‘제네릭의약품 영문 심사보고서’ 양식

Bioequivalence Study Review Report

Bioequivalence Evaluation Division

작성일자를 월 일 년 순서로 기재한다.

① Applicant Name	*영문회사명을 기재하고 개인인 경우 성명을 기재한다.*
② Application Number and Submission Date(s)	*소비자 담당관실 또는 약효동등성과 접수번호, 접수일자를 기재한다.*
③ Drug Product Name	*신청제품명과 주성분명을 기재한다.*
④ Dosage Form and Strength	*제형과 주성분의 함량을 기재한다.(대한민국약전 참고)*
⑤ Code of drug categories	*분류번호 및 약효분류를 기재한다.(참고 : 의약품 분류 기준에 관한 규정(식약처 예규))*
⑥ Storage and Shelf life(Expiration)	*저장방법과 사용(유효)기간을 기재한다.(참고 : 대한민국약전 영문판)* *<저장용기 예시>* *well-closed(밀폐), tight(기밀), hemetic(밀봉), light-resisteant(차광)* *<저장온도 예시>* *at a temperature of 2~8℃(2~8℃보관), at below 5℃(5℃이하 보관)*
⑦ Regulations	· Regulation on Pharmaceuticals Approval, Notification and Review (MFDS Notification *고시번호와 일자를 기재한다.*) · Standard on Pharmaceuticals Equivalence Test (MFDS Notification *고시번호와 일자를 기재한다.*) · Regulation on Bioequivalence Test Management (MFDS Notification *고시번호와 일자를 기재한다.*) · Regulation on Designation as a Pharmaceutical Equivalence Required Compounds (MFDS Notification *고시번호와 일자를 기재한다.*)
⑧ Submitted Data	Data on Boequivalence study (Reference Listed Drug : *대조약 명칭과 제조사를 기재한다.*)
⑨ Outcome Decision	*Adequate(적합) 또는 Inadequate(부적합) 중 하나를 기재한다.*
※ Note - *자료제출 목적을 기재한다.* *<의약품 제조(수입)판매품목 허가: Application for pharmaceutical manufacturing(import) & marketing approval>* ※ Attachment 1. Bioequivalence Study Review Summary	

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<Attachment 1> Bioequivalence Study Review Summary

○ Regulations

·Regulation on Pharmaceuticals Approval, Notification and Review (MFDS Notification *고시번호와 고시를 기재한다.*)

·Standard on Pharmaceuticals Equivalence Test (MFDS Notification *고시번호와 고시를 기재한다.*)

·Regulation on Bioequivalence Test Management (MFDS Notification *고시번호와 일자를 기재한다.*)

·Regulation on Designation as a Pharmaceutical Equivalence Required Compounds (MFDS Notification *현 고시번호와 일자를 기재한다.*)

○ List of submitted data

1. Bioequivalence (BE) study data - Bioequivalence study report
2. Dissolution test data - *비교용출시험이 제출된 경우 작성하며 용출시험 조건을 기재한다.(예시 기준 및 시험방법조건: dissolution test method of drug product specification and tests, 의동고시조건: Standard on Pharmaceuticals Equivalence Test method)*

○ *검토 요약 사항을 기재한다. (예시 aaa tablet of AAA Pharm. falls under the 3(a(가목),b(나목),c(다목)) of the Article 25(2) of the Regulation on Pharmaceuticals Approval, Notification and Review. The product has proven to be bioequivalent with the reference listed drug(RLD), bbb tablet(CCC acetate) of BBB Pharm. As for the aaA tablet, comparative dissolution test data with aaa tablet have been submitted according to the Article 7(2) of the Standard on Pharmaceuticals Equivalence Test.)*

1. Bioequivalence study

생동성시험의 검토 요약 사항을 기재한다. (예시 To evaluate the bioequivalence of the aaa tablet(AAA Pharm.) compared to the bbb tablet(BBB Pharm.), the 2×2 cross-over study was conducted in 00 healthy male volunteers by orally administering 2 tablets each under the fasting(fed) condition. When statistically evaluating log-transformed AUC_t and C_{max} estimated from the CCC concentration in plasma, the 90% confidence intervals for the difference in mean values between the test and reference be within log 0.8 ~ log 1.25.)

		$AUC_{0\text{-}12hr}$ (*pg·hr/mL*)	C_{max} (*pg/mL*)	T_{max}(hr)	$t_{1/2}$(hr)
Reference	*bbb tablet (BBB Pharm.)*	*000±000*	*000±000*	*000±000*	*000±000*

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Test	*aaa tablet (AAA Pharm.)*	*000±000*	*000±000*	*000±000*	*000±000*
90% Confidence Interval* (criteria: log 0.8 ~ log 1.25)		*log 0.91~1.00*	*log 0.90~1.11*	-	-

(Arithmetic Mean±S.D., n=*00*)

AUC_t : Area under the plasma concentration curve from administration to last observed concentration at time t
C_{max} : Maximum plasma concentration
T_{max} : Time until C_{max} is reached
$t_{1/2}$: Plasma concentration half-life
* 90% confidence intervals for the ratio of the logarithmic transformed mean value

2. Comparative dissolution test

1) Linear elimination kinetics of the active drug substance

· *주성분의 선형소실자료가 제출되었을 경우 작성한다.*

2) Comparative dissolution test

· *함량고저에 의한 용출자료가 제출되었을 경우 작성한다. (예시 Comparative dissolution test data of the test product aAA tablet(AAA Pharm.) with the reference product aaa tablet(AAA Pharm.) was submitted in accordance with the test method in the Standard on Pharmaceuticals Equivalence Test, and similar dissolution profile results were obtained. Therefore, bioequivalence was proved by the submitted data.)*

영문판은 한글판의 참고사항임을 기술한다.(예시 This English version of the MFDS review report is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Korean original and this English translation, the former shall prevail. The MFDS will not be responsible for any consequence resulting from the use of this English version.)