

meeting - 98-136

Minutes of the 98th meeting of Drug Control Committee

The 98th meeting of the Drug Control Committee was held on 5.6.85 at 9 a.m. in the conference room of Dhaka Medical College under the chairmanship of Prof. Waliullah, Professor of Medicine, Dhaka Medical College, Dhaka.

The following members attended the meeting.

1. Prof. A. Jabbar
2. Prof. Mofazzal Hossain,
3. Brigadier Anis Wais
4. Prof. M.Q.K. Talukder
5. Mr. Kazi Abdul Fattah,
6. Dr. Md. Jahangir.

The following decisions were taken in the meeting.

1. Minutes of the 97th meeting was confirmed.
2. The committee decided to modify the Inspection report proforma in next meeting.
3. Prayer of M/S.I.C.I. Bangladesh Manufacturers Ltd., vide letter No. nil dt. 30.5.85 for approval of the formula and the manufacturing process of Propranolol Hydrochloride B.P. basic material was permitted.
4. Prayer of Memorial Christian Hospital vide letter No. nil dt. 28.4.85 for N.O.C. for import of Ketalar Injection (Ketamine Hcl) and Pontacaine Spinal anesthesia (Tetracaine Hcl) was allowed if it is free gift.
5. Memo of M/O. Health & Population Control vide memo No. Dev-1/FVO-20/84/207 dated 13.5.85 requesting for views about import of some drugs for Ram Krishna Mission was placed before the committee. The prayer was rejected by the committee because, "most of the drug are banned. Aspirin and Panacetamol are available in plenty in the country".
accepted as a gift
6. Prayer of B.C.S.I.R. vide letter No. Sectt/PPP/1(209)/8/2174 dated 9.5.85 requesting to know whether toxicity test report of the Institute of Food Science & Technology on Garlic Pearl will be acceptable to the authority, was discussed by the committee. The committee opined that the matter may be considered when such toxicity report is received.
make all lists covered under scientific procedure will be accepted, but the committee reserves the right to reject it as and when necessary
7. Prayer of Export Promotion Bureau vide letter No. EPB/Fairs/P(7)/84 dt. 4.6.85 informing that Malaysia may import large quantity of Garlic capsules and requesting to know whether the Pharmaceuticals Industries of the country can produce the item for export was placed before the committee.

Contd...P/2.

approved
Waliullah
28/6/85

The committee opined that since no Pharmaceuticals Industries has such item in their Manufacturing Licence yet, the question of export of the item does not arise, *at present*

8. It was decided that henceforth the meetings of the committee will be held on every wednesday at 11.30 a.m. in the office chamber of the chairman Prof. Waliullah, Professor of Medicine Dhaka Medical College, Dhaka. *for time being.*
9. It was also decided by the committee that animal feeds (which usually contains hormones, antibiotics and vitamins etc) will fall under the pervue of Drugs.
10. Recipe of Nizoral tablet, 200mg (Ketoconazole) of M/S. Square Pharmaceuticals Ltd. was approved as underlicence drug with M/S. Janssen, Belgum, subject to the condition of approval of Ministry of Industries to manufacture the drug as under licence drug.

The recipe was recommended by Prof. Sale^huddin of Dhaka Medical College.

11. It was decided by the committee that M/S. Opsonin will be allowed to manufacture Opsaline (Oral Rehydration Salt) in 1000 ml. packsize for the time being.

The meeting ended with vote of thanks to the chair.

approved
Waliullah
26/6/65

Minutes of the 100th meeting of the Drug Control Committee held on 3.7.85.

The 100th meeting of the Drug Control Committee was held on 3.7.1985 at 11.30 a.m. in the ~~conference room~~ of the Dhaka Medical College Hospital under the chairmanship of Prof. Waliullah, Professor of Medicine, Dhaka Medical College Hospital Dhaka.

The following members attended the meeting.

1. Prof. A. Jabbar,
2. Prof. A.T.Siddique,
3. Prof. Mofazzal Hossain,
4. Dr. Md. Jahangir.

The following decisions were taken in the meeting.

1. Minutes of the 99th meeting was confirmed.
2. The recipes of the following firms were considered.

A) M/S. Drug International, Dhaka.	i) Dimoxyl drop (Amoxycillin)	Approved.
	ii) Cloxacillin Sodium.	Pending. ✓
	iii) Clomin (Dicyclomine Hcl).	Approved.
B) M/S. G.A. Company.	i) Relactin Cap. (Tolmetin)	Approved. ✓ <i>name</i>
	ii) Tofenal Cap. (Vit. E)	Rejected, cap from not necessary.
C) M/S. Cipla Ltd.	i) Furazolidone Susp.	Rejected, high strength.
	ii) Vit. C syrup.	Rejected, not allowed as M.D.P.
D) M/S. Scientific Drug Ind.	i) Furalin Susp. (Furazolidone)	Approved with change & indication and excipients.
E) M/S. Squibb of (BD) Ltd.	i) Anthel (Mebendazole)	Approved.
F) M/S. Gonoshasthaya	i) G-Thiazide with (Triamterine, Tab)	Approved.
G) M/S. Najat Pharmaco	i) Milk of Magnesia (Mg(OH) ₂) Susp.	Approved & change of excipients. ✓ <i>new formula</i>
H) M/S. Zeman PharmCo.	i) Pyridoxine Tab.	Approved & change of indication.
I) M/S. Globe Ch. Ind.	i) Antomox (Mebendazole)	Approved & change in excipients.
	ii) Furason-K (Furazolidone)	Rejected as high strength and Keolin Pectin not allowed.

Contd...P/2.

Approved
Waliullah
10/7/85

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|-----------------------------------|--|--|
| J) M/S. Albert David
(BD) Ltd. | i) Alcodin Syrup
(Codine phosphate) | Pending, whether they have narcotic licence. |
| K) M/S. National Lab. | i) Enzyphen
(Pancreatin) | Higher strength, name change pending dose schedule to be examined. |
| L) M/S. Square | i) Clofenac
(Diclofenac) | Approved. |
| | ii) Dipantin 25mg
(Dipyridamole) | Rejected, the dose is too small, similar strength will be de-registered. |
| | iii) Clorston 25mg
(Chlorthalidone) | Rejected. Low dose. |
| | iv) Isordin
(Isosorbide Dinitrate) | The use of diluted form to be clarified. |
| | v) B-50 Forte Cap. | Amendment approved. |
| M) M/S. G.A. Co. | i) Calcenate Inj.
(Calcium Panthothenate) | Approved. |
| | ii) Asmalet Sy.
(Theophylline Sod. Glycyrrhizate) | Approved & indication to be changed. |
| N) M/S. Eden Research | i) Codine Phosphate Syrup. | Pending whether they have narcotic licence. |

The meeting ended with vote of thanks to the chair.

*Approved.
Walla
10/7/83*

Registration of *B* Persentin tablet (Reg No. 5-963-77) manufactured by Boehringer C.H. West Germany may be cancelled as it contains 25 mg dipyridamole.

*Walla
24/7/83*

Minutes of the 101st meeting of the Drug Control Committee

The 101st meeting of the Drug Control Committee was held on 10.7.85 at 11.30 A.M. under the chairmanship of Prof. Laliullah, Professor of Medicine, Dhaka Medical College Hospital, Dhaka.

The following members attended the meeting.

1. Prof. A. Jabbar
2. Prof. Mofazzal Hossain,
3. Brig. Aniz Waiz
4. Prof. A.T. Siddique,
5. Dr. Md. Jahangir.

The following decisions were taken in the meeting.

1. Minutes of the 100th meeting was confirmed.
2. Consideration of dose schedule of Vitamin B Pancreatin was kept pending for maximum presence of members and further study of Drug Administration.
3. The following decisions were taken in respect of recipes.

A) M/S. Square Ph. Ltd.	i) Dirupres T. Tab. (Hydrochlorothiazide with Trisarteren)	Approved.
	ii) Fulvin Susp. (Griseofulvin)	Rejected, dose is low.
	iii) Nebsol Powder (Neomycin, Bucitracin Cystine, Glycine)	Approved.
	iv) Clorston 50 (Chlorthalidone)	Approved
B) M/S. Wee Pharma	i) Tinct. Benzoin ^{Ca}	Approved
C) M/S. Medicare Lab.	i) Chlomyphicol susp.	Rejected, confused dose
	ii) Furazolidone susp.	Approved, indication to be changed.
D) M/S. Opsonin Ch.	i) Utirer (Melidinic Acid)	Approved
E) M/S. Pubali Ph. Ind.	i) Pzyme cap. (Pancreatin)	Pending for dose schedule.
	ii) Codine Phosphate Syrup.	Pending for narcotic licence.
F) M/S. Wee Pharma	i) Pantra Cap (Pancreatin)	Pending for dose schedule.
	ii) Furyl susp. (Furazolidone)	Approved, indication to be changed.
G) M/S. G.A. Company	i) Mydriline Eye oint (Atropine sulphate)	Rejected to clarify a water for inj. 5gm.
	ii) Mydrisil Eye drop. (Tropicamide)	Approved, name to be changed. <i>W</i>

Contd...P/2.

Approved
W. S. A.
24.7.85

H) M/S. Seema Ph. Ltd.

- i) Vit. Seema-C Syrup (Vit. C) Rejected, not allowed ~~by~~ NDP.
- ii) Seema -C Drop. Approved ^{with} change of excipients.
- iii) Fulkolin drop (Furzolidon) ~~Rejected, not permitted.~~ *was approved.*
- iv) Seemacillin drop. Rejected, defective ~~in~~ formulation & wrong ~~form.~~ *pack. size*

I) M/S. Square Ph. Ltd.

- i) Pantocol Tab. (Calc-D-Pantothenate) Pending for information about individual drugs. *approved*
- ii) Esaril (~~Thiomediazine Hcl~~) *was approved*
2-Mercidazole Approved with change in indication.

The meeting ended with vote of thanks to the chair.

approved
Wally
 24/7/68

Minutes of the 102nd meeting of the Drug Control Committee.

The 102nd meeting of the Drug Control Committee was held on 14.7.1985 at 11.30 A.M. under the chairmanship of Prof. Waliullah, Professor of Medicine, Dhaka Medical College Hospital, Dhaka.

The following members attended the meeting.

1. Prof. A. Jabbar,
2. Prof. A.T. Siddique,
3. Prof. M.Q.K. Talukder,
4. Brig. Aniz Waiz,
5. Dr. Md. Jahangir.

1. The following decision were taken in the meeting.
2. Minutes of the 101st meeting was confirmed.
3. Consideration of dose schedule of Vitamin E Pancreatin was kept pending for maximum presence of members and further study of Drug Administration.
4. The following decisions were taken in respect of recipes.

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|---------------------------------------|---|--|
| A) M/S. Square Ph. Ltd. | i) Levafex Powder
(Levamisole) | Pending for Vet. expert. |
| | ii) Flukinil, Blous
(Bromophosphos) | -do- |
| | iii) Rumental
(Febantel) | -do- |
| | iv) Tepenil, bolus
(Piperazine Citrate) | -do- |
| | v) Zincoric Powder
(Zinc oxide, Boric acid) | Rejected not required. |
| B) M/S. Standard Chemical Industries. | i) Theophylline Sodium Glycinate syrup. | Approved except to be changed. |
| | ii) Phenyl Salicylate | Rejected, not required. |
| C) M/S. Fisons (BD) Ltd. | i) Nadecon 0.05% Pediatric Nasal drop
(Xylometazoline) | Approved |
| | ii) Nadecon 0.1% Nasal Drop
(Xylometazoline) | Approved. |
| D) M/S. Medicare Lab. Ltd. | i) Amoxycillin Cap. <input type="checkbox"/> | Pending to get upto date report on microbiological section for antibiotic preparation. |
| | ii) Cephalixin cap. <input type="checkbox"/> | |
| | iii) Doxycycline cap. <input type="checkbox"/> | |
| E) M/S. Beximco Ph. Ltd. | i) Nitrofurazone Cream | Approved. |

Contd...F/2.

Approved
Waliullah
31.7.85

Registration

1. M/S. Fisons (Bangladesh) Ltd.

Drugs Control Committee has already approved the recipes of Bezalip tablet (Benzilicilate) and lanitop tablet and injection (Methyl Digoxin) last september. These they belong to Bechlbesser Mannheim of West Germany. Fisons has applied to the D.C. Industries for approval as under licence products. In this connection the Expert Committee for Pharmaceuticals ket this pending for the opinion of D.C. All the three drugs do not have any local substitute. Placed before DCC for opinion.

fractin
2. M/S. Jayson Pharmaceuticals.

Seven products of tincture and aqua, were recommended by the DCC for cancellation it because similar products were banned in the Drug Policy and the products were regarded as useless and unnecessary in Bangladesh context. The firm requested reconsideration of the cancellation order as the products appear in the BP 1980 and BPC 1979.

3. Land Reclamation Project.

NOC for import of poultry and cattle vaccine not registered in Bangladesh has been sought by the Project tan Land. The NOC is required for clearing the assignment from customs.

4. Pharmace International.

Prancetin I Powder has been banned under Schedule III of the Drug (Control) Ordinance, 1982 under guideline No. I. The firm applied for reconsideration, the smaller item is listed in the Import Gazette. The DCC approved their prayer on 5.12.84. A again referred by the licensing Authority (Drugs) for further discussion.

5. Aloe Pharma Ltd.

Blacedron tablet (Tinelel Meleate), MSD, was given provisinal registration for import upto 2-6-83. The firm applied for extention of the registration placed before DCC for opinion.

Rifampicin dose in modified as per up should be only sublet in. It should be not except Tuberculosis. Leprosy should be to latest knowledge monthly dose indicated in this we saw leprosy
W. Ullah
7/3/85

The 103rd meeting of the Drug Control Committee was held on 31/7/65 at 11:30 AM in the conference hall of Dhaka Medical College and Hospital, Dhaka under the chairmanship of Prof. Waliullah, Professor of Medicine, Dhaka Medical College, Dhaka.

The following members attended the meeting.

1. Prof. A. Jabbar.
2. Prof. A.T. Siddique.
3. Prof. ~~Munir Kabir~~. Sayed Anwar Begum
4. Dr. Md. Jahangir.
5. Prof. ~~Muazzal Husain~~

The following decisions were taken in the meeting.

1. Minutes of the 102nd meeting was confirmed.
2. The recipes of the following firms were considered.

M/s. National Laboratories Ltd., Dhaka.

The following recipe was kept pending for update inspection on Micro Laboratory.

1. Bacampicillin 400 mg tab.

M/s. Globe Research Laboratory Ltd., Feni.

The following recipe was rejected.

- i. Thiocol Syrup. (Potassium Guaiacol sulfonate) 1.75%.

Reason: Dose low, warning for children not mentioned, should be in generic name.

M/s. Opsonin Chemical Industries, Barisal.

The following recipe was approved.

- i) Trimin syp. (Trimethoprim)

Condition: Strength to be 1 g/100ml, and to be sugar free. Similar instructions to be communicated to all.

M/s. K.D.H. Laboratories Ltd., Dhaka.

The following recipe was approved.

- i) Felecan capsule, 10 mg. (Piroxicam).

The following recipe was kept pending for want of narcotic licence.

- i) Phelcodine Syrup.

M/s. Scientific Drug Industries, Dhaka.

The following recipes were kept pending.

1. Enx Nasal drop (Ephedrine HCl), for want of information whether similar preparation is permitted.

- ii) Codeine Phosphate syrup, for narcotic licence.

M/s. Pharmachem (Bangladesh) Ltd, Dhaka.

The following recipe was approved.

- i) Phagmacyin ointment, (Neomycin Sulphate 0.5g + Gramicidin 0.025 g per 100 mg). Condition: 'Carbuncles' to be deleted from indication.

The following recipe was rejected.

- i) Phamazone ointment (Nitrofurazone)

Reason: ~~xxxx~~ Wrong formula.

The following recipe was kept pending for opinion of paediatrician.

- i) Spemodin drop (Hyoscine Butyl bromide)

approved
Waliullah
7/8/65

Cont'd.....P/2.

M/s. Gopsonin Chemical Industries Ltd., Barisal.

The following recipes were rejected.

i) Bromosol Syrup (Bromhexin HCL)

Reason: Not allowed & approved list.

The decision to be communicated to M/s. Acne Lab. Ltd., and other firms, who were accorded approval of similar medicinal product earlier.

ii) Bromasol Tablet (Bromhexine HCL)

Reason: As above.

iii) Bromosol Injunctin (Bromhexine HCL)

Reason As above.

M/s. Goneshasthaya Pharmaceuticals, Dhaka.

The following recipe was approved.

i) G-Pancuronium Injection, 4 mg/2ml ampoule.

M/s. Square Pharmaceuticals Ltd., Pabna.

The following recipe was rejected.

i) Probenic tab. (Probenecid)

Reason: Not required in our country, Similar items, xxx registered for import to be cancelled.

M/s. Batali Pharma Ltd. Chittagong.

The following recipe was approved.

1. Trilose Syrup (Lactulose 67 g + Lactose 6 g + Galactose 11 g per 100ml).

M/s. Mukti Laboratories Ltd., Dhaka.

The following recipe was approved.

i) Mylidom suspension (urazolidone) 500mg/100ml.

Condition: Indication to be giardiasis & Cholera only

The following recipe was kept pending for upto date report on Microbiological Laboratory.

i) Amocil capsule (Amoxycillin Trihydrate) 250 mg.

ii) M-Phenicol capsule (Cleramphenicol) 250 mg.

The following recipe was kept pending for decision about strength of such preparation.

i) Vitanel capsule (B-Complex Vitamin)

M/s. Fpsens (Bangladesh) Ltd., Dhaka.

The following recipe was approved.

1) Inscma Tablet 5 mg (Nitazepam).

M/s. Al-Amin Laboratories Ltd., Mymensingh.

The following recipe was approved.

i) Dolocid - M suspension (Mefaldrate) 3%

Condition: Glycerine, Veega-K, Methyl and Propyl Paraben and Cinnamyl oil to be deleted from indication. Composition and "gastro pain, nausea, vomiting & allied symptoms" to be deleted from indication.

The following recipe was rejected.

i) Mebezol suspension (Mebendazole) 200 mg/100ml.

Reason: Wrong dose.

M/s. Pharmachemie (Bangladesh) Ltd., Dhaka.

The following recipe was approved.

i) Pharamycin ointment 0.5% (Neomycin Sulphate).

Condition: 'Carbuncles' to be deleted from indication.

Contd....P/3.

*Approved
would
7/9/55*

ii) Prayer of M/s. Cpsena Chemical Industries, Barisal to include their name in the list of Essential Drugs and its material in the list of duty free goods of Import Policy Order.

The meeting concluded with vote of thanks to the chair.

Approved
Wally
7/8/85

Minutes of the 104th meeting of the Drug Control Committee held on 7th August, 1985.

The 104th meeting of the Drug Control Committee was held on 7th August, 1985 at 11.30 a.m. in the chamber of Director, Drug Administration under the chairmanship of Prof. Waliullah, the Chairman of Drug Control Committee.

The following members attended the meeting.

- a) Prof. A. Jabbar
- b) Prof. A. T. Siddique
- c) Prof. Mofazzal Hossain
- d) Brig. Anis Waiz
- e) 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 103rd meeting of the DCC were confirmed.
2. The appropriateness of yoscine butylbromide in oral liquid form was discussed. It was noted that no such form is recommended in official pharmacopoeias. It was decided to cancel registration of all such preparations, to gradually withdraw them from the market, and also not to approve any such preparation in future.
3. Furazolidone is now manufactured locally. M/s. SK&F has also been licensed to manufacture Furoxone brand tablet and liquid. Registration of furazolidone brands of foreign origin should now be cancelled and the finished product should no longer be imported.
4. The indications of rifampicin, as well as its dosage schedule in leprosy should be revised as per latest literature and WHO recommendations. The drug should be used only in Mycobacterial infections (tuberculosis and leprosy), and in leprosy it should be given along with other drugs according to a monthly dosage schedule. All local inserts, labels, cartons and promotional literatures should be amended accordingly.
5. The prayer of M/s. Fisons (Bangladesh) Limited (dated 18.4.85) for locally manufacturing Bezalip (tablet) and Lanitop (tablet & injection) under licensing agreement with M/s. Boehringer Mannheim of West Germany was discussed. It was noted that none of these drugs fall under the category of essential drugs as approved in Bangladesh. None of these drugs are also included in official pharmacopoeias or codex. However, bezafibrate (active substance of Bezalip) has an important therapeutic role and there is no local product which can substitute it. The committee did not approve manufacture of these products under licensing agreement. However, M/s. Fisons may locally manufacture bezafibrate under their own brand name and also consider manufacturing digoxin tablet and injection as per list of essential drugs) without any licensing agreement. The previous decision of the committee to allow registration of the above three products (without knowledge of a licensing agreement with a 3rd party) is hereby revoked.
6. Prayer of M/s. Jays Pharmaceuticals Limited (dated 2.5.85) for restoring the registration of some galenical preparations, which was cancelled earlier, was rejected by the committee on the ground that these items are not required.

Prof. Waliullah

absence of information regarding licensing agreement to a party

*approved
cancelled
11.8.85*

contd....2

issuing 072

7. The committee recommended for allowing NOC for the import of some veterinary vaccines (for poultry and cattle) for the Land Reclamation Project of the Bangladesh Water Development Board, provided Dr. K.A. Fattah also agrees, and also such unregistered products are not sold in the market or used commercially.
8. In response to the application of M/s. Alco Pharma (dated 31.7.85) for extension of registration of Blocadren tablet (timolol maleate) of M.S.D., USA, the committee recommended that the registration may be renewed on payment of renewal fees.
9. The prayer of M/s. Pharmaco International for re-registration of Francetin T powder of M/s. Mochida Pharmaceuticals of Japan was reviewed. It was noted that the registration of this product was cancelled under the Drugs (Control) Ordinance 1982, and therefore it cannot be registered again without an amendment of the Ordinance. The earlier decision of the committee to allow registration of this product was to be revoked. The committee decided that all such cases should be placed before the DCC in the next meeting for a review. *The committee rejected the prayer for registration of this item, because it is not required.*
10. The committee decided that a uniform dosage form should be introduced for Pancratin tablets/capsules and also for the therapeutic and supplementary dosage forms of Vitamin preparations. Director, Drugs Administration was advised to work out a draft proposal for this purpose.

It was decided that the next meeting of the DCC should also be held at the same venue on 14.8.85 at 11.30 a.m.

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

Approved
W. Ullah
14/8/85

Minutes of the 105th meeting of the Drug Control Committee held on 14th August 1985 at 11.30 a.m.

The 105th meeting of the Drug Control Committee was held on 14th August 1985 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:

- a) Prof. A. Jabbar
- b) Prof. A.T. Siddique
- c) Brig. Anis Waiz
- d) Prof. M.Q.K. Talukder
- e) 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 104th meeting of the DCC were confirmed.
2. While discussing the following pending recipes of veterinary medicines of M/s. Square, it was decided that those be sent to Dr. K.A. Fattah for his opinion. These may be resubmitted after his opinion is available. The products are :- i) Levafex powder, ii) Flukinil bolus, iii) Rumental granules, and iv) Tapenil bolus. *with correction of experiments*
3. The recipes of the following firms were placed and discussed. Decisions taken are as mentioned in the remarks column.

<u>Name of the firm</u>	<u>Brand</u>	<u>Remarks</u>
i) M/s. National Laboratories, Dhaka	Rimpazid-300 cap. (rifampicin 300mg + isoniazid 150mg)	Kept pending for inspection report confirming availability of facilities to manufacture and assay the drug.
ii) M/s. Pfizer Lab., Dhaka	Combantrin chewable tab. 250mg & 125mg (pyrantel pamoate)	Rejected because chewable form is not required.
iii) M/s. Standard	a) Inj. Calcium Gluconate 10% USP	Rejected because no sterile facilities for manufacturing injectable exist in the firm.
	b) Sulphanilamide powder BPC	Rejected because such drug is not required. It was further decided that all similar items are to be cancelled.

contd.....2

*Approved
Waliullah
21/8/85*

- iv) M/s. Acme Lab., Dhaka
 - a) Pyrocaine ear drops (antipyrine + benzocaine) Rejected because the drug would not be suitable in a water-base.
 - b) Phenirin nasal drops (phenylephrine 500mg/100ml & 250mg/100ml) Rejected because no specification given for the diluent (conc. rose water); and the preparation is not sterile.
 - c) Acemox tab; (acetazolamide 250mg) Approved with condition to delete endrazit, methyl cellulose, polysorbate 80 and calcium phosphate from the formula.
 - d) Cellulose tab. (methyl cellulose '2500' 400mg + microcrystalline cellulose 220mg) Approved with condition to delete the indication 'appetite suppressant'.
 - e) Polimycin ear drops (polymyxin B sulphate 1000000 units per 100ml) Rejected because the preparation is water based; and not sterile.

4. Prayer for import registration of the following firms were placed and discussed. Decisions taken are as mentioned in the remarks column.

- i) M/s. Medimpex, Hungary
 - a) Devermin tab. ^(N. closoamide) Approved.
 - b) Hypothiazide Tab. (hydrochlorothiazide) Rejected because adequate alternative diuretics are available locally.
 - c) Mydocalm tab. & inj. (tolperison HCl) Approved.
 - d) Zitazonium tab. (tamoxifen citrate) Approved.
 - e) Mannisol A inf. (d-mannitol 10%) Approved.
 - f) Mannisol B inf. (d-mannitol 20%) Approved.
- ii) M/s. Green Cross, Japan.
 - a) Nutrisol 12% inj. (amino acids) Approved, with condition to be used only by specialists and in hospitals.
 - b) Nutrisol-S inj. (amino acids + sorbitol) Approved with condition to be used only by specialists and in hospitals.

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

5. A list of medicinal products included under schedule II and III of the Drug (Control) Ordinance, 1982 and subsequently re-registered on recommendation of the Drug Control Committee was reviewed and discussed. It was decided that such ~~similar~~ items of schedule III will not be considered by the committee in future.

provid
W. S. S. S.
21/8/85

Minutes of the 106th meeting of the Drug Control Committee held on 21.8.85 at 11.30 a.m.

The 106th meeting of the Drug Control Committee was held on 21st August 1985 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. A. Jabbar
2. Brig. Anis Waiz
3. Mr. Kazi Abdul Fattah
4. Dr. Humayun K.M.A. Hye

Proceedings and Decisions

1. The minutes of the 105th meeting were confirmed.
2. Matters arising from the minutes of the last meeting:
The following recipes of veterinary medicines of M/s. Square, which were kept pending for the opinion of Mr. K.A. Fattah, were disposed of after obtaining the opinion of Mr. K.A. Fattah who was present in the meeting.

<u>Product</u>	<u>Decision</u>
a) Levafex powder in sachet (levamisole)	Rejected because powder form not needed and indication not correct.
b) Flukinil bolus (bromophenophos 1.20g)	Approved.
c) Rumental granulate in sachet (febantel 10g)	Approved.
d) Tapenil bolus (piperazine citrate 2.5g)	Approved with correction of excipients.
e) Zincoric powder (zinc oxide + boric acid)	Rejected because not needed.

3. The recipes of the following firms were placed and discussed. Decisions taken are mentioned in the last column.

<u>Firms/Brands</u>	<u>Decision</u>
i. <u>M/s Opsonin, Barisal</u>	
a) Opsomycetin inj. (chloramphenicol sodium succinate 1g/vial)	Approved with correction of indication, dosage and warning; and subject to upto date inspection. Indication: mainly against typhoid fever where oral medication is not possible; also used for meningitis attributed to ampicillin-resistant strains. Dosage: Adult: 1g 3 - 4 times daily preferably by i.v. route. Warning: high initial dose should be avoided.
b) Opsozyme cap.	Kept pending; to place all previous pending cases of pancreatin in the next meeting.
ii. <u>M/s Pacific, Dhaka</u>	
a) Codeine phosphate liquid	Kept pending for submission of narcotic license.
iii. <u>M/s Square, Pabna</u>	
a) Ulcerid 800 tab. (cimetidine 800mg)	Approved.
iv. <u>M/s GACO, Dhaka</u>	
a) Frematren powder (neomycin 250mg+ bacitracin 500mg)	Approved with modification of excipients. To omit starch and use sterile containers.

contd...../2

Approved
Waliullah
4.9.85

- v. M/s Albert David, Dhaka
a) Cephalin cap. (cephalexin 250mg) Kept pending for inspection report confirming availability of facilities for testing cephalixin.
- vi. M/s Pharmachemie, Dhaka
a) Soporin tab. (nitrazepam 5mg) Approved.
- vii. M/s Square, Pabna
a) Framoson eye/ear drops (framycetin 500mg+ gramicidin 5mg + dexamethasone Na meta sulpho benzoate 75mg per 100ml) Approved with condition that it must be in sterile containers.
b) Nalid tab. (nalidixic 500mg) Approved.
- viii. M/s Therapeutics, Chittagong
a) Theracillin drops (ampicillin 100mg per ml) Approved with correction of specification as 'BP'.
b) Amoxin drops (amoxycillin 100mg per ml) Approved with correction of specification as 'BP' and omission of tartrazine yellow colour because it may cause hypersensitivity in some people.
c) Gloxilin drops (cloxacillin 100mg perml) Approved with correction of specification as 'BP' and to give specification of the Antifoaming agent.
- ix. M/s Skylab, Comilla
a) Buscogen drops (hyoscine butylbromide) Rejected because not required.
- x. M/s Standard Chemical, Dhaka
a) Dextromethorphan syrup 200mg/100ml Approved with condition to use generic name only.
- xi. M/s GACO, Dhaka
a) Tetracycline animal formula tab. 500mg Approved with correction of specification as 'BP Vet.'
b) Flukodin vet. tab. (hexachlorophene 1g) Approved. *W.S. Rep & Pending for open 25. 24.8.85*
- xii. M/s Opsonin, Barisal
a) Tussinil linctus (noscapine 300mg per 100ml) Approved with condition to use generic name as 'Noscapine syrup' and omission of chloroform water and tartrazine solution. Warning: 'Not recommended for children' should appear in label, carton, insert, etc.
b) Tussinil tablet (noscapine 300mg) Approved with condition to use generic name only; and Warning: 'Not recommended for children' should appear in label, carton, insert, etc.

*Approved
W.S.
4.8.85*

4. Miscellaneous:

- a) It was decided that registration of all imported brands of furazolidone including Furoxone of SK&F will be cancelled because abundant local substitutes are available.
- b) It was observed that presently olive oil worth nearly taka ^{150 gm} two crores is being imported in the country under the Wage ^{450 gm} Earners scheme, in containers of 150gm to 450gm, under provision of annexure 4 of the national Import Policy Order 1985-86 under the section 'Drugs & Medicines (allopathic)'.

Now if the import of small container packs are stopped and the local pharmaceutical manufacturers are allowed to import bulk and repack the same in small containers, a substantial savings in foreign currency exchange is envisaged. This is because local refining and packaging will be much more economical than imported brands. It is estimated that the price of locally repacked containers will come down by approximately 50%.

On the basis of the above observations, decision was taken to allow ~~some~~ local pharmaceutical manufacturers to repack the olive oil BP grade so that import of the finished form in small containers can be banned in course of time.

Accordingly the following recipe was considered and approved.

<u>Firm/Brand</u>	<u>Decision</u>
i. M/s <u>Organ, Dhaka</u>	
a) Lucy brand olive oil (olive oil BP in packs of 150gm and 450gm and 450gm and 150gm)	Approved with condition to omit 'eczema and psoriasis' from the indication.
c) Prayer no. MA-3/371 dated 7.3.85 of M/s Jaysons to review the decision of reformulating Ascocson syrup as drops of 15ml pack size from the existing 115ml pack size was discussed. Decision was kept pending for the next meeting.	
d) It was decided that the next meeting of the Drug Control Committee will be held on 4th September 1985 at 11.30 a.m. in the chamber of Director, Drug Administration.	

50 gm
450 gm

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

Approved
(Signed)
4.9.85