STATE OF KUWAIT
MINISTRY OF HEALTH
Drug & Food Control
Pharmaceutical & Herbal Medicines
Registration & Control Admn.

دولة الكويت
وزارة الصحة
الرقابة الدوائية والغذائية
إدارة تسجيل ومراقبة
الأدوية الطبية والنباتية

Documents and Materials Required for Registration of Non-Classified Products and Medical Devices as per Ministerial Decree 201/99

1. Original Manufacturing License and G.M.P Certificates, legalized by the Kuwait Embassy in the country of origin.

2. Original Free Sale Certificate which should mention the Trade name, scientific name, Indications, and Detailed Composition for Active and Inactive Ingredients, should be issued from the health authority at country of origin and legalized by the Kuwait Embassy.

3. Status of registration of the product in the country of origin.

4. Original Letter of appointment for Sole Agency should be legalized by Arab Chamber of Commerce & Kuwait Embassy.

5. List of countries where the product is registered with registration dates and numbers.

6. Information of the product on the outer packs, inner packs samples should be in English or Arabic and satisfy the requirements of Ministry of Commerce of State of Kuwait.

- Information should include: Name, Composition, Uses, Batch No., Manufacturing date, Expiry Date & Storage Conditions as well as Indication.

7. Certificate of Analysis of finished product (with the same batch number as the sample(s) submitted. The certificate should include all tests mentioned in the Finished Product Specifications, the limits and results (if applicable)

8. Safety and Efficacy Studies from approved international authority (and or Clinical Studies if applicable)

9. In addition, if the committee requests for more information of that particular product they have to be complied with.