**<안전성·유효성 심사관련 제출자료 목록>**

○ 관련조항 : 의약품등의안전성·유효성심사에관한규정 (식품의약품안전청고시 제2003-17호, 2003.4.14.) 제2조제1항제2호 [별표2] 라. 유효성분의 새로운 조성 또는 함량만의 증감 (단일제 → 단일제)

| 구분 \ 자료번호 | 1 | 2 | 3 | | 4 | | | | | | | | 5 | | | 6 | | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 가 | 나 | 가 | 나 | 다 | 라 | 마 | 바 | 사 | 아 | 가 | 나 | 다 | 가 | 나 | | |
| 1. 제출자료 | ○ | × | ○ | × | × | × | × | × | × | × | × | △ | ○ | X | X | ○ | X | ○ | ○ |
| 2. 제출여부 | ○ | × | ○ | × | X | X | × | × | × | × | × | X | X | X | X | ○ | X | ○ | ○ |
| 3. 면제사유 | 1. 동규정 제7조제5항에 따른 약리시험자료 면제 (고함량제제 추가) | | | | | | | | | | | | | | | | | | |

*주 : 자료번호 1 내지 8은 동규정 제5조제1항제1호 내지 제8호의 자료를 말한다.

○ 제출자료 목록

1. 기원 또는 발견 및 개발경위에 관한 자료

2. 안정성에 관한 자료 : 24개월간의 장기보존시험자료 및 6개월간의 가속시험자료

3. 약리에 관한 자료 : 제7조제5항에 따른 약리시험자료 제출면제 (고함량제제 추가)

4. 임상시험성적에 관한 자료

가. 생물학적동등성시험자료

1) A bioequivalence study comparing a single dose of 32mg candersartan cilexetil, given either as a 32mg tablet or as two 16mg tablets (SH-AHC-0014)
2) A single dose bioequivalence study of candesartan cilexetil comparing 1x16mg with 2x8mg tablets

나. 치료적 탐색시험

1) Evaluation of the efficacy and safety of candesartan cilexetil in the treatment of patients with hypertension : a multicentre, randomized, double blind, placebo controlled, dose response study (AM113)
2) Evaluation of the safety and efficacy of candesartan clexetil in the treatment of patients with hypertension : a multicentre, randomized, double blind,

placebo controlled, dose escalation study (AM119)

다. 치료적 확증시험

1) Efficacy of candesartan cilexetil in hypertensive black patients : A double-blind, randomised, parallel group design study with an open label, long term extension (AM 140 DB)
2) Comparison of the safety and antihypertensive efficacy of the fixed combination of candesartan cilexetil and hydrochlorothiazide(32mg/12.5mg) once daily with the individual blind, placebo-controlled, parallel-design study (AM153)
3) Evaluation of the antihypertensive effect of candesartan cilexetil in comparison to losartan : a double-blind, multicenter, parallel design, randomized study (the CANDLE study, AM175)
4) Evaluation of the antihypertensive efficacy, safety and tolerability of candesartan cilexetil in comparison to amlodipine : a multicenter, double-blind, randomized, parallel group, forced titration study (The CASTLE study, AM176)
5) Evaluation of the antihypertensive efficacy of candesartan cilexetil in comparison to losartan : a multicenter, double-blind, randomized, parallel-group, forced titration study (AM230)
6) Evaluation of the antihypertensive efficacy of candesartan cilexetil in comparison to losartan : a multicenter, double-blind, randomized, parallel-group, forced titration study (AM231)
7) Evaluation of the efficacy and tolerability of candesartan cilexetil in hypertensive patients across several aspects of patients demographics (AM205)
8) Efficacy of candesartan cilexetil in hypertensive black patients : a double-blind, randomized, placebo controlled, parallel-group design study with an open-label, long term extension (AM104QL)

5. 외국의 사용현황 등에 관한 자료 : 유럽 및 미국의 허가사항

6. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료