

**DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**

CHECKLIST

Application for Product/Substance Registration

Please lodge this checklist and arrange the documents in the following order with your application form.

- | | Yes | No |
|--|--------------------------|--------------------------|
| 1. Is this a <u>priority</u> application? | <input type="checkbox"/> | <input type="checkbox"/> |
| (i). change of name, dosage form or active ingredient, please provide the original registration certificate of the existing product; or | <input type="checkbox"/> | <input type="checkbox"/> |
| (ii). change of product certificate holder, please provide a statement from manufacturer for the change. | | |
| 2. Copy of <u>business registration certificate</u> of applicant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you provided a covering letter from the applicant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Have you provided an authorization letter from the manufacturer for products manufactured outside Hong Kong? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Have you provided evidence that the product is manufactured by a licensed manufacturer? (e.g. certified true copy of <u>manufacturer's licence</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Have you provide evidence of Good Manufacturing Practices (GMP) compliance of the manufacturer? (e.g. certified true copy of <u>GMP Certificate of the manufacturer</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you provided evidence that the product is allowed for sale in the country of origin? (i.e. original or certified true copy of <u>free sale certificate</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Is the product a <u>new</u> chemical or biological entity? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Have you provided <u>clinical and scientific papers</u> as required? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Have you enclosed one set of prototype <u>sales pack</u> (outer carton) and container label of each pack size of your product?
If product under application is an over-the-counter product, the dosage, route and frequency of administration are required to be labeled in both English and Chinese. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Have you enclosed copy of <u>documents to support the proposed indication(s), dosage, route of administration</u> and other contents of the package insert (if any) ? | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. (i) Have you provided the scanned image (not less than 300dpi) or photograph of pixel size (not less than 320x200) of your product sample, including sales pack, inner container/packaging and image of the drug sample or
(ii) sample of your substance as it will be sold to the purchaser? | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Have you provided information on both active and inactive ingredients of your product? (i.e. <u>complete master formula</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Have you provided the <u>specifications</u> issued by the manufacturer? Documents showing compliance with one or more of the following pharmacopoeias are required unless otherwise justified: Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia. | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Have you provided the <u>method of analysis</u> of the product? | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Have you provided a <u>certificate of analysis</u> of a representative batch of the product? | <input type="checkbox"/> | <input type="checkbox"/> |

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION

Appendix 1

17. Have you provided stability test data to justify the proposed shelf-life?
18. Have you provided Bioequivalence data for anti-epileptic drugs?