



INDIES PHARMA JAMAICA LIMITED

“Caring for the Nation’s Health”

Unit-5 Montego Bay Trade Center, Howard Cooke Blvd, Montego Bay, JAMAICA, WEST INDIES. Toll free: 1-888-CALL-IPJ (225-5475),
Tel: 1-876-940-7984 / 7985. Fax: 1-876-940-6940 / 7980. E-mail: indiespharma@gmail.com

STATUTORY REQUIREMENTS
NEEDED THE PHARMACEUTICALS REGULATORY AFFAIRS UNIT
of
STANDARDS & REGULATIONS DIVISION – (FDA)
MINISTRY OF HEALTH - JAMAICA

MANDATORY STATUTORY REQUIREMENTS ON THE EXTERNAL CARTON & THE PRODUCT LABEL & the PACKAGING INSERT & SUMMARY OF THE PRODUCT CHARACTERISTICS also:

1. Keep out of the reach of children.
2. Store below 25 c.
3. Please read the package insert before use.
4. To be sold in retail on the prescription of a Registered Medical Practitioner only.
5. Batch number and manufacturing & expiry dates.
6. Name & address of the Manufacturer.

OTHER MANDATORY NEEDS FOR THE DOSSIERS:

- METHOD OF ANALYSIS MUST IN DUPLICATE IN EACH DOSSIER (NEW INCLUSION BY INDIES PHARMA - JAMAICA)
- The shelf life of the Finished formulations & the Working standards must be of at least 12months. PLEASE DO NOT SEND THE NEAR EXPIRY DATE SAMPLES.
- All Certificate of Analysis for the finished formulations & the Working standards samples must be in ORIGINAL.
- All the certificates & other documents must be signed & stamped by the concerned authorities with their names printed underneath.
- ALL PACKAGING INSERTS MUST HAVE FONT SIZE NOT LESS THAN **8**. (Except for Eye drops since the carton is already very small).
- All tablets, capsules, creams, ointments, inhalers, Nasal sprays, syrups & solution samples quantity must be 5 PACKS OF EACH PRODUCT with 5 count of the label drafts, carton boxes & the 5 count of packaging inserts along with the dossier are needed.
- Sample quantities for **INJECTIONS & EYE DROPS** must be in the count of **35 each**.



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- Every finished formulation sample must have its packaging insert in the carton box.
- Send us more registration samples than the required samples. We suggest you to send us at least 2 additional samples of each. We use the additional samples as standby should in case if any of the sample is spoiled or damaged during the shipment & also may be for obtaining the market feedback through the marketing executives.
- **The summary of the product characteristics in the dossier must reflect the quantities of both the active and inactive ingredients of the formulation**

MANDATORY NEEDS FOR DOSSIERS especially all oral formulations:

BE STUDY IS A MANDATORY for all oral tablet, capsule & suspensions- ethical formulations.

The BE study must be against the ORIGINATOR brand only. For Ex: Amlodipine the BE study must be done against the PFIZER’s brand only (NORVASC or ISTIN) procured from any where in the world.

BE study must be done with a minimum group size of **12 & upwards**.

BE study is not needed for Injections, Eye drops, Inhalers, Nasal sprays, Syrups & Solutions.

FDA in Jamaica does not accept the dossiers if they do not have the BE studies where ever it is applicable at the time of submission.

OTHER MANDATORY ISSUES:

The product that is being registered in Jamaica must have been on the local market (Country of manufacturing) for at least a period of 1 year before it can be accepted for registration by the FDA.

STANDARD CHECK LIST FOR ALL THE DOSSIERS – MANDATED BY INDIES PHARMA

ALL DOSSIERS MUST BE ACCOMPANIED WITH A DUPLICATE COPY.

Please also be advised that the local FDA will accept the dossiers only if the product is in the market for at least 1 year in the country of origin and also you must ensure that the clause 1.2 and 1.3 of the COPP's must read as YES.



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IMPORTANT ISSUES FOR SUCCESSFULL MARKETING:

2. Impressive physical appearance & Packaging aspect of the product.
3. Meaningful brand names.
4. Bar codes.
5. Good amount of back up with the articles in the popular journals and the dossiers must be bulky and large in Size.
6. Leave behind cards must be very colorful & informative.

PRECAUTIONS & SUGGESTIONS for Dossier Shipping:

- Please always send the dossiers and the registration samples in a polythene protective covers so that they will not be damaged during shipment.

OTHER IMPORTANT ISSUES TO BE TAKEN CARE OF:

- Please ensure necessary precautions are taken so that the registration samples are packed securely different from the dossier files so that they will not get crushed during the shipment.
- Novelties, complimentary gadgets of **highest quality** with the your logo on them are needed whenever you ship the dossiers since their presence will make a lot of difference whenever we go to the FDA, Ministry of Health to submit our dossiers and distribute to the staff at that particular office.
- All dossiers must be complete with all the requirements otherwise the FDA will not accept the dossiers.

REGISTRATION FEE:

The current registration fee is US\$83.00 per product (J\$ 5,000.00) and the cabinet has approved the same to be increased to US\$500.00 per product. Hence it is very much important to register as many products as possible in the closest available time.

TENURE OF REGISTRATION:

The registration is valid for life.



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ATTESTATION OF COPP’S for JAMAICA:

May we suggest to you that the following authorities need to attest & stamp their seal on the COPP’s in the interim:

1. DIRECTORATE of Drug Control Authority of your state.
2. CHAMBER OF COMMERCE – your state.
3. Attestation by the Ministry of Foreign affairs & Trade.
4. Attestation by the JAMAICAN EMBASSY in JAPAN.

The cost of attestation is US\$20 per copy, payable in cash or by certified manager’s cheque in the name of “Embassy of Jamaica”.

Please pre-pay return postage by FedEx or DHL, or authorize us to use your FedEx or DHL Account Number to return the documents to you. Alternatively, send an additional US\$20 for return postage by regular mail or US\$50 for postage by FedEx.

Please note that all documents should be legalized in India by the Ministry of External Affairs of India, before sending them to the Embassy of Jamaica in Tokyo. For requirements of the Ministry of External Affairs of India, please consult missioncons@nic.in, socons@mea.gov.in.

Embassy of Jamaica

ATT: MS. ANGELLA ROSE-HOWELL

(Authentication officer)

**Embassy of Jamaica, Tokyo
Toranomom Yatsuka Bldg. 2F
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