Revised Provision for Drug Equivalence

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Regulation for Management of Drug Equivalence Test was revised to extend the range of drug products for drug equivalence test and run drug equivalence test well.

The main contents are as follow;

1. The multiple active ingredients of prescription drug products should be conducted drug equivalence test and the range of documents according to level of manufacturing method and site change is made clear.

2. The selection range of reference drug products is extended and the selection process is improved clearly.

3. The batch size of the test drug product should be at least 100, 000 units. Test drug product should be that the total content of the active drug substance is within 5 % of the labeled content (100 %) of reference drug product or the difference in content between test and reference drug product is within 5 %.

4. Drug equivalent test method is extended to conduct test by dissolution condition in specification and test method.

5. Bioequivalence test is made clear to meet "Minium Requirement for Bioequivalence Test"

6. Comparative dissolution test method and report are made clear by transferring those from attachment to text.

7. Comparative disintegration test method and report are made clear by transferring those from attachment to text.

8. The evaluation process of comparative test is made clear by establishment of attached form.