

Minutes of the 107th meeting of the Drug Control Committee held on 4.9.85 at 11.30 a.m.

The 107th meeting of the Drug Control Committee was held on 4th September 1985 at 11.30 a.m. in the chamber of 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. A.T. Siddique
3. Brig. Anis Waiz
4. Prof. M.Q.K. Talukder
5. Dr. Humayun K.M.A. Hye

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

Proceedings and Decisions

1. The minutes of the 106th meeting were confirmed.

2. Matters arising out of the last meeting.

- a) It was observed that codeine, a <sup>narcotic alkaloid of</sup> derivative of opium, was being used for quite some time as a single ingredient cough syrup. It is liable to be misused for addiction. As alternative single ingredient cough syrups are being allowed there is no justification to allow a drug like codeine with so much abuse potential.

Therefore after a thoughtful deliberation it was decided that all codeine syrup preparations available in the market will be withdrawn by 31st December 1985 and their registration will be revoked. Similarly all approved recipes of codeine phosphate syrup which has not yet been licensed shall also be revoked immediately. However, in place of codeine syrup the manufacturer may submit recipes for single ingredient ~~cough~~ syrup containing noscapine, pholcodine, dextromethorphan or similar other approved ingredients <sup>under generic name</sup>.

- b) While considering the prayer dated 7.3.85 of M/s Jaysons for review of the decision regarding Ascason syrup, it was decided that they may be allowed to continue production of Ascason syrup in their original pack size of 114ml. It was further decided that similar single vitamin C oral liquid preparations which were converted to a reduced pack size of 15ml may also be allowed to be manufactured in their original larger pack size. Necessary instruction may be communicated to the concerned manufacturer accordingly.

*manufacture*  
*x of 114ml*  
*sc 2/2/85*

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*Approved*  
*Waliullah*  
*10/9/85*

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

<u>Firms/Brands</u>	<u>Decisions</u>
i. <u>M/s Square, Pabna</u>	
a) Dermalex oint. (vet) (benzoic acid + salicylic acid)	Kept pending for the opinion of Mr. K. A. Fattah.
ii. <u>M/s National, Dhaka</u>	
a) Evinal tab. (vitamin E acetate)	Approved with condition to change indication as: To be used in vitamin E deficiency states; and recommended dosage as: As advised by the physician.
iii. <u>M/s Albert David, Dhaka</u>	
a) Gemicin paed. inj. (gentamicin sulphate)	Kept pending for upto date inspection report confirming availability of manufacturing and testing facilities.
b) Gemicin inj. (gentamicin sulphate)	-do-
iv. <u>M/s Fisons, Dhaka</u>	
a) Reprosmin tab., syrup and inj. (reproterol)	Kept pending for original clinical and pharmacological study report.
b) Xipamexan tab. (xipamide)	-do-
v. <u>M/s Jalpha, Sylhet</u>	
a) Narist nasal drop (xylometazoline)	Rejected because the preparation is not sterile. <i>W/</i> because lack of faith.
b) Codeine phosphate syrup	Rejected because not needed in syrup form.
c) Furox liq. (furazolidone 500mg/100ml)	Approved with condition to change indication as: Giardiasis and vibrio cholera; and deletion of tatrazine yellow colour which may provoke hypersensitivity reactions.
d) Dymin liq. (dicyclomin 200mg/100ml)	Approved with condition to change name.
e) Phyllin liq. (theophylline sodium glycinate)	Approved with change in dosage as: 1/2 to 1 teaspoonful t.d.s. for children.

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

*ppvvw*  
*WZalki*  
*11/9/53*

Minutes of the 108th meeting of the Drug Control  
Committee held on 11.9.85 at 11.30 a.m.

The 108th meeting of the Drug Control Committee was held on 11th September 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. Prof. A.T. Siddique
3. Brig. Anis Waiz
4. Dr. Humayun K.M.A. Hye

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

Proceedings and decisions

1. The minutes of the 107th meeting were confirmed.
2. Matters arising out of the minutes of the last meeting:

While discussing the Narist nasal drops (xylometazoline) of Jalpha, Sylhet it was observed that USP and BP does not require this product to be sterile. However, such nasal drops should be bacteria-free and bacteriological limit tests should be routinely performed during the manufacture and quality control of such preparations. Such products should also be marketed in a sealed container in semi-sterile condition.

3. The recipes of the following firms were placed for discussion; decisions taken are mentioned in the last column.

<u>Firms/Brands</u>	<u>Decisions</u>
i <u>Bigben, Dhaka</u> Furaben liquid (furazolidone 0.5%)	Approved with condition to change name and indication as: For giardiasis and vibrio cholerae.
ii <u>Edruc, Pabna</u> Diaptozyme capsule (pancreatin)	Rejected because the formula is defective.
iii <u>Square, Pabna</u> Syrup Codeine Phosphate	To resubmit the formula with alternate approved active ingredient, such as, noscapine, pholcodine, dextromethorphan HBr, potassium guaicol sulphate and isoaminile. It was also decided that similar decision will be applicable to all pending codeine syrup recipes.
iv <u>Azad Pharma, Dhaka</u> a) Optropine eye drops (atropine 1%) b) Optamine eye drops (sulphacetamide 10%)	Kept pending for inspection report confirming existence of facilities for preparing sterile preparations. -do-

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*A. Hye*

*Waliullah*  
27/9/85

- v National Lab., Dhaka
- a) Cemon syrup  
(ascorbic acid 2%) Approved with condition to change name; deletion of excipients viz. glycerine, propylene glycol and tartrazine; and indication to be: For vitamin C deficiency disease.
- b) Hemgel-M susp.  
(magaldrate) Rejected because formula is defective. It was also observed by the committee that such item has no advantage over common antacids.
- c) Hemgel-M tablet  
(magaldrate) -do-
- d) Dextromethorphan syrup 2% Approved with condition to delete overage.
- vi Reliance Lab., Rajshahi  
Cream of Magnesia Approved.
- vii Pioneer, Dhaka
- a) Furazolidone susp. 0.5% Approved.
- b) Chloramphenicol cap. 250mg Approved with condition that details of side-effects including that it may cause blood dyscrasias should appear in insert/literature, etc.
- viii Bio-Pharma, Dhaka
- a) Furox tablet  
(furazolidone 100mg) Approved with condition to change indication as: For giardiasis and vibrio cholerae.
- b) Furox susp.  
(furazolidone 0.5%) Approved with condition to change indication as above and deletion of overage and excipients viz. sodium saccharin, avicel, glycerine and polysorbate 80.
- c) Biovit capsule  
(vitamin B-complex) Approved with condition to change formula and dosage as per the standard formulation approved by DCC.
- d) Biozyme capsule Approved with condition to change formula as per the standard approved by the DCC.
- ix Acme, Dhaka  
Furazyl susp.  
(furazolidone 0.5%) Approved with condition to change indication as: For giardiasis and vibrio cholerae; and deletion of excipients viz. glycerine & tween 80. It was further decided that from now on all furazolidone recipes will be kept pending for statistics indicating import, production and sales figure to evaluate the necessity of additional similar products.
- x Drug Int., Dhaka
- a) Codeine syrup Rejected, may resubmit with approved alternate active ingredients.
- b) Potassium guaicol  
sulphonate syrup 2.5% Approved.
- xi Orion, Dhaka  
Riboflavine tablet 5mg Approved with condition to delete calcium phosphate, tartaric acid, complexone III & sodium lauryl sulfate.

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*Scanned by 1024/10/19*

- xii Hoechst, Dhaka  
Amblosin drops  
(ampicillin) To resubmit with 15ml pack size and proper specification of flavours.
- xiii Jams, Dhaka
  - a) Codeine syrup Rejected, may resubmit with alternate approved active ingredient.
  - b) Dextromethorphan HBr  
0.2% syrup Approved with deletion of chloroform from excipients.

Further the following pending recipes of Pancreatin were placed and discussed.

- xiv Opsonin, Barisal  
Opsozyme capsule Approved with condition to change formula, indication and dosage as per the standard formulation approved by the DCC.
- xv Al-amin, Mymensingh  
Tricozyme capsule -do-
- xvi GACO, Dhaka  
Pancristal capsule -do-
- xvii Wee Pharma, Dhaka  
Capsule Pantra -do-
- xviii Pubali, Dhaka  
Pzyme capsule -do-
- xix National Lab., Dhaka  
Enzypan capsule Approved with condition as above and change of name.

Further the following pending recipes of Codeine Phosphate syrup were placed and discussed.

- xx Albert David, Dhaka Alcodine syrup
- xxi Pubali, Dhaka Codeine phosphate syrup
- xxii Pacific, Dhaka -do-
- xxiii Eden Research, Barisal -do-

It was observed that since codeine phosphate syrup is not allowed, the firms may resubmit alternative single ingredient cough syrup with approved active ingredient. This decision will also be applicable for all pending or new recipes received for codeine syrup. In this connection it was also decided that such recipes when resubmitted as desired by the DCC may be accepted without further fees and such modified recipes will be placed in their earlier/original serial.

4. Miscellaneous.

- a) It was observed that Pancreatin in capsule and tablet form are available in various strengths. In order to bring uniformity in the strength and dosage of pancreatin, the following decision was taken: Pancreatin will be allowed in the strength of 325mg per capsule or tablet expressed in the potency of BP 1980 which specifies that it will contain not less than 455 units of protease, 6500 units of lipase and 7800 units of amylase activities. The dosage forms should contain pancreatin in the form of enteric coated granules or enteric coated tablets. Indication and dose should be as specified as in the BP 1980 or latest BNF. It was further decided that this decision will be applicable to all recipes kept pending or new recipes, as well as, all existing pancreatin preparations including those under registration.

contd....4

*Handwritten signatures and notes:*  
K. L. Das  
S. M. W. 29/7

b) The dosage and formulation of B-Vitamin tablets and capsules were discussed. In order to bring uniformity to all available vitamin B-complex tablets/capsules, it was decided that the following standard formulations and dosage forms as recommended in different official reference books will only be acceptable:

i Compound Vitamin B (complex) Tablets (BPC 1979)

Nicotinamide 15mg  
Riboflavine 1mg  
Thiamine HCl 1mg

Dose: Prophylactic, 1 or 2 tablets daily. (Also listed in BNF)

ii Strong Compound Vitamin B Tablets (BPC 1979)

Nicotinamide 20mg  
Pyridoxine HCl 2mg  
Riboflavine 2mg  
Thiamine HCl 5mg

Dose: Therapeutic, 1 or 2 tablets thrice daily.  
(Also listed in BNF)

iii Compound Vitamin B Tablets (USP XIV)

Aneurine HCl 2mg  
Riboflavine 3mg  
Nicotinamide 20mg

It was further decided that the above formulations and dosage will be applicable for all existing registered Vitamin B-complex tablets/capsules, as well as, all pending or new recipes. It was also decided to circulate this information to the manufacturers and to ensure the change over within the next six months.

- c) A publication in The Pharmaceutical Journal indicating the hypersensitivity of azo dyes colouring agent, namely, tartrazine, amaranth, sunset yellow, and ponceau 4R, were placed and discussed. It was decided that these colouring agents be gradually withdrawn from all existing and new products.
- d) It was discussed and decided that a summarized activity report of the Drug Control Committee from January 1985 till date will be prepared and submitted to the Ministry of Health & Population Control for information.

The meeting ended with avote of thanks to the chair.

*Approved*

*A. V. S.*

*25.9.85*

*Seen  
W. S. D. G.  
25/9/85*

Minutes of the 109th meeting of the Drug Control  
Committee held on 25.9.85

The 109th meeting of the Drug Control Committee was held on 25th September 1985 at 11.30 a.m. in the chamber of the Director, Drug Administration. Prof. Waliullah, the Chairman of the Drug Control Committee, joined the meeting after some time and thereafter presided. During his absence the meeting was presided over by Brig. Anis Waiz.

The following other members attended the meeting:

Prof. A.T. Siddique  
Prof. M.Q.K. Talukder  
Mr. Kazi Abdul Fattah  
Dr. Humayun K.M.A. Hye

Proceedings and Decisions

1. The minutes of the 108th meeting of the DCC were confirmed.

2. Matters arising out of the last meeting:

While discussing about standardization of the formulations of vitamin B-complex tablets/capsules, it was decided that such amendments as required for the existing products will be disposed off by the Director, Drug Administration (DDA) as per guidelines adopted. Further, it was decided that all new applications for the approval of recipes of vitamin B-complex tablets as well as capsules will be similarly disposed off by the DDA.

3. The following recipes which were resubmitted as per direction of the DCC were considered and decisions taken as described below:

<u>Firms/Brands</u>	<u>Decisions</u>
<u>Square, Pabna</u>	
a) Isordine tab (isosorbide dinitrate)	Approved with condition to declare active ingredient as equivalent to 10mg isosorbide dinitrate.
b) Tinazol tab (tinidazole 500mg)	Approved with condition to change indication as: For amoebiasis, giardiasis, trichomoniasis and anaerobic bacterial infections.
c) Atrosul eye drop (atropine 1%)	Approved.
d) Atrosul eye drop (atropine 0.5%)	Rejected because such strength is not included in official pharmacopoeas and considered unnecessary.
d) Dextromethorphan syrup 0.2%	Approved with condition to mention indication as 'antitussive' only & delete 'HBr' from name.
<u>K.D.H. Lab., Dhaka</u>	
Pholcodine syrup 0.1%	Approved with condition to mention indication as 'antitussive' and deletion of chloroform water, amaranth colour and overage. Alternate preservative and colour may be allowed by DDA.

*Approved*  
*24/9/85*

contd.... /2

Nipa, Dhaka

Fencin syrup 2.5%  
(potassium guaicol  
sulphonate)

Approved with condition to change name to generic; delete overage; change indication to 'antitussive'; reduce sucrose content to 50g & sodium saccharin to 100mg; and mention warning 'not for children's use' on label and carton, etc.

Delta, Dinajpur

Potassium guaicol  
sulphonate syrup 2.5%

Approved with condition to mention the warning 'not for children's use' on label and carton, etc.

Beximco, Dhaka

Dextromethorphan  
syrup 0.2%

Approved with condition to change amaranth red colour; alternate permissible colour may be allowed by DDA.

BPI, Dhaka

Phdcodine syrup 0.1%

Approved with condition to change indication to 'antitussive' and delete 'Williams Ariavit Amaranth'; alternate colour may be allowed by DDA.

Batali, Chittagong

a) Dextromethorphan  
syrup 0.2%

Approved with condition to change indication to 'antitussive' and delete colour FD&C yellow no. 6; alternate colour may be allowed by DDA.

b) Potassium guaicol  
sulphonate syrup 2.5%

Kept pending since the firm has been allowed another cough preparation.

Gonoshasthaya, Dhaka

a) G-Bacampicillin cap 400mg Approved.

b) G-Betamethasone &  
Neomycin cream

Approved with condition to use sterile water instead of purified water.

c) G-Betamethasone &  
Neomycin ointment

Approved.

Fisons, Dhaka

Isoaminile syrup 0.4%

Approved with condition to change indication to 'antitussive' and delete amaranth red colour; alternate colour may be allowed by DDA

4. The following recipes which have earlier been referred for opinion were placed and decisions taken are as follows:

Hoeschst, Dhaka

Trental dragees  
(pentoxifylline 400mg)

Approved.

Square, Pabna

a) Motilium tab  
(domperidone)

Rejected because the drug is not considered necessary.

b) Rehydra tab (ORS)

Rejected because the recipe is not as per approved ORS formula and also because of higher cost.

5. The following recipes of import substituted drugs were placed and decisions taken are as described below:

Pharmadesh, Dhaka

Nalidixin tab  
(nalidixic acid 500mg)

Approved.

contd..../3

WZ

Opsonin, Barisal

Nifedin cap (nifedipine 10mg) Approved.

Beximco, Dhaka

Nalidixic acid tab 500mg Approved.

Fisons, Dhaka

a) Fimoxy 250 inj (amoxycillin 250mg) Approved.

b) Fimoxy 500 inj (amoxycillin 500mg) Approved.

c) Ficimet 200 tab (cimetidine 200mg) Approved.

d) Ficimet 400 tab (cimetidine 400mg) Approved.

e) Rifazid 150 cap (rifampicin 150mg + isoniazid 100mg) Approved.

f) Rifazid 300 cap (rifampicin 300mg + isoniazid 150mg) Approved.

Opsonin, Barisal

Adevit soft gelatine cap (cod liver oil containing vit A 600.IU + vit D 60IU) } Approved with condition to use vit. E as antioxidant and delete 'vitamin E deficiency' from indication. *Facilis in soft capsule to be checked before licens*

6. The following other recipes of veterinary drugs were placed and decisions taken as described below:

GACO, Dhaka

Flukodin vet. tab (hexachlorophene 1g) Approved.

Square, Pabna

Dermalex vet. oint (benzoic + salicylic) Rejected because not considered necessary.

7. The following ophthalmological preparations of Alcon, Belgium were placed for approval in place of similar registered preparations of Alcon, USA, in order to keep the C&F price of these items stable. The committee approved the recipes of these items from Alcon, Belgium and recommended deregistering similar items of Alcon, USA.

- a) Isopto Atropine 1% eye drop (atropine sulphate)
- b) Isopto Carpine 1% eye drop (pilocarpine HCl)
- c) Isopto Carpine 2% eye drop
- d) Isopto Carpine 4% eye drop
- e) Isopto Catapred eye drop (prednisolone 0.25%+sulfacetamide 10%)
- f) Isopto Cetamide 15% eye drop (sodium sulfacetamide)

8. The following veterinary preparations of foreign origin were placed and decisions taken as described below:

Rhone Merieux, France

a) Extencilline vet. tab (benzathine penicillin) Approved.

b) Lindiffa vet. (lindane) Approved.

c) Ramatane vet. (bithionol sulfoxide) Referred to Prof. A. Rahman and Prof. A.N.M. Abdul Qadir of BAU, Mymensingh for opinion.

WZ

Ciba-Geigy, Switzerland

- a) Fasinex bolus for cattle (triclobendazole 90mg) Referred to Prof. A. Rahman and Prof. A.N.M. Abdul Quadir of BAU, Mymensingh for opinion.
- b) Fasinex bolus for sheep (triclobendazole 25mg) -do-
- c) Valbazine bolus vet (albendazole 600mg) Approved.

9. Miscellaneous:

- a) The committee observed that the US FDA and several other countries require that the labelling of sulphonyl urea hypoglycaemic agents should bear a warning that these drugs may be associated with increased cardio-vascular mortality. The committee decided that similar warning may be included in the inserts and literatures of all locally available oral sulphonyl urea hypoglycaemic agents.
  - b) The committee also observed that other <sup>many</sup> anthelmintics have a more favourable benefit-risk ratio than Piperazine, which may give rise to carcinogenic nitroso derivative. Netherlands and some other countries have withdrawn products containing piperazine. Nephrotoxicity of the drug has also been reported by Italian health authorities. After threadbare discussion it was decided that since piperazine is still included in the Essential Drug List, decision about restriction of piperazine may be kept pending.
  - c) It was further observed by the committee that even when applied topically, in the eye, chloramphenicol may induce blood dyscrasias. There are such reports from different countries. In view of this, it was decided that similar warning may be included in the inserts and literatures of locally available topical chloramphenicol preparations.
  - d) The Director, Drug Administration placed ~~before the committee the case of cancellation of~~ <sup>cancelled</sup> registration of some products of UCPL, Ctg., in view of ~~them~~ <sup>these</sup> being found sub-standard and also in view of the firm found selling the items in violation of the suspension order. The products are:- i) Thysolate syrup; ii) Parasol liquid; iii) Almasil suspension; and iv) Vermipar liquid. The committee retrospectively approved the action taken by the Director, Drug Administration.
  - e) Ronicol retard tab (beta-pyridyl carbinol) which is manufactured by M/s Hoffman La Roche, Switzerland is presently registered for import. Earlier, DCC approved the item for local manufacture by Square Pharm. under a licence agreement with Roche. After discussion it was decided that a licencing agreement for this product alone is not necessary, because the product is neither essential nor included in approved pharmacopoeas. However, M/s Square Pharmaceuticals may manufacture this item under their own brand name without any licensing agreement.
- The meeting ended with a vote of thanks to the chair.

*Handwritten notes:*  
 Approved  
 2/10/75  
 WZ

Cough Preparation

In the 5th meeting of the Army Council

held on 18-3-84 and minutes

conferred on 7.4.84 it was decided

that cough ingredients cough preparations

will be allowed to be manufactured with

the active ingredients namely, Prochlorperazine

Dextromethorphan, HBr, Doxamine HCl

Potassium Guaiacolate Sulfonate and

Ammonium Chloride.

Now, division is required regarding

strength of the preparation containing these

ingredients, indications and returns

to be allowed for such preparations.

It has been suggested on factors:-

Ingredient

Strength & the Dose allowed

Prochlorperazine 0.1% 5 to 15 mg per 5 ml of preparation for relief of symptoms. Cough suppression. Hot + water.

Dextromethorphan 0.2% 15 to 30 mg one to four times daily. - do - water.

Doxamine HCl 4% 40 mg - do - Glycyrrhizin water.

Pot. Guaiacolate Sulfonate 2.5% 15 to 19 gm. 3 to 4 times daily. Expectoration & in bronchitis. Water.

Ammonium Chloride 3% 3 to 9 gm daily. - do - Glycyrrhizin 4.9%.

End wanted for decision pl.

Ingredients strength and indication of vapourab & Iodine ointments to be allowed.

Iodine ointment

<u>Active ingredient</u>	<u>Strength</u>	<u>Indication.</u>
1. Iodine	4%	1) Relief of pain in lumbago, sciatica, and rheumatic condition
2. Methyl Salicylate	2 to 10%	2) Painful muscle and joints
		3) as counter irritant
		4) as local antiseptic.

The following ingredients may be allowed to be added as excipients:

- 1. Cassia oil 5% to 15%
- 2. Almond oil 5% to 7%
- 3. Soybean oil 9% to 10%

Other excipients:

- Petrolium jelly
- Vaseline
- Soft paraffin
- Hard paraffin etc.

Vapourab.

<u>Active ingredient</u>	<u>Strength</u>	<u>Indication.</u>
1. Menthol	0.5% to 2%	To relieve
2. Camphor	1% to 3%	colic,
3. Oil of eucalyptus	1% to 4%	Congestive rhinitis,
4. Oil of clove	1% to 3%	nasal catarrh,
5. Oil of Turpentine	5%	Rheumatic condition as counter irritant and as analgesic.

Other optional ingredients.

- 1. Oil of Thyme
- 2. Oil of Sassafras
- 3. Colophony resin

Excipient

- 1. Petrolium jelly
- 2. Vaseline
- 3. Soft paraffin.

*as counter irritant for local application for aches & pains of rheumatic condition*

1. Compound Vitamin B (Complex) Tablet (BPC 1979).

Nicotinamide 15 mg.  
Riboflavine 1mg.  
Thiamine HCL 1mg.

Dose : Prophylactic, 1 or 2 tabs. daily.

(Also listed in BNF).

2) Strong Compound Vitamin B Tablets (BPC 1979).

Nicotinamide 20 mg.  
Pyridoxine HCL 2mg.  
Riboflavine 2mg.  
Thiamine HCL 5mg.

Dose : Therapeutic 1 or 2 tabs. three daily.

(Also listed in BNF).

3. Compound Vitamin B tablet (USP XIV).

Anectine HCL 2mg.  
Riboflavine 3 mg.  
Nicotinamide 20mg.

This is also the composition of Triasyn UNICEF DD Kit).  
The Compound Tablet has been deleted from U.S.P. XV.

*Approved*  
*W. J. Waller*  
*11. 9. 85*

Agenda of the 109th meeting of the Drug Control  
Committee to be held on 25.9.85.

1. To confirm the minutes of the 108th meeting.
2. To discuss about matters arising out of the minutes of the last meeting.
3. To consider the following recipes which have been resubmitted as advised by the DCC:

Square	Isordine tab
	Tinazole tab
	Atrosul eye drops
	Dextromethorphan syrup
KDH	Pholcodine syrup
Nipa	Potassium guaicol syrup
Delta	-do-
Beximco	Dextromethorphan syrup
BPI	Pholcodine syrup
Batali	Dextromethorphan syrup
	Potassium guaicol syrup
Gonoshasthaya	G-Bacampicillin tab
	G-Betamethasone + Neomycin oint./cream
Fisons	Isoaminile syrup

4. To consider the recipes which have earlier been referred for opinions:

Hoechst	Trental dragees
Square	Motilium tablet
	Rehydra tab

5. To consider the following recipes of import substitute drugs:

Pharmadesh	Nalidixin tab	16.5.85
Opsonin	Nifedin cap	22.5.85
Beximco	Nalidixic tab	11.6.85
Fisons	Fimoxyl inj 250mg & 500mg	11.6.85
	Ficimet 200mg & 400mg tab	"
	Rifazid cap 150 & 300	"
Opsonin	Adevit cap	24.6.85
Square	Ranitid tab	27.6.85
Peoples Pharma	Vasodil tab	17.7.85
Square	Perkimet tab	"
Beximco	Ranitidine tab	24.7.85
Square	Dipantin tab	30.7.85

6. To consider the following other recipes:

GACO	Flukodin vet tab	
Square	Dermalex vet oint	16.3.85
Opsonin	Metocol inj	2.1.85
	Opsovit inj	"
Delta	Kidicee	20.1.85
Drug Int	Cloxpen drop	
Scientific	Enox nasal drop	24.3.85
Medicon	Mexacil cap & syrup	24.6.84
Ambee	Amfuron tab	19.5.85
Beximco	Isoprinosine tab & syrup	21.5.85
KDH	Sedinol tab	22.5.85
	Caldipan tab	"
Asiatic	Pholcodine syrup	23.5.85
	Pot. guaicol syrup	"

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*change*  
*Killed*  
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Skylab	Hydrotalcite tab & susp	25.5.85
	Amoxycillin cap	26.5.85
	Riboflavine tab	"
Therapeutics	Riboflavine tab	26.5.85
	Furantin tab	"
Wee Pharma	Amoxycillin dry syrup	1.6.85
Beximco	Stopain inj	4.6.85
	Vitamin B-complex inj	"
Albert David	Aldalin inj	9.6.85
Fisons	Pancreatin tab	10.6.85
	Pilactazid tab	"

7. To consider the import registration of the following already approved eye preparations for import from alternative cheaper sources as a special case. (see annex)

Alcon, Belgium	<del>Zincfrin</del>	
	<del>Statrol</del>	
	Isopto Atropine 1%	
	Isopto Cetapred 1%	
	Maxider	
	Maxitrol	
	Isopto Homatropine Carpin 1%, 2%, 4%	
	Isopto Citamidi 15%	

8. Miscellaneous: (see working paper annex)

- i To discuss about incorporating a warning in the inserts and literatures of oral hypoglycaemic agents (sulphonyl ureas), that their use may be associated with increased cardiovascular mortality.
- ii To discuss about the discontinuation of Piperazine preparation.
- iii To discuss about incorporating a warning about chloramphenicol topical eye preparations.
- iv To discuss about the sub-standard sample report of United Chemists.
- v To discuss about the prayer of employees of SK&F to ban import of finished products by the firm.
- vi to review approval of Renicul
- vi New drug information.

  
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Working Paper

10911 meeting gdec  
held on 25.9.85

i Warning about oral hypoglycaemics

As per WHO Drug Information bulletin no. PDT/DI/844 p.23, & 'the US Food & Drug Administration now requires that the labelling of sulphanylurea hypoglycaemic agents bears a warning that these drugs may be associated with increased cardiovascular mortality. In view of this information, similar warnings may be included in the inserts and literatures of all locally available oral sulphanylurea hypoglycaemic agents.

ii Discontinuation of Piperazine preparations

As per WHO Drug Information bulletin no. PDT/DI/84.4 p. 24, 'the Board for the Evaluation of Drugs in the Netherlands has concluded that other anthelmintics have a more favourable benefit-risk ratio than piperazine, which may give rise to carcinogenic nitroso-derivatives. Accordingly, manufacturers have been requested to withdraw products containing piperazine from the market by January 1985.'

Nephrotoxicity of the drug has also been reported by the Italian health authorities, when used at higher than recommended dosage, or in patients with known renal impairment or with pre-existing disease of the central nervous system. (p. 20 of the bulletin)

In view of the adverse reactions reported, the drug Piperazine may be discontinued, as safer more effective alternative anthelmintic preparations are available. However it has to be noted that Piperazine is still not listed as essential drug in Bangladesh.

iii Warning about chloramphenicol eye preparations

As per WHO Drug Information bulletin PDT/DI/84.4, p.20, & 'the regulatory body of the Netherlands has reminded doctors that, even when applied topically in the eye, chloramphenicol may induce blood dyscrasias.'

In view of the above information, similar warning may be included in the inserts and literatures of locally available chloramphenicol topical preparations.

iv Substandard sample report of United Chemicals & Pharm., Chittagong

Market samples of drugs are routinely collected from different parts of the country and sent to the Drug Testing Lab for test & analysis.

On one occasion the following medicinal products of UCPL were found sub-standard by the Govt. Analyst. They are, i) Thysolate syrup, ii) Parasol liquid, iii) Almasil susp and iv) Vermipar liquid.

The firm was informed about this finding and asked to withdraw the relevant batches from the market and show cause as to why the above mentioned products should not be cancelled from their manufacturing licences.

The reply to this effect was not satisfactory and therefore the production and sale of the above products were suspended till further order. They were also asked to notify in the press about this. It was found after this from records seized at different shops and from their sales office that they continued selling the products ~~inspite~~ of the suspension order.

They were again asked to show cause about these violations of the Licensing Authority (Drugs) order and Drug Rules thereof. Their reply and personal hearing to this effect was again found unsatisfactory.

Finally, decision ~~has been~~ <sup>was</sup> taken to cancel the registration of these products because of the gross violation of the Drugs Act and Rules. This is placed before the committee for information and ~~action~~ <sup>was</sup> ~~recommended~~ <sup>without consulting DCC</sup> ~~in this regard~~ <sup>in this regard</sup> ~~the committee~~ <sup>was</sup> ~~has~~ <sup>was</sup> ~~been~~ <sup>been</sup> ~~asked~~ <sup>asked</sup> ~~to~~ <sup>to</sup> ~~show~~ <sup>show</sup> ~~cause~~ <sup>cause</sup> ~~about~~ <sup>about</sup> ~~these~~ <sup>these</sup> ~~violations~~ <sup>violations</sup> ~~of~~ <sup>of</sup> ~~the~~ <sup>the</sup> ~~Drugs~~ <sup>Drugs</sup> ~~Act~~ <sup>Act</sup> ~~and~~ <sup>and</sup> ~~Rules~~ <sup>Rules</sup> ~~thereof~~ <sup>thereof</sup> ~~and~~ <sup>and</sup> ~~to~~ <sup>to</sup> ~~show~~ <sup>show</sup> ~~cause~~ <sup>cause</sup> ~~about~~ <sup>about</sup> ~~these~~ <sup>these</sup> ~~violations~~ <sup>violations</sup> ~~of~~ <sup>of</sup> ~~the~~ <sup>the</sup> ~~Drugs~~ <sup>Drugs</sup> ~~Act~~ <sup>Act</sup> ~~and~~ <sup>and</sup> ~~Rules~~ <sup>Rules</sup> ~~thereof~~ <sup>thereof</sup> ~~and~~ 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<sup>about</sup>

109th meeting of SCA  
held on 25.9.85

Agenda.

M/s. Ardent has applied for approval of the following Alcon, Belgium products for import registration.

1. Isopto atropine 1% eye drops (atropine sulphate).
2. Isopto Carpine 1% (Pilocarpine HCL). eye drops.
3. Isopto Carpine 2% (Pilocarpine HCL) eye drops.
4. Isopto Cetopred eye drops (Prednisolone acetate 0.25% + Sodium Sulphacetamide 10%).
5. Isopto Cetamide 15% (Sodium Sulfacetamide).
6. Isopto Carpine 4%.

Cancel USA  
importation  
OK  
L. J. H.  
3519

The above items of USA origin are already registered. The party has requested to change the source of supply from their USA factory to Belgium factory, as the C & F prices of USA has been increased 30% - 150% to some product which that from Belgium factory may almost be kept at ~~be kept~~ at present level.

In view of above contention the above items of Alcon, Belgium origin may be recommended for registration and registration of similar items of USA origin may be cancelled.

*Deco* <sup>plus</sup> may give it ~~its~~ their opinion