

Documents needed for for soft file submission of new veterinary product

Local & F-Toll products:

- Covering letter from the applicant signed & stamped showing the following data:
 - Product Name
 - Dosage Form
 - Type of Registration (New or Re-reg)
- Fees (1000 L.E.)
- Fees (10000 L.E.)
- Copy of Name Approval Letter.
- Package Insert (leaflet) of the product on the company letter head, signed & stamped supported by necessary references . (original & copy)
- Declaration of pack volumes on company paper signed & stamped in case of injection.
- Base calculation on company paper signed & stamped supported with references . (if needed)
- Reference for the composition (Original approved translation should be attached if needed)
- License of the applicant manufacturing factory.(copy)
- Letter of attorney for a person authorized for communication on behalf of the applicant company with correction of signature. (copy)

In case of Under license products these documents are needed in addition to the previous documents:

- Under license manufacturing agreement with list of products authenticated by the Egyptian Embassy & chamber of commerce.(original & copy)
- Certificate of Pharmaceutical Product (CPP) issued by ministry of health or ministry of agriculture in country of origin authenticated from the Egyptian Embassy & chamber of commerce.(original & copy)

In case of (Toll) manufacturing these documents are needed in addition to the previous documents:

- Copy of the toll card .

For imported products:

- Covering letter from the applicant signed & stamped showing the following data:
 - Product Name
 - Dosage Form
 - Type of Registration (New or Re-reg)
 - Manufacturer & License Holder Name
- Fees (1000 L.E.)
- Fees (10000 L.E.)
- Original Certificate of composition on the company letter head, signed & stamped
- Original Insert (leaflet) of the product on the company letter head, signed & stamped .
- Declaration of pack volumes on company paper signed & stamped in case of injection.
- Certificate of Pharmaceutical Product (CPP) issued by ministry of health or ministry of agriculture in country of origin authenticated by the Egyptian Embassy & chamber of commerce.(original & copy)
- Agency agreement or authorization letter with list of products authenticated by the Egyptian Embassy & chamber of commerce. .(original & copy)
- GMP (if GMP not mentioned in CPP of the product). (copy)
- The register of importers for the company (copy)
- The register of trade (copy).
- Letter of attorney for a person authorized for communication on behalf of the applicant company with correction of signature. (copy)

