Ethiopian Food and Drug Authority (EFDA)

Guideline for Registration of Low-Risk Medicines

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Contents

Abbreviations

API	Active Pharmaceutical ingredient
cGMP	Current Good Manufacturing Practice
CPP	Certificate of Pharmaceutical Products
CTD	Common Technical Document
EFDA	Ethiopian Food and Drug Authority
eRIS	Electronic Regulatory Information System
FPP	Finished Pharmaceutical Products
MA	Marketing Authorization
NMRs	National Medicine Regulators
OTC	Over-the Counter
PIL	Patient Information Leaflet
PoM	Prescription only Medicine
SmPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority

1. Background

The Ethiopian Food and Drug Authority (EFDA) is mandated by the Proclamation No. 1112/2019 to ensure safety, efficacy and quality as well as rational use of medicines. Article 19 sub-article 1 of the proclamation decrees that "the rigor of regulatory assessment of medicines shall be commensurate with the products type, nature and potential risk to human health". Accordingly, the evaluation process to ensure safety, efficacy and quality of low risk medicines needs minimum exertion for effective utilization of limited resource and to ease the accessibility of the products for consumers. Products that are relatively safe and of proven efficacy; such as some over the counter (OTC) medicines, products fulfilling criteria for risk categorization of medicines set in this guideline are pharmaceutical products that fall in the jurisdiction that permits abbreviated assessment as they are generally considered as low risk products.

Risk-based dossier assessment approach is one of the strategic directions of the regulatory authority to expedite marketing authorization process and its implementation requires classification of products in to low and high-risk category so as to proportionate risks during dossier assessment. For low risk medicines, the evaluation process will be limited to a 'partial review of the product dossier; concentrating on the assessment of administrative requirements, product information, specifications, stability and shelf life, and others as applicable. However, full and rigorous dossier assessment might be conducted for a product designated as low risk if there is satisfactory reason for in-depth evaluation.

This guideline is prepared based on the provisions in the Proclamation No. 1112/2019 and other NMRs experiences regarding regulation of low risk medicines and consists of criteria for low risk designation and requirements to process marketing authorization of medicines.

Therefore, the intentions of this guideline is to set criteria and provide guidance for applicants on how to apply for marketing authorization (MA) of such products through low risk approval pathway.

All users of this guideline are kindly requested to forward their valuable comments and suggestions to the Food and Drug Authority of Ethiopia, P.O.Box. 5681, Tel. 251-11 552 41 22, or email: contactefda@efda.gov.et, Addis Ababa, Ethiopia.

2. Definitions

For the purpose of this guideline the following definitions are applicable.

Authority means Ethiopian Food and Drug Authority

Low-risk Medicine means medicinal products that contain known chemical entity with established safety profile over years both in local and global markets, indicated for well-documented conditions, provided by conventional dosage forms such as oral solids, liquids, and topical preparations. This includes OTC medicines and other products designated as low risk products by the Authority.

Lower-risk medicine applications means an application for marketing authorization of medicines eligible for approval by low risk application track based on the EFDA`s low risk designation criteria as outlined in this guideline.

OTC Product means a product designated and listed as OTC medicines by the Authority.

Partial or abbreviated review means a dossier assessment process that is carried out for evaluating low risk products by focusing on selected section of product dossier.

3. Scope

This guideline is applicable to dossier assessment and market authorization of all medicines designated and listed as low risk medicines by the authority.

4. Objective

The objective of this guideline is to set requirements for registration of low risk medicines and enhance the availability of these products in the market.

5. Criteria for risk categorization of medicines

In this guideline, medicines are classified as low risk based on the criteria listed below;

1. Medicine inherent characteristics (e.g. bioavailability, solubility, polymorphism etc)
    - Medicines with API that have low bioavailability & solubility and that exists in different polymorphs can be an example of high-risk product.
2. Dosage form and route of administration

- Dosage forms such as injectable, manufactured by lyophilization, and product which administered by IV, IV infusion and some inhalation products are generally considered as high risk.

3. Therapeutic index of medicines
    - Products with narrow therapeutic index are considered as high-risk product.
4. Safety of medicine (active ingredient) under consideration
    - There must be enough supporting scientific evidence that the medicine have a wide margin of safety
    - Its mode of action and pharmacokinetics; such as its absorption, metabolism and excretion are not affected by other commonly used drugs or display marked fluctuations between individuals because of concomitant diseases, interactions with food, or genetic or environmental factors (working conditions, climate, and so forth)
5. Complexity in medicine manufacturing and the impact of poor quality in manufacture
6. The risk associated with the claims including labelled use
    - Labelling and package inserts and other information forming the basis for advertising and promotion shall fulfil EFDA's labelling requirements for medicinal products
7. The nature of the condition being treated or prevented
    - Medicines used in life threatening conditions are example of high-risk product.
8. The nature and number of the population using the product
    - Medicines that have low and well-documented risks in specific patient groups, for example in elderly people, during pregnancy and lactation, and in patients with impaired liver or kidney function can generally be considered as a low risk product
9. Potential for drug resistance
    - Products that do not have potential impact on the development of anti-microbial resistance in the general population are considered as low risk products
10. The potential for misuse, abuse, and with a potential for causing dependence
    - Narcotic and psychotropic medicine are considered as high-risk product

11. Use of medicines as Prescription vs Over-the-counter (OTC)
    - Medicines reasonably regarded as appropriate for self-diagnosis, self-medication and self-monitoring are generally considered as low risk products

6. Low risk products categories

Based on the criteria set above; the general category of products listed below are eligible for low risk products for market authorization.

a. Keratolytic
b. Anti-dandruff;
c. Topical antibacterial
d. pholcodine linctus or a codeine-containing combination analgesic
e. Medicated plasters/ patch/ pad
f. Non-steroidal and antihistaminic having wide therapeutic index
g. Multivitamin and minerals
h. Anthelmintic having local action
i. Dermatological products having local action
j. Locally-acting lozenges/ pastilles;
k. Topical analgesic/ counter-irritants;
l. Anti-acne
m. Oral mucosal analgesic

The lists of specific products indicated in annex I of this guideline are recognized as low risk products. However, the list will be regularly updated for products that fit in to the above general category of medicines based on the Authority`s inclusion criteria.

7. Required documents

7.1. Administrative documents

For low risk medicinal products with API(s) that are not new to the Ethiopian market, all administrative documents need to be completed, signed and submitted by the applicant. The date of application should correspond to the date of submission of the registration dossier to the Authority. A list of major administrative documents required for low risk products market authorization applications are described below:

a) Application form

An application for new marketing authorization of low risk products should be submitted on-line through the (https://www.eris.efda.gov.et/) under low risk medicine application pathway. The application form is provided in Annex I of Guideline for registration of medicines 4th edition, 2020 to facilitate the online submission.

b) Application letter

A dated and signed letter for submission of the dossier by mentioning the product included in the dossier from the manufacturer and/or local agent responsible for registration.

c) Agency agreement

1. An agency agreement should be submitted in line with the requirements indicated under the Module 1 (Administrative and product information section) of the Medicine registration guideline, 4th Edition, 2020.
2. The agreement should state that if any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization, all the party's (local agents, manufacturer, and/or license holder) mentioned in the agreement will be responsible for the product recall and for substantiating any related consequences and liable for legal action as per article 38 (1&4) of proclamation No 1112/2019 or other relevant laws of the country

d) Certificate of good manufacturing Practices

A copy of valid Good Manufacturing Practice (GMP) and Manufacturing License Certificate of FPP manufacturer should be provided. Inspection of the manufacturing site (by the Authority) may not be pre-request for submission of application for registration of medicine. However, the manufacturing site should be inspected before issuance of the marketing authorization of the medicine under consideration. Thus, the copy of GMP certificate or GMP waiver letter issued by the Authority shall be requested prior to issuance of marketing authorization.

e) Certificate of pharmaceutical product

A valid Certificate of pharmaceutical product or marketing authorization certificate should be provided. Certificate of pharmaceutical product as a requirement for registration could be optional

provided that valid cGMP Certificate and Market Authorization Certificate issued by NMRA in the country of manufacture are submitted. The format of the CPP is provided in Annex II of Guideline for registration of medicine 4th edition, 2020. The CPP should be valid at a time of submission and should be in line with the explanatory notes of the CPP and summary of product characteristics.

f) Marketing Authorization status in other countries

The list of the countries in which the product under consideration is approved (registered), pending application, withdrawn (the reason thereof) should be summarized (in tabular form) and provided.

The countries in which the final product under consideration has already been marketed should be listed and the approval paperwork for granted marketing authorization as a low risk or equivalent category (such as OTC) of product should be provided.

For a low risk drug products registered by SRA, the information submitted should be true and have confirmations for composition (formulation), strength, manufacturing, specifications, packaging, manufacturing site and Product information sameness with the product on the market in the SRA country or country of manufacturing at all times.

g) Product information

Product information including the package insert, labelling, and summary of product characteristics (SmPC) should be provided in accordance with the requirements of EFDA`s directive for labelling. All product information label statements are required to be in English or Amharic. The information provided should not vary significantly from the claims made for the same product in any other jurisdiction. Any information appearing in the product information [labels, patient information leaflet (PIL), and SmPC] should be based on scientific justification.

Labelling (immediate and outer label)

Labels should be only original labels or computer-ready colour-printed labels and in the case where the text of the labels is printed directly on plastic bottles through a silk screen process, photocopies of these labels will be accepted for approval. The titles for batch number, manufacturing, and expiry dates should be part of the printing (type written materials, stickers,

etc., are not acceptable). If the labelling technology of the manufacturer is such that this information is to be printed on the label during production, a written commitment to show all the required information on the label of the finished product must be submitted. The contents of the label should at least contain:

a) The name of the product– brand and generic/International Non-proprietary Name (INN)
b) Pharmaceutical form and route of administration
c) Qualitative and quantitative composition of active ingredient(s), preservative(s), and antioxidant(s)
d) The volume of the contents, and/or the number of doses, or quantity in container
e) Directions to consult the package insert or the carton label for complete directions for use
f) Handling and storage conditions
g) Batch number
h) Manufacturing date
i) Expiry date
j) Name and site address of manufacturer
k) Country of origin

Patient Information Leaflet (PIL) or Package Insert

The general content of the PIL should be prepared in line with SmPC of Medicines**.** The PIL should not be described or presented in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its use in any respect, either pictorially or in words. The leaflet should provide clear information on the following:

a) Restriction on the maximum single dose or maximum daily dose, but without compromising on the dose that retains the necessary efficacy
b) Indication on whether the product is intended for children or adults; and specific dosage strengths suitable for pediatric use. Adult dosage consideration to be given to the need for several strengths
c) Display recommendation about duration of treatment to prevent unnecessary prolonged use
d) Simple consumer information that is not open to misinterpretation
e) The use(s) for which the product is intended

f) Furthermore, as per Food and medicine administration proclamation No 1112/2019, the information on leaflet of medicine that is included in the national essential medicine list of Ethiopia or widely circulated in Ethiopian market is required to be at least in English and Amharic.

h) Payment of service fees

Each application should be accompanied by a relevant service fee for registration as per the regulation 370/2015. For details, the applicants are advised to contact the Authority for the amount and modalities of payment.

7.2. Technical Document

a) An application dossier should be submitted in CTD format and should contain the required information, including technical data that support the safety, quality and efficacy of the product. The following technical documents shall be submitted for review:
   - Specifications of the API (s) and FPP
   - Methods of analysis of API(s) and FPP
   - Stability of FPP
   - certificate of analysis, and
   - compatibilities in relation to the following:
     a) Active pharmaceutical ingredient
     b) Excipients
     c) Container & closure.

b) Applications for marketing authorization of low risk products that has already been approved by SRAs, the applicant should provide evidences of approval by the SRAs and documents listed under section 7.2 (a) of this guideline.

8. Application and Assessment procedure

8.1. Application procedure

During application submission for MA of low risk products, the applicant shall give due diligence considerations to verify its suitability for marketing authorization via such approval pathway. At least the following aspects should be considered to decide whether a product is suitable and rational for approval by low risk MA pathway:

a) Products included in the detailed list of low risk medicines (Annex 1) which will be reviewed and updated periodically (annually).
b) Products which are not in the list of low risk categories but claimed to be low risk by the applicant will be subjected for decision by the EFDA technical committee for such product designation as per criteria in section 5 of this guideline.
c) Products switched from high risk to low risk (Example PoM to OTC) as per the principles provided in section 8.2 of this guideline.
d) Applications for low risk medicine must be submitted electronically (via eRIS system). The application dossier must be in Common Technical Document (CTD) format.

8.2. Switching high risk to low risk or vice versa.

Medicines under consideration having many years of marketing authorization approval as high-risk product and long-term use and established low risk profile, may be switched to low risk medicines category after inclusion in the low risk products based on available scientific evidence. On the other hand for medicines market authorization status shift from low risk to high risk, the authority will demand all requirements indicated in medicine registration guideline 4th edition for market authorization approval based on full assessment.

8.3. The review procedure

As the low risk medicine applications needs abbreviated review process, shorter target times apply to these types of applications. The Authority may make requests for further information from the applicant if there are issues arising at any stage of the evaluation process and granting the marketing authorization will be based on the outcome of the abbreviated review outcome.

Verifying eligibility of the medicine under consideration

Before the assessment the application needs to be verified against the list of low risk medicine, as indicated in general category of medicines listed under section 6 (including Annex 1) of this guideline. It should also be validated to determine whether it is eligible for such approval pathway, complete and meets the requirements for an effective application.

Return to the applicant

The applicant will be advised to shift the application path way if the application is found ineligible for this approval pathway or found to be incomplete to initiate review. However, submitting fabricated data will end up in rejecting the application or all applications from the same the same manufacturer based on the severity of consequences of the fabricated data.

Review of documents

Although the applicants are required to submit complete dossier as per the Common Technical Document (CTD) format, the evaluation should mainly focus on the administrative section (Module 1) and technical documents indicated on 7.2 (a) of this guideline.

9. Post approval control Activities

It is well known that there is no medicinal product that is 100 percent safe. As a result, lessening the requirements for marketing authorization of low risk products and simplifying the depth of evaluation of these products needs to be accompanied by strengthened follow up on post approval regulatory activities so as to minimize the unpredicted risks. Hence, EFDA will give due emphasis on the following post approval regulatory activities.

a) Taking robust, appropriate and timely regulatory actions as per the proclamation No 1112/2019 and other relevant laws based on cGMP, Port clearance or ware houses and retail outlets inspection findings, QC test reports, and/or ADE reports.
b) Revising low risk products list on predetermined regular basis
c) Establish and implement flexible system for switching high risk to low risk and vice versa

10. Post approval Changes and Re-registration Applications

10.1. Variation

For post approval variations, the applicants are advised to refer to and provide all relevant documents required by the guideline for submission of post approval variation medicine application. Whenever a product has been withdrawn from the market and/or its marketing authorization has been rejected, deferred, or withdrawn from market for any reason (such as deficiencies in GMP, product quality defect or ADE reports) in other countries, the local agent or the manufacturer should notify EFDA as per the article 67(17) of proclamation No 1112/2019.

10.2. Re- registration

Applications for re-registration of these category of medicines shall follow requirements specified in Appendix 4 (Requirements for Re-registration) of **the** Authority`s guideline for registration of medicines, 4th Edition, 2020**.**

Annex 1: Medicinal products listed as Low-Risk

S/No.	Name	Strength	Dosage Form
1. Antacid			
1	Aluminum Hydroxide	320 mg/5 ml 360 mg/5 ml 500 mg	Mixture/Gel Suspension Tablet (Chewable)
2	Aluminum Hydroxide + Magnesium Hydroxide	220 mg + 195 mg/5ml 400 mg + 400 mg	Suspension Tablet (Chewable)
3	Aluminum Hydroxide + Magnesium Trisilicate	310 mg + 620 mg/5ml 120 mg + 250 mg ; 250 mg + 500 mg	Suspension Tablet (Chewable)
4	Aluminium Hydroxide+ Magnesium Hydroxide+ Simethicone	225mg+200mg+25mg/5ml 400 mg+400 mg+40 mg	Suspension Tablet
5	Calcium carbonate	500 mg	Tablet(Chewable)
6	Magnesium Hydroxide	375 mg/5 ml, 7.75 % 300 mg; 311 mg	Mixture Tablet (Chewable)
7	Magnesium Trisilicate	500 mg	Tablet (Chewable)
2. Antispasmodics / Spasmolytic Analgesics			
1	Hyoscine (Scopolamine) Butylbromide	5mg/5ml 10mg 7.5mg, 10mg	Drops, Syrup, Tablet Suppository
2	Dimenhydrinate	50mg	Tablet
3	Hyoscine hydrobromide	150 microgram, 300 microgram	Tablet

S/No.	Name	Strength	Dosage Form
3. Cathartics and Laxatives			
1	Bisacody	5mg, 10mg 5mg, 10mg	Suppository Tablet
2	Castor oil	30ml, 60ml	syrup
3	Glycerin	1g, 1.36g, 2g, 2.76g	Suppository
4	Magnesium Sulphate		Oral powder
4. Medicines Used for Diarrhea			
1	Oral Rehydration Salt (ORS)		Powder
2	Zinc tablet	10mg, 20mg	tablet
5. Antiflatulents			
1	Activated Charcoal	125mg, 250mg	Tablet
2	Simethicone	60mg, 80mg, 95mg 95 mg, 125 mg 40 mg ; 150 mg ; 250 mg ; 62.5 mg/5 mL	Tablet (chewable) Capsule drop
6. Antihaemorrhoidal Agents			
1	Bismuth Subgallate Compound (Bismuth Subgallate +Bismuth Oxide + Peru Balsam+ Zinc Oxide)	2.25% +0.875%+ 1.875% +10.75% 59mg +24mg +49mg+296mg	Ointment Suppository
2	Lidocaine HCl + Tribenoside	(2.12gm+5gm)/100gm	Cream
7. Antitussives/Expectorants/Mucolytics			
1	Bromhexine Hydrochloride	4mg/5ml	Elixir

S/No.	Name	Strength	Dosage Form
2	Chlorpheniramine maleate + Ammonium chloride	(2mg + 100mg)/5ml	Linctus
3	Chlorpheniramine maleate + pseudoephedrine + paracetamol	4mg + 60mg + 500mg 2mg + 30mg + 500mg	Tablet
4	Dexchlorpheniramine+ Guaifenesin+ Pseudoephedrine	2mg +100mg + 20mg/5ml	Syrup
5	Dextromethorphan Hydrobromide	15mg/ml 5mg,7.5mg,15mg/5ml 15mg	Drops Syrup Tablet
6	Dextromethorphan Hydrobromide + Guaicol Sulphonate	0.3gm+7.6gm/100ml	Syrup
7	Diphenhydramine+ Sodium Citrate+ Ammonium Chloride	12.5mg +60mg + 130mg/5ml	Syrup
8	Guaifenesin	100mg, 200mg 200mg 100mg/5ml	Tablet Capsule Syrup
8. Antiasthmatics			
1	Ephedrine + Theophylline	6mg + 30mg/5ml 2.24% + 0.30% 11mg + 120mg	Elixir Syrup Tablet
2	Salbutamol (Albuterol)	0.1mg/dose 2mg/5ml	Oral Inhalation (aerosol) Syrup

S/No.	Name	Strength	Dosage Form
		2mg, 4mg, 4mg(s/r)	Tablet
3	Theophylline+ Guaifenesin	150mg + 90mg; 300mg + 180mg 150mg + 90mg/15ml 150mg + 90mg	Capsule Elixir Tablet
9. Analgesics / Antipyretics			
1	Acetylsalicylic Acid	300mg,324mg(microfined) 100mg,500mg (enteric coated)	Tablet
2	Diclofenac Sodium	25mg, 50 mg,100mg 100mg 50mg	Tablet Suppository Powder
3	Diclofenac Potassium	50mg	Tablet
4	Diclofenac diethylamine	1.16%	Gel
5	Ibuprofen	200mg, 400mg (enteric coated) 100mg/5ml	Capsule Tablet Syrup
6	Paracetamol	100mg/ml 125mg, 250mg 120mg/5ml, 250mg/5ml 100mg, 500mg	Drops Suppository Syrup Tablet
7	Paracetamol + Caffeine	500mg + 65mg	Tablet
10. Antimigraine Headache Medicine			

S/No.	Name	Strength	Dosage Form
1	Acetylsalicylic Acid + Paracetamol+ Caffeine	250mg + 250mg + 65mg	Tablet
2	Ibuprofen	300mg, 200mg, 400mg (enteric coated) 100mg/5ml	Capsule Tablet Syrup
3	Paracetamol + Caffeine	500mg + 65mg	Tablet
11. Antirheumatics			
1	Acetylsalicylic Acid	100mg, 300mg,324mg (microfined) 500mg (enteric coated)	Tablet
2	Acetylsalicylic Acid+ Paracetamol + Caffeine	250mg + 250mg + 65mg	Tablet
3	Diclofenac Sodium	25mg, 50 mg,75mg,100mg 100mg 50mg 1%	Tablet Suppository Powder Gel
4	Diclofenac Potassium	50mg	Tablet
5	Indomethacin	25mg, 50 mg, 75mg 25mg(enteric coated) 100mg	Capsule Tablet Suppository
6	Ibuprofen	300mg 200mg, 400mg (enteric coated) 100mg/5ml	Capsule Tablet Syrup
7	Methyl salicylate		Ointment

S/No.	Name	Strength	Dosage Form
12. Anthelmintic			
1	Albendazole	100mg/5ml 200mg, 400mg	Oral Suspension Tablet Tablet
2	Levamisole	40mg	Tablet
3	Mebendazole	100mg/5ml 100mg, 500 mg	Oral Suspension Tablet Tablet
4	Niclosamide	500mg	Tablet (chewable)
5	Praziquantel	600mg	Tablet
6	Piperazine	500mg, 622.5mg, 706mg, 750mg,937.5mg, 1g /5ml (Citrate) 300mg (Adipate)	Elixir Tablet
7	Pyrantel Pamoate	250mg base/5ml 125mg base	Oral Suspension Tablet
13. Vitamins and Minerals			
1	Ascorbic Acid (Vitamin C)	100mg, 500mg, 1g	Tablet
2	Folic acid	5mg	Tablet
3	Multivitamin Preparations		Drops Syrup Tablet
4	Multivitamin with Minerals and/or Extracts		Drops Syrup Tablet

S/No.	Name	Strength	Dosage Form
5	Vitamin B Complex Preparations (B_1+B_6+B_{12})	100mg + 200mg + 1000µg	Tablet
14. Ear, Nose and Throat Preparations			
1	Amyl-Meta-Cresol + Dichlorobenzyl Alcohol	0.6mg + 1.2mg	Lozenges
2	Chlorhexidine Gluconate	0.12%	Oral Solution
3	Dequalinium Chloride	0.25mg	Lozenges
4	Hexetidine	0.1%	Solution
5	Hexidine	0.1gm/100ml, 0.2%	Oral Solution
6	Menthol + Eucalyptus Oil + Light Magnesium Carbonate	2% +10% 7%	Inhalation
7	Saline Solution	0.09%	Solution
15. Antihistamines And Antiallergics			
1	Cetirizine	5 mg, 10 mg 1mg/1ml	Tablet Syrup
2	Chlorpheniramine Maleate	2mg/5ml 2mg, 4mg, 6mg	Syrup Tablet
3	DexchlorpheniramineMaleate	2mg, 4mg, 6mg 2mg/5ml	Tablet Syrup
4	DiphenhydramineHydrochloride	12.5mg/5mL 25mg, 50mg	Elixir Capsule
5	Loratadine	5mg/5mL 10mg	Syrup Tablet
6	Loratadine + pseudoephedrine	5mg + 120mg	Tablets

S/No.	Name	Strength	Dosage Form
7	Pheniramine Aminosalicylate	50mg, 75mg	Tablet
16. Anti-infectives, Topical			
1	Benzoic Acid+ Salicylic Acid	6% +3%, 12% +6%	Ointment
2	Benzyl Benzoate (BBL)	25%	Lotion
3	Gentian Violet (GV)	0.5%, 1%	Solution
4	Nitrofuranzone	30gm, 45mg	Ointment
5	Sulphur	5%, 10%	Ointment
6	Zinc Undecenoate + Undecenoin Acid	20% +5% 20% +2% 20% +2%	Ointment Powder Powder (aerosol)
17. Keratolytics /Caustics Agents			
1	Benzoyl peroxide	2.5%, 5%, 10% 2.5%, 5%, 10%	Gel Solution
2	Camphor		Cream, Lotion, Solution
3	Salicylic Acid	2%, 5%, 10%	Ointment
4	Salicylic Acid + Lactic Acid + Polidocanol	2gm+0.5gm+0.2gm/10gm	Tincture
18. Topical Agent For Psoriasis and Eczema			
1	Ichthammol	10%, 20%	Ointment
2	Zinc oxide	15%	Ointment

S/No.	Name	Strength	Dosage Form
19. Antiprurities			
1	Calamine	5%	Lotion
2	Calamine+ Zinc Oxide	4%+3% 15%+5%	Cream Lotion
20. Dermatologicals, Others			
1	Methylsalicylate		Ointment
2	Talc Dusting Powder		Powder
21. Miscellaneous			
1	Formaldehyde	3%, 8% (w/w or v/v)	Solution
2	Halazone	4mg	Tablet
3	Sodium Dichloroisocyanurate	67mg, 75mg	Tablet
4	Sorbitol	The initial dose for use as a laxative in adults is 30-150 mL of an oral 70% solution	Oral Solution 70%