb, Greece

Modecate inj 25mg/ml Rejected because same brand of other sources registered.

Kenacort A IM inj 40mg/ml -do-

Velosef inj 500mg -do-

Ayerst, USA

Isordil tembide cap. sustained release (isosorbide dinitrate 40mg) Rejected because not required.

Farmaitalia, Italy

Pharmarubicin inj IM vial (epirubicin HCl 10mg, 50mg) of DMC for opinion.

Astra, W. Germany Sweden

Marcaine inj (bupivacaine) Approved.

Marcaine + Adrenaline inj Kept pending for further study.

7. Miscellaneous.

- a) The prayer of Square dated 16.1.86 for review of their Rifazid 225 tab recipe was considered. The Committee upheld their earlier decision and rejected the review prayer of the firm.
- b) The Committee cancelled the registration of Serpasil ampoules of Ciba-Geigy, Switzerland as the drug has been withdrawn by the firm from the market world wide. However the use of the existing stock of the drug has been allowed upto June 1987.

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

*Confirmed*  
*Wald*  
*18/4/88*

H. W. ...  
Parasitology

11.08.1986

Minutes of the 127th meeting of the Drug Control Committee

The 127th meeting of the Drug Control Committee was held on 16.4.86 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:

1. Brigadier Anis Walz
2. Mr. Kazi Abdul Fattah
3. Dr. Md. Jahangir,
4. Dr. Humayun K.M.A. Hye.

Proceedings and Decisions.

1. The minutes of the 126th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting.
  - a) The Committee referred to their earlier decision on Vitamin B-Complex Injection taken in the 119th meeting of DCC held on 1.1.86 and observed that Vitamin B-Complex inj. should be available in 2-ml unit dose packsize only. This will prevent misuse and contamination associated with the ~~Committee~~ Multidose vials. In this connection the Committee also observed that all Multidose vials registered or under approval will be converted to 2-ml within a year. This will be circulated to all concerned for necessary action.
  - b) The committee further observed that because of the sophisticated nature and importance of stability of vitamins in injectable form it is important that the multinationals continue to manufacture Vitamins either singly or as Vitamin B-Complex excluding vitamin B12 in injectable form only. This can only allow the country from importing vitamin B-complex or other injectable vitamins saving hard earned foreign currency. *to be kept self sufficient in Vitamins*
3. The following recipes of essential import substitute drugs were placed and decision taken are as follows:

Firms/Brands

Decisions.

Jayson, Dhaka.

Injection Orabex  
(thiamin HCl 250mg + riboflavin-5-phosphate sodium 20mg + Pyridoxine HCl 50mg + nicotinamide 500mg + d-panthenol 25mg per 10ml vial).

Approved with condition to market 2-ml ampoule only, amend the formula for such packsize and give indication as per BNF.

4. The following resubmitted recipes were placed and decision taken are as follow.

Doctor's, Bogra.

Haemodin susp.  
(ferrous fumarate 4%)

Approved with condition to indication in 'iron deficiency anaemia' only give warning as, 'keep out of reach of children, delet 114 ml. packsize and use parabens as sodium salt.

Pressin tablet  
(propranolol HCl 10mg)

The firm may resubmit the recipe along with that of ~~for~~ 40mg tab.

Dactone tab.  
spironolactone 25mg)

Approved.

Contd...P/2.

Approved  
W. S. ...  
23/9/86

Seema, Dhaka.

Seemaplex sugar coated tab.  
(thiamine HCl 5mg  
+riboflavin 2mg +pyridoxine Hcl 2mg.  
+ nicotinamide 20mg)

Approved.

5. The following other recipes of essential drugs were placed and decision taken were as follows:

Square, Pabna.

Cetamol drops  
(paracetamol 10%)

Rejected because not required.  
*Similar other drugs are available in the market.*

S.K. & F., Dhaka.

Fefol Spansule capsule  
(dried ferrous sulphate  
+folic acid)

Rejected because folic acid does not needed in time-release product.

Feospan Spansule capsule  
(dried ferrous sulphate 150mg)

Approved conditionally for one year to be manufactured with imported banded sustained release pellets/granules within which period the firm must develop technology of preparing ~~xxxxxx~~ sustained release pellete locally failing ~~which~~ which the product will be deleted from the licence. It was observed that all approval of recipe of SK&F are based on that the firm will shift ~~by~~ their factory premises to an industrial area by November 1986.

Suscopan film-Coated tab.  
(Hyoscine butyl bromide 10mg)

Approved with condition to change name delete overage, ~~xxxxxxx~~

Cosat tab.  
(cotrimoxazole (400mg +  
80mg)

Approved.

~~Rifampicin 300mg cap. SK&F Company, Dhaka~~  
(Refatan-300 cap  
(rifampicin 2%) 300mg)

Approved.

G.A. Co, Dhaka.

Refatan-300 cap  
(rifampicin 300mg)

Approved.

Refatan susp  
(rifampicin 2%)

Approved

Gonoshathaya, Dhaka.

G-Aspirin tab.  
(paediatric) 60mg dispersible,

Approved.

G-Chloramphenicol eye oint.

Approved with condition to use sterile raw material, market in sealed sterile pack and give warning as per BNF.

Dhh Sina, Dhaka.

Thiosina tab.  
(thiamine HCl 100mg)

Approved.

Ampicina dry syrup  
(ampicillin trihydrate 2.5%)

Approved.

Contd...F/3.

*Handwritten notes:*  
23/4/86

6. Import.

The Committee considered the application of M/s. Bichitrita Trading Company for registration of the following Veterinary products manufactured by M/s. Alvetra GmbH, West Germany. In this connection the opinions of the Director, Livestocks Services, Mr. Kazi Abdul Fattah, Deputy Director, Livestocks Services and member, Drug Control Committee, as well as, the representations of Bangladesh Aushad Shilpa Samity dt. 3.3.86, & 5.3.86, Bangladesh Pharmaceutical Industry Ltd dt. 5.3.86 & 7.4.86 Pfizer Laboratories (BD) Ltd at 12.3.86 were taken into account.

Decisions taken are shown below:

<u>Firms/Brands</u>	<u>Decisions.</u>
<u>M/s. Alvetra GmbH, West Germany</u>	
1. Mucocit Solution 1 ml. contains: 100mg Tolnaftate	Approved
2. Trichlorfon 95% 1 g contains: 950mg Trichlorfon	Approved
3. Plastisan Forte Disodium arseno acetate 5% sterile solution	Approved
4. Xylapin (Xylazine 2% solution)	Approved
5. Mesulphon 1 ml. contains: 100mg Mesulphen	Approved
6. Cvo-Gonaden 500 + E (Cily suspension of H.C.G. 500 I.U. + 10mg vit. E)	Approved.
7. Dipsol powder 1 g contains: Metriphosphate	Approved
8. Alvemint 10% powder 1 g contains: 100mg Oxibendazole	Approved.
9. Metaphosol + B12 1 ml contains: 100mg Toldimphos sodium 50mg Vitamin B12	Approved.
10. Biter-Chloramphenicol Syringes 1 syringe contains: 175,000 I.U. Procain Penicillin G 175,000 I.U. Dihydrostreptomycin 1,000 mg Diaphenylsulfone 1,000 mg Sulfanilamide 500 mg Chloramphenicol 200 mg Nitrofurazone 60 mg Sulfapyridine	Approved
11. Penicillin pure 1 vial contains: 2,000,000 I.U. Penicillin G Procaine 2,000,000 I.U. Penicillin G Sodium	Approved.

*moved*  
*Waller*  
*23/4/86*

12. Oxycillin -tablets Approved.  
1 tablet contains:  
800mg Oxytetracycline  
hydrochloride
13. Oxycillin 5% Approved.  
1 ml contains: 50mg  
Oxytetracycline hydrochloride
14. Oxycillin 20% LA Approved  
1ml contains: 200mg  
Oxytetracycline hydrochloride.
15. Morantel Citrate Soluble Powder Approved.  
1 g contains: 120mg Morantel Citrate.
16. Hexachlorophene Approved  
Contains: 1000 mg  
Hexachlorophene
17. Trizine Bolus Approved  
1 bolus contains:  
80mg Trimethoprim  
400mg Sulphadiazine
18. Piperazine Adipate 19% Powder Approved
19. Gamma BHC powder 19% Approved.  
1 g contains: 190mg gamma BHC
20. Fascet injection 1 ml. Approved  
contains: 40mg Niclofolan
21. Disulfin Bolus Approved  
1 bolus contains:  
150mg Dichlorhydroxyguinoline  
3,000 mg Sulphanilamide  
1,000 mg Sulphayridine
22. Sulphadimidin Tablet Approved.  
1 tablet contains:  
3500mg Sulphadimidine sodium
23. Sulphadimidine 33% injn. Approved  
1 ml contains: 330mg  
Sulphadimidine sodium.
24. S.S.T. Approved.  
1 ml. contains: 40mg  
Trimethoprim, 100mg  
Sulfadoxine sodium, 100mg  
Sulphadiazine sodium.
25. Glucophone 24% Approved.  
100ml contains:  
24,000 mg Calcium Gluconate  
1,000 mg Sodium Glycerino-  
phosphoricum  
5,000 mg Magnesium chloride  
3,500 mg Boric acid  
200mg Manganese chloride  
20 mg Cobalt chloride  
4 mg Nickel chloride  
0.8 mg Copper Sulphate
26. Ampivet 10% Approved.  
1 ml contains: 100mg  
Ampicillin trihydrate

15/10  
SALD  
23/4/54

26. Mastitis syringe 500,000 Approved.  
 1 syringe contains:  
 400,000 I.U. Procaine  
 Penicillin G  
 100,000 I.U. Dihydrostreptomycin sulphate
27. Precillan forte Approved.  
 1 ml contains: 150,000 I.U.  
 Procaine penicillin G  
 150,000 I.U. Benzathine penicillin.
28. Oxytocin Approved.  
 1 mle contains: 10 I.U.  
 Oxytocin
29. Prednisolon 1 ml contains Approved.  
 Prednisolone 7.5 mg +  
 Dexamethasone trimethylacetate  
 2.5 mg
30. Sulfapylocin  
 1 ml contains:  
 250mg Sulphamethoxypanidazine sodium Approved.
31. S.T.40 1 g contains: Approved.  
 Sodium sulphachloropyridazine  
 200 mg + Trimethoprim 40mg
32. Sulfaclozine Powder  
 1 g contains: 300mg Approved  
 Sulphadimidine sodium
33. Respal:  
 1 ml contains: 75mg N.N.-Dimethyl-2-N  
 acetylcrotonamido-butyramide Approved.
34. Duosulf powder 1 g contains. Approved.  
 200mg 2-Sulphanilamidothiazole +  
 500mg 2-Formosulphanilamido Thiazole.
35. Vebenzan  
 1 ml. contains: <sup>2</sup>30mg *Tripelenamine*  
 Hydrochloride <sub>mg</sub> Approved
36. Vetisol  
 1 ml contains: 50mg Approved.  
 Hydrochlorthiazide
37. Fascet tablets  
 1 tablet contains: 150mg Approved  
 Niclofolan
38. Alvemint Boluses Approved.  
 1 Bolus contains: 400mg  
 Oxibendazole
39. Oxycillin tablet Approved. *duplicate with SL.N.C.12*  
 1 tablet contains;  
 500mg Ox ytetracycline hydrochloride
40. Alvemint 70% Rejected.  
 1 g contains: 200mg Levamisole Hydrochloride  
 500mg Piperazine Citrate.
41. Tripelsulf plus bolus Rejected.  
 Each bolus contains:  
 700mg Sulphadiazine  
 700mg sulphamerazine  
 700mg Sulphapyridene  
 500mg Streptomycin base

Contd...P/6.

42. Tripelsulf bolus  
1 bolus contains:  
1,000 mg Sulphadiazine  
1,000 mg Sulphamerazine  
1,000 mg Sulphapyridene  
Rejected

43. Phosol 500  
100ml contains:  
2.75 g Calcium hypophosphite  
~~10.00 g Calcium gluconate x H<sub>2</sub>O~~  
~~6.65 g Glucose x H<sub>2</sub>O~~  
10.00 g Calcium gluconate x H<sub>2</sub>O  
1.60 g Boric acid  
5.00 g Magnesium chloride x 6 H<sub>2</sub>O  
6.65 g Glucose x H<sub>2</sub>O  
Rejected

44. Trichlorfon inj.  
1 ml contains:  
500mg Trichlorfon  
5 mg Atropine Sulphate  
Rejected.

7. Miscellaneous:

In view of the withdrawal of different brands of cyclandelate by US FDA, and opinion of the local experts (Prof. SCM Chowdhury, Prof. M.A. Mannan, Brigadier A. Malik) registration of the following brands of drugs were recommended for cancellation of the registration due to its ~~lack of~~ <sup>devoid of</sup> efficacy.

<u>Manufacture</u>	<u>Brand</u>
Norgine U.K.	Cyclo bral cap (Regn.No. 7-1856-82)
Mochida, Japan	Venala cap. (regn.No. 36-860-77)

The meeting ended with vote of thanks to the chair.

*passed*  
*W. J. ...*  
*23/11/50*

6. Inert.

The Committee considered the application of M/s. Bichtrita Trading Company for registration of the following Veterinary products manufactured by M/s. Alvetra GmbH, West Germany. In this connection the opinions of the Director, Livestocks Services, Mr. Kazi Abdul Fattah, Deputy Director, Livestocks Services and member, Drug Control Committee, as well as, the representations of Bangladesh Aushad Shilpa Samity dt. 3.3.86, & 5.3.86, Bangladesh Pharmaceutical Industry Ltd dt. 5.3.86 & 7.4.86 Pfizer Laboratories (BD) Ltd at 12.3.86 were taken into account.

Decisions taken are shown below

Firms/Brands

Decisions

M/s. Alvetra GmbH, West Germany

- | <u>Firms/Brands</u>  | <u>Decisions</u>  |
|--|---|
| 1. Mucecit Solution<br>1 ml. contains: 100mg Tolnaftate BP   | Approved (1) ✓ <u>Dr. Fazlul Hoque</u> 12/23/84                       |
| 2. Trichlorfon 95%<br>1 g contains: 950mg Trichlorfon B.V.T<br>(substantive)   | Approved (2) ✓ <u>do &amp; Prof. Rahman</u> 12/23/84                  |
| 3. Plastisan Forte<br>Disodium arsene acetate 5%<br>sterile solution   | Approved (3) ✓ <u>do</u> 12/23/84                                     |
| 4. Xylapin (Xylazine 2% solution)  | Approved (4) ✓ <u>do</u> 12/23/84                                     |
| 5. Mesulphen<br>1 ml. contains: 100mg Mesulphen M.P.C  | Approved (5) ✓ <u>Prof. A. Rahman</u> 12/23/84                        |
| 6. Ove-Conaden 500 + E<br>(Oily suspension of H.C.G. 500 I.U. + 10mg vit. E)   | Approved (6) ✓ <u>Prof. A. Rahman &amp; Dr. Fazlul Hoque</u> 12/23/84 |
| 7. Dipsol powder<br>1 g contains: Metriphonate B.V.T M.C   | Approved <del>12/23/84</del>  |
| 8. Alve mint 10% powder<br>1 g contains: 100mg Oxibendazole  | Approved. <del>12/23/84</del>   |
| 9. Metaphesol + B12<br>1 ml contains: 100mg Toldimphos sodium<br>50mg Vitamin B12  | Approved. <u>Prof. A. Rahman &amp; Dr. F. Hoque</u> 12/23/84          |
| 10. Biter-Chloramphenicol Syringes<br>1 syringe contains:<br>175,000 I.U. Procain Penicillin G<br>175,000 I.U. Dihydrostreptomycin<br>1,000 mg Disphenylsulfone<br>1,000 mg Sulfanilamide<br>500 mg Chloramphenicol<br>200 mg Nitrofurazone<br>60 mg Sulfapyridine | Approved (7) ✓ <u>Dr. Fazlul Hoque &amp; Prof. A. Rahman</u> 12/23/84 |
| 11. Penicillin pure<br>1 vial contains:<br>2,000,000 I.U. Penicillin G Procaine<br>2,000,000 I.U. Penicillin G Sodium  | Approved.   |

12. Oxytetracycline - tablets *BP* Approved.  
 1 tablet contains:  
 800mg Oxytetracycline  
 hydrochloride
13. Oxytetracycline 5% *BP* Approved.  
 1 ml contains: 50mg  
 Oxytetracycline hydrochloride
14. Oxytetracycline 20% LA *BP* Approved  
 1ml contains: 200mg  
 Oxytetracycline hydrochloride.
15. Morantel Citrate Soluble Powder  
 1 g contains: 120mg Morantel Citrate. Approved.
16. Hexachlorophene *BP/BPF* Approved  
 Contains: 1000 mg  
 Hexachlorophene
17. Trizine Bolus *BP* Approved  
 1 bolus contains:  
 80mg Trimethoprim  
 400mg Sulphadiazine
18. Piperazine Adipate 19% Powder *BP* Approved
19. Gamma BHC powder: 19% *B v e* Approved.  
 1 g contains: 190mg gamma BHC
20. Fascet injection 1 ml. *BP* Approved (8) ✓  
 contains: 40mg Nicrofolan
21. Disulfin Bolus *BP* Approved (9) ✓  
 1 bolus contains:  
 150mg Dichlorhydroxyquinoline  
 3,000 mg Sulphanilamide  
 1,000 mg Sulphayridine
22. Sulphadimidin Tablet *BP* Approved.  
 1 tablet contains:  
 3500mg Sulphadimidine sodium
23. Sulphadimidine 33% injn. *BP* Approved  
 1 ml contains: 330mg  
 Sulphadimidine sodium.
24. S.S.T. *BP* Approved.  
 1 ml. contains: 40mg  
 Trimethoprim, 100mg  
 Sulfadoxine sodium, 100mg.  
 Sulfadiazine sodium.
25. Glucophene 24% *BP* Approved. (10) ✓  
 100ml contains:  
 24,000 mg Calcium Gluconate  
 1,000 mg Sodium Glycerine-  
 phosphoricum  
 5,000 mg Magnesium chloride  
 3,500 mg Boric acid  
 200mg Manganese chloride  
 20 mg Cobalt chloride  
 4 mg Nickel chloride  
 0.8 mg Copper Sulphate
26. Ampivet 10% *BP* Approved.  
 1 ml contains: 100mg  
 Ampicillin trihydrate

*Prof. A. Rahman*  
*4/23/4*

*Dr. Fazlul Hoque*  
*4/23/4*

*Dr. Fazlul Hoque*  
*& Prof. Rahman 4/23/4*

26. Martitis syringe 500,000  
1 syringe contains:  
400,000 I.U. Procaine  
Penicillin G  
100,000 I.U. Dihydrostreptomycin sulphate

Approved. (11) Dr. Fazlul Hoque  
4/23/4

27. Precillin forte  
1 ml contains: 150,000 I.U.  
Procaine penicillin G  
150,000 I.U. Benzathine penicillin.

Approved.

28. Oxytocin  
1 ml contains: 10 I.U.  
Oxytocin

Approved.

29. Prednisolon 1 ml contains  
Prednisolone 7.5 mg +  
Dexamethasone trimethylacetate  
2.5 mg

Approved.

(12) Dr. F. Hoque  
Prof. A. Rahman  
4/23/4

30. Sulfapylocin  
1 ml contains:  
250mg Sulphamethoxypanidazine sodium

Approved.

(13) Dr. Fazlul Hoque  
4/23/4

31. S.I. 40 1 g contains:  
Sodium sulphachloropyridazine  
200 mg + Trimethoprim 40mg

Approved.

(14) Prof. A. Rahman  
4/23/4

32. Sulfaclozine Powder  
1 g contains: 300mg  
Sulphadiazine sodium

Approved

33. Respal:  
1 ml contains: 75mg N.N.-Dimethyl-2-N  
acetylcretonamido-butyramide

Approved.

(15) Prof. Rahman  
Dr. Fazlul Hoque  
4/23/4

34. Duesulf powder 1 g contains.  
300mg 2-Sulphanilamidothiazole +  
500mg 2-Fermosulphanilamido Thiazole.

Approved.

35. Vebenzan 20  
1 ml. contains: 50mg Tripelenamine  
Hydrochloride

Approved

(16) Dr. Fazlul Hoque  
4/23/4

36. Vetisol  
1 ml contains: 50mg  
Hydrochlorthiazide

Approved.

(17) Prof. A. Rahman  
& Dr. F. Hoque  
4/23/4

37. Fascet tablets  
1 tablet contains: 150mg  
Niclofolan

Approved

38. Alverint Boluses  
1 bolus contains: 400mg  
Oxibendazole

Approved.

39. Oxyillin tablet  
1 tablet contains:  
500mg Ox ytetracycline hydrochloride

Approved.

(18) Prof. Rahman  
4/23/4

40. Alverint 70%  
1 g contains: 200mg Levamisole Hydrochloride  
500mg Iperazine Citrate.

Rejected.

41. Tripelsulf plus bolus  
Each bolus contains:  
700mg Sulphadiazine  
700mg sulphamerazine  
700mg Sulphapyridene  
500mg Streptomycin base

Rejected.

42. Tripalsulf bolus  
 1 Bolus contains:  
 1,000 mg Sulphadiazine  
 1,000 mg Sulphamerazine  
 1,000 mg Sulphapyridine

Rejected

43. Phosol 500  
 100ml contains:  
 2.75 g Calcium hypophosphite  
~~10.00 g Calcium gluconate x H<sub>2</sub>O~~  
~~10.00 g Calcium gluconate x H<sub>2</sub>O~~  
 10.00 g Calcium gluconate x H<sub>2</sub>O  
 1.60 g Boric acid  
 5.00 g Magnesium chloride x 6 H<sub>2</sub>O  
 6.65 g Glucose x H<sub>2</sub>O

Rejected

44. Trichlorfon inj.  
 1 ml contains:  
 500mg Trichlorfon  
 5 mg Atropine Sulphate

Rejected.

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<u>Manufacture</u>	<u>Brand</u>
Norgine U.K.	Cyclo bral cap. (Regn.No. 7-1858-82)
Ichida, Japan	Venala cap. (regn.No. 36-860-77)

The meeting ended with vote of thanks to the chair.