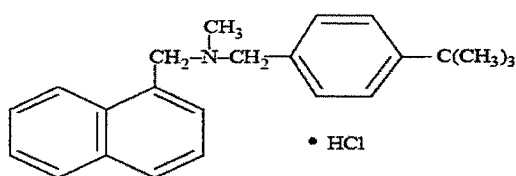


Chapter 3

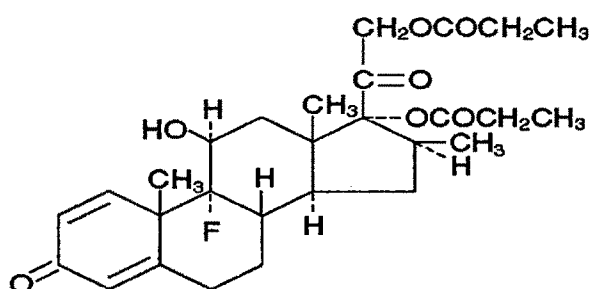
Drug Profile

3. DRUG PROFILE¹⁻⁵**3.1 Butenafine Hydrochloride****a. Category:** Antifungal**b. Molecular formula:** C₂₃H₂₇N•HCl**c. Molecular weight:** 353.93g/mole**d. Chemical Structure:****e. Chemical Name:** *N*-4-*tert*-butylbenzyl-*N*-methyl-1-naphthalene methylvamine hydrochloride**f. Physicochemical Properties:**

- **Description:** A white, odorless, crystalline powder.
- **Solubility:** It is freely soluble in methanol, ethanol, and chloroform, and slightly soluble in water.
- **Melting point:** 210-214 °C

g. Official Status: Not official in any pharmacopoeia

Marketed Formulations		Company	Composition
BUTENASKIN	BM	Elder Pharmaceuticals	Butenafine 1% + Betamethasone
CREAM		Ltd.	dipropionate 0.05 %

3.2 Betamethasone dipropionate ⁶⁻¹³**a. Category:** Glucocorticoid steroid with anti-inflammatory and immunosuppressive abilities**b. Molecular formula:** $C_{28}H_{37}FO_7$ **c. Molecular weight:** 504.59 g/mole**d. Chemical Structure:****e. Chemical Name:** 9-fluoro-11, 17, 21-trihydroxy-16-methylpregna-1, 4-diene-3,20-dione**f. Physicochemical Properties:**

- **Description:** a white to pale yellowish white, crystalline powder
- **Solubility:** It is freely soluble in acetone, in 1,4-dioxane and in chloroform, soluble in methanol, sparingly soluble in ethanol, slightly soluble in diethyl ether, and practically insoluble in water and in hexane.
- **Melting point:** 176 – 180°C

g. Official Status: official in U.S. Pharmacopoeia (USP), European Pharmacopoeia, and British Pharmacopoeia

Marketed Formulations		Company	Composition
BUTENASKIN	BM	Elder Pharmaceuticals Ltd.	Butenafine 1% + Betamethasone dipropionate 0.05 %
CREAM			

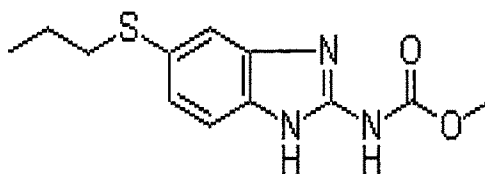
3.3 ALBENDAZOLE ¹⁴⁻¹⁶

a. Category: It is a broad spectrum anthelmintic, effective against: roundworms, tapeworms, and flukes of domestic animals and humans. (ref-1)

b. Molecular formula: C₁₂H₁₅N₃O₂S

c. Molecular weight: 265.34 g/mole

d. Chemical Structure:



e. Chemical Name: methyl-[5-(propylthio)-1-*H*-benzimidazol-2-yl] carbamate Methyl [6-(propylthio)-1*H*-benzoimidazol-2-yl] carbamate

f. Physicochemical Properties:

- **Description:** a white yellowish powder
- **Solubility:** Practically insoluble in water. Freely soluble in anhydrous formic acid, very slightly soluble in mythylene chloride, practically insoluble in alcohol.
- **Melting point:** 209°C

g. Official Status: official in U.S. Pharmacopoeia (USP), European Pharmacopoeia, and British Pharmacopoeia, Indian Pharmacopoeia

Marketed Formulations	Company	Composition
BANDY PLUS	Mankind	Albendazole-400mg + Ivermectin-6 mg
BANDY PLUS	Mankind	Albendazole-400 mg + Ivermectin-12 mg

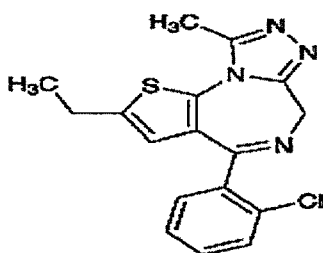
3.4 Etizolam¹⁷⁻²⁰

a. Category: It possesses amnesic, anxiolytic, anticonvulsant, hypnotic, sedative and skeletal muscle relaxant properties(ref-1)

b. Molecular formula: C₁₇H₁₅ClN₄S

c. Molecular weight: 342.85

d. Chemical Structure:



e. Chemical Name: 4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno-[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine

f. Physicochemical Properties:

- **Description:** Etizolam occurs as a white to pale yellowish white crystalline powder.
- **Solubility:** It is soluble in ethanol, methanol, dichloromethane and chloroform. sparingly soluble in acetonitrile and in acetic anhydride, and practically insoluble in water
- **Melting point:** 146 – 149°C

g. Official status: Etizolam is not official in USP, BP, EP

Marketed Formulations	Company	Composition
ETIZOLA PLUS	MCLEODS	Etizolam 0.5 mg+Escitalopram 5 mg
EZOLENT PLUS	TALENT INDIA	Etizolam 0.5 mg+Escitalopram 5 mg

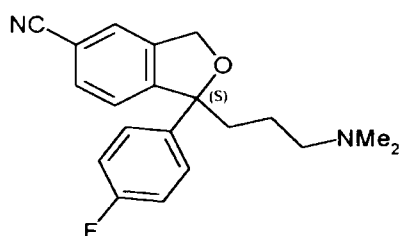
3.5 Escitalopram oxalate⁴⁸⁻⁵¹

a. Category: Escitalopram oxalate is an antidepressant of the selective serotonin reuptake inhibitor (SSRI) class (ref-1)

b. Molecular formula: $C_{20}H_{21}FN_2O \cdot C_2H_2O_4$

c. Molecular weight: 414.43

d. Chemical Structure:



e. Chemical Name: S-(+)-1-[3-(dimethyl-amino) propyl]-1-(p-fluorophenyl)-5-phthalancarbonitrile oxalate.

f. Physicochemical Properties:

- **Description:** Escitalopram oxalate occurs as a fine white to slightly yellow powder
- **Solubility:** freely soluble in methanol and dimethyl sulfoxide (DMSO), soluble in isotonic saline solution, sparingly soluble in water and ethanol, slightly soluble in ethyl acetate, and insoluble in heptane.
- **Melting Point:** 146-149°C

g. Official Status: Escitalopram oxalate is official in Indian Pharmacopoeia

Marketed Formulations	Company	Composition
NEXITO FORTE	SUN PHARMA	Escitalopram oxalate 10 mg+Clonazepam 0.5 mg
ETIZOLA PLUS	MCLEODS	Etizolam 0.5 mg+Escitalopram 5 mg

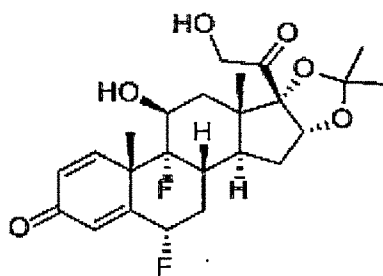
3.6 Fluocinolone acetonide²¹⁻²⁵

a. Category: Fluocinolone acetonide is a corticosteroid used topically for its glucocorticoid activity primarily in dermatology to reduce skin inflammation and relieve itching.

b. Molecular formula: C₂₄H₃₀F₂O₆

c. Molecular weight: 452.49

d. Chemical Structure:



e. Chemical Name: Pregna-1,4-diene- 3,20-dione, 6,9-difluoro-11,21-dihydroxy- 16,17-[(1-methylethylidene) bis(oxy)]-, (6.alpha.,11.beta.,16.alpha.)- (67-73-2)

f. Physicochemical Properties:

- **Description:** Fluocinolone Acetonide is a white or almost white, crystalline powder.
- **Solubility:** Insoluble in water; soluble 1 in 45 of alcohol, 1 in 25 of chloroform, and 1 in 350 of ether; soluble in methyl alcohol.
- **Melting point :** 267-269 °C

g. Official Status: Fluocinolone acetonide is official in U.S. Pharmacopoeia (USP), European Pharmacopoeia, and Indian Pharmacopoeia

Marketed Formulations	Company	Composition
ZOLE-F(Ointment)	REXEL(RANBAXY)	Miconazole nitrate 2% +
ZOLE-F(Lotion)		Fluocinolone Acetonide 0.01%
SUPRICORT-N(Ointment)	GLENMARK	Fluocinolone Acetonide 0.025% + Neomycin Sulphate 0.5%

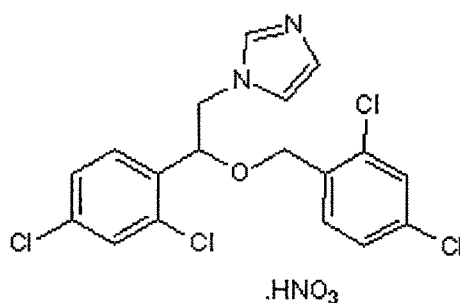
3.7 Miconazole nitrate²⁶⁻³²

a. Category: Miconazole Nitrate is an antifungal agent used to treat superficial candidiasis, dermatophytosis and pityriasis versicolor

b. Molecular formula: $C_{18}H_{14}Cl_4N_2O \cdot HNO_3$

c. Molecular weight : 479.14

d. Chemical Structure:



e. Chemical Name: 1-[2-(2,4-Dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole nitrate

f. Physicochemical Properties

- **Description:** white or almost white crystalline or microcrystalline
- **Solubility:** Freely soluble in methanol, slightly soluble in ethanol(95%) and in chloroform, very slightly soluble in water and ether
- **Melting point :** 170-184°C

g. Official Status: Miconazole nitrate is official in U.S. Pharmacopoeia (USP), European Pharmacopoeia, British Pharmacopoeia, and Indian Pharmacopoeia

Marketed Formulations	Company	Composition
ZOLE-F(Ointment)	REXEL(RANBAXY)	Miconazole nitrate 2% +
ZOLE-F(Lotion)		Fluocinolone Acetonide 0.01%

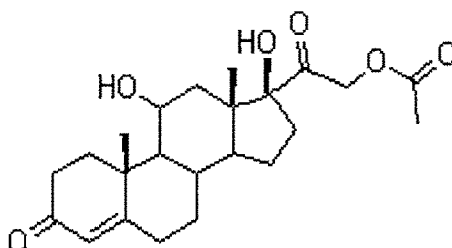
3.8 Hydrocortisone acetate³²⁻³⁶

a. Category: Hydrocortisone acetate is used as an anti-inflammatory.

b. Molecular formula: C₂₃H₃₂O₆

c. Molecular weight: 404.50

d. Chemical Structure



e. Chemical Name: 11, 17-Dihydroxy-3,20-dioxopregn-4-en-21-yl acetate

f. Physicochemical Properties

- **Description:** white to practically white, crystalline powder; odourless
- **Solubility:** Insoluble in water. slightly soluble in alcohol
- **Melting point:** 222-225 °C

g. Official Status: Hydrocortisone acetate is official in U.S. Pharmacopoeia (USP), British Pharmacopoeia

Marketed Formulations	Company	Composition
DACTACORT (Gel)	JOHNSON & JOHNSON	Hydrocortisone acetate 1% + Miconazole Nitrate 2%
FUMIC (Cream)	APURVA BIOPHARM INC	Hydrocortisone acetate 1% + Miconazole Nitrate 2%

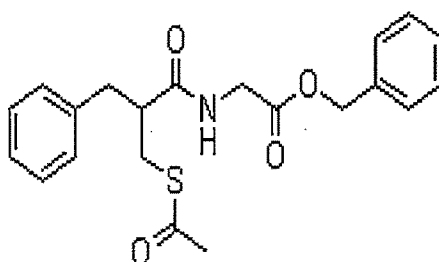
3.9 Racecadotril ³⁷⁻⁴⁰

a. Category: Racecadotril (acetorphan) is an enkephalinase inhibitor used in the treatment of acute diarrhea.

b. Molecular formula: $C_{21}H_{23}NO_4S$

c. Molecular weight: 385.48

d. Chemical Structure:



e. Chemical Name: chemically N-[(R, S)-3-acetylmercapto-2-benzylpropanol]-glycine benzyl ester

f. Physicochemical Properties

- **Description:** white crystalline powder
- **Solubility:** Soluble in methanol and chloroform
- **Melting point :** 75-76°C

g. Official Status: Racecadotril is not official in any pharmacopoeia

Marketed Formulations	Company	Composition
REDOTIL (Capsule)	DR. REDDY'S LAB	Racecadotril 100mg
ZEDOTT (Powder sachet)	TORRENT PHARMA	Racecadotril 10mg + Racecadotril 30 mg

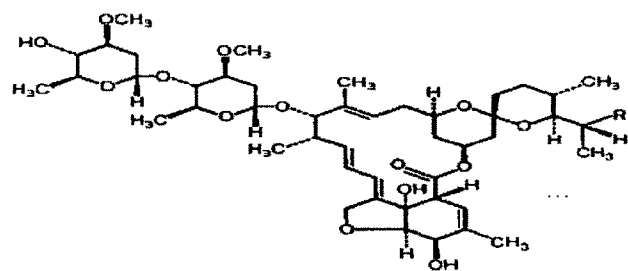
3.10 Ivermectin⁴¹⁻⁴⁷

a.Category: Ivermectin is a semisynthetic, anthelmintic agent for oral administration. Ivermectin is derived from the avermectins, a class of highly active broad-spectrum, anti-parasitic agents isolated from the fermentation product of *Streptomyces avermitilis*.

b.Molecular formula: The respective empirical formulas are C₄₈H₇₄O₁₄ and C₄₇H₇₂O₁₄.

c. Molecular weight: It is a mixture consisting of ≥80% of compound A and <20% homolog B ,the molecular weight of this drug will range from 872.21 to 875.10

d. Chemical Structure:



Component B_{1a}, R = C₂H₅.....Component B_{1b}, R = CH₃

e.Chemical Name: Ivermectin is a mixture containing at least 90% 5-*O* demethyl-22,23-dihydroavermectin A_{1a} and less than 10% 5-*O*-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)avermectin A_{1a}, generally referred to as 22,23-dihydroavermectin B_{1a} and B_{1b}, or H₂B_{1a} and H₂B_{1b}, respectively

Description: Ivermectin is a white to yellowish-white, nonhygroscopic, crystalline powder

Solubility: It is insoluble in water but is freely soluble in methanol and soluble in 95% ethanol.

Melting point: 155°C

g. Official Status:

Marketed Formulations	Company	Composition
BANDY PLUS(TABLET)	MANKIND	Albendazole-400 mg + Ivermectin-6 mg
BANDY PLUS(TABLET)	MANKIND	Albendazole-400 mg + Ivermectin-12 mg
AZ PLUS(SUSPENSION)	CURE PHARMA	Albendazole-200mg + Ivermectin-3 mg

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