

<안전성·유효성 심사관련 제출자료목록>

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○ 관련규정 : 의약품등의품목허가·신고·심사규정(식품의약품안전청고시 제2008-56호, 2008.08.14) 제25조제2항제7호, 적응증 추가 변경

구분 \ 제출자료		자 료 번 호																			
		1	3				4 ^{**}							5 ^{**}			6		7	8	
			가		나		가	나	다	라	마	바			가	나	다	가			나
			1)	2)	1)	2)						(1)	(2)	(3)							
II.자료제출의약품 3. 유효성분의 새로운 조성 또는 함량만의 증감																					
자료범위	○	×	×	×	×	×	×	×	×	×	×	×	×	○	×	×	○	×	○	○	
제출여부	○	×	×	×	×	×	×	×	×	×	×	×	×	○	×	×	○	×	○	○	

○ 제출자료 목록

1. 기원 또는 발견 및 개발경위에 관한 자료 (변경사유)

5.약리작용에 관한 자료

5.1. 효력시험

- 1) Brown S. In vitro spectrum of activity of tigecycline using fresh broth for MIC determinations; protocol number CMI-04-01. Pearl River: Wyeth Research; 2004. RPT-53923.
- 2) Jones RN, Fritch T. Tigecycline MIC testing results using fresh media. Pearl River: Wyeth Research; 2004. RPT-53924.
- 3) Milatovic D. In-vitro susceptibility of bacterial isolates to tigecycline using fresh media. Pearl River: Wyeth Research; 2004. RPT-53925.
- 4) Johnson B. In vitro susceptibility of bacterial isolates to tigecycline: a comparison of fresh and aged media. Pearl River: Wyeth; 2004. RPT-56441.
- 5) Petersen PJ, Bradford PA. Effect of medium age and supplementation with the biocatalytic oxygen-reducing reagent Oxyrase on in vitro activities of tigecycline against recent clinical isolates. Antimicrob. Agents Chemother. September 1, 2005 2005;49(9):3910-3918.
- 6) Edelstein PH, Weiss WJ, Edelstein MAC. Activities of tigecycline (GAR-936) against Legionella pneumophila in vitro and in guinea pigs with L. pneumophila pneumonia. Antimicrob. Agents Chemother.

2003;47(2):533-540.

- 7) Jones CH. Minimal inhibitory concentration calculations for tigecycline against *Legionella pneumophila* and *Legionella* species. Pearl River: Wyeth; 2004. RPT-53928.
- 8) Gales AC, Jones RN. Antimicrobial activity and spectrum of the new glycylcycline, GAR-936 tested against 1,203 recent clinical bacterial isolates. *Diagnostic Microbiology & Infectious Disease*. 2000;36(1):19-36.
- 9) Fritsche TR, Sader HS, Stilwell MG, Dowzicky MJ, Jones RN. Antimicrobial activity of tigecycline tested against organisms causing community-acquired respiratory tract infection and nosocomial pneumonia. *Diagn Microbiol Infect Dis*. Jul 2005;52(3):187-193.
- 10) Bouchillon SK, Hoban DJ, Johnson BM, Johnson JL, Hsiung A, Dowzicky MJ. In vitro activity of tigecycline against 3989 Gram-negative and Gram-positive clinical isolates from the United States Tigecycline Evaluation and Surveillance Trial (TEST Program; 2004). *Diagn Microbiol Infect Dis*. Jul 2005;52(3):173-179.
- 11) Hoban DJ, Bouchillon SK, Johnson BM, Johnson JL, Dowzicky MJ. In vitro activity of tigecycline against 6792 Gram-negative and Gram-positive clinical isolates from the global Tigecycline Evaluation and Surveillance Trial (TEST Program, 2004). *Diagn Microbiol Infect Dis*. Jul 2005;52(3):215-227.
- 12) Zhanel GG, Palatnick L, Nichol KA, Low DE, The CROSS Study Group, Hoban DJ. Antimicrobial resistance in *Haemophilus influenzae* and *Moraxella catarrhalis* respiratory tract isolates: results of the Canadian respiratory organism susceptibility study, 1997 to 2002. *Antimicrob. Agents Chemother*. June 1, 2003 2003;47(6):1875-1881.
- 13) Betriu C, Gomez M, Rodriguez-Avial I, Culebras E, Picazo JJ. In vitro activity of tigecycline against ampicillin-resistant *Haemophilus influenzae* isolates. *J Antimicrob Chemother*. May 2005;55(5):809-810.

6. 임상시험성적에 관한 자료

가. 임상시험자료집

- 효능효과 추가 (지역사회 획득 세균성 폐렴)

1.1) 지역사회 획득 폐렴(CAP, community-acquired pneumonia)을 가진 환자들을 대상으로한 타이제사이클린의 집단 약동학 - 3074A1-308-WW,

3074A1-313-WW (ICPD 보고서 번호: ICPD00117-02, ICPD00117-Appendices), CSR-67076

1.2) 지역사회 획득 폐렴(CAP, community-acquired pneumonia)을 가진 환자들에서 시행한 타이제사이클린의 노출-반응 분석 - 3074A1-308-WW, 3074A1-313-WW (ICPD 보고서 번호: ICPD00117-02), CSR-67077

1.3) 지역사회 획득 폐렴이 있는 입원 피험자를 치료하기 위해 타이제사이클린(Tigecycline)과 레보플록사신(Levofloxacin)의 유효성과 안전성을 비교한 3상 다기관 무작위배정 양측 눈가림 비교 시험 (시험계획서 3074A1-308-WW, CSR-63128), CSR-63128

1.4) 지역사회 획득 폐렴(CAP, community-acquired pneumonia)이 있는 입원 피험자를 치료하기 위한 정맥주사 타이제사이클린과 정맥주사 레보플록사신의 유효성과 안전성에 대한 3상 다기관 무작위 배정, 비교시험 (시험계획서 3074A1-313-WW, CSR-61261), CSR-61261

- 용법용량 변경

- 주사액의 조제(조제 후 48시간 냉장보관) 및 혼합가능한 정맥투여 용액 : 링거 주사액(Lactated Ringer's)

- 2) Admixture Compatibility Evaluation of Reformulated Tygacil (50 mg/Vial) at 50 mg or 100 mg Dose With Lactated Ringer's Injection (RPT-70624)

- 3) Y-Site Chemical Compatibility Testing of 1 mg/mL Reformulated Tygacil (Tygacil Lactose formulation) Solutions in 5% Dextrose Injection, USP with Various Drugs (RPT-72160)

- 4) Admixture Compatibility Evaluation of 24-Month Room Temperature Samples for Reformulated Tygacil (50 mg/vial) at 50 mg and 100 mg Dose (RPT-69887)

- 배합 금기

- 5) Y-Site Chemical Compatibility Testing of Reformulated Tygacil IV Admixture with Various Drugs and Diluents (RPT-60680)

- 6) Simulated Y-Site Compatibility Testing of Tigecycline Intravenous Solutions with Various Intravenous Diluents and Drugs Using Physical Techniques (RPT-62363)

- 7) Y-Site Physical and Chemical Compatibility Testing of 1 mg/mL Tygacil (Lactose Formulation) Solutions in 0.9% Sodium Chloride Injection, USP and 5% Dextrose Injection, USP with Esomeprazole Sodium Injection, and

Metoclopramide Injection (RPT-74976)

- 사용상의 주의사항 변경

- 감염 종류별 사망의 결과가 나타난 이상반응

- 8) Clinical investigation of GAR-936 protocol 3074A1-ES mortality in integrated phase 3 studies modified ITT population by indication

- 9) Clinical investigation of GAR-936 protocol 3074A1-ES mortality in HAP Study modified ITT population TIGECYCLINE ww/sNDA

- 10) Biostatistical Analysis Provided on 15-Feb-2009

- 11) Clinical investigation of GAR-936 protocol 3074A1-IES

- 12) Justification for a Safety Labeling Decision Cholestasis and Hepatic Dysfunction 05 December 2008

- 13) Rationale for the Precautions Section Modification 19 February 2009

- 원내감염 폐렴 환자

- 14) Final report: A phase 3, Multicenter, randomized, double-blind, comparative study of the efficacy and safety of tigecycline versus imipenem/cilastatin for the treatment of subjects with nosocomial pneumonia (CSR-68685)

7. 외국의 사용현황 등에 관한 자료

미국허가사항

8. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료

허가국 허가사항