**CHECKLIST OF CLINICAL TRIAL APPLICATION DOSSIER**

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| Investigational product:Sponsor:Investigational site: |

| Documents |  | Note |
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| 1. Application letter for clinical trials |  |  |
| 1. Qualified notarized GMP certificate copy |  |  |
| 1. Certified copy of CPP or FSC for marketed products |  |  |
| 1. Clinical figure which has been certified by the authority (for the licensed product) |  |  |
| 1. Investigator’s brochure (IB) – Vietnamese version (PL.TNLS.01.03a hoặc PL.TNLS.01.03b) |  |  |
| 1. Investigator’s brochure (IB)\_ English version (for foreign products) |  |  |
| 1. Investigator’s brochure (IB)\_ Vietnamese summary version (if the full Vietnamese version not available) |  |  |
| 1. Curriculum vitae of principle investigator and investigators certified by the organization |  |  |
| 1. Principal Investigator’s GCP certificate (MOH certificate or other organizations recognized by the MOH |  |  |
| 1. Certificate of Good Laboratory Practice (GLP) or equivalent or written appraisal and approval of the MOH for testing facilities (notarized). |  |  |

Comments:

The dossiers are sufficient: 🞎 The dossiers are not satisfactory: 🞎

If not satisfactory, reasons:

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| Date of review | Reviewer | Signature |
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