<안전성·유효성 심사관련 제출자료목록>

○ 관련조항 : 의약품등의안전성·유효성심사에관한규정 (식품의약품안전청고시 제2003-17호, 2003.4.14.) 제2조제1항제2호 [별표2] 나. 새로운 조성 (복합제)

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	○	×	○	×	○	△	×	×	×	×	×	△	○	×	×	○	×	○	○
2. 제출여부	○	×	○	×	×	×	×	×	×	×	×	×	○	×	×	○	×	○	○
3. 면제사유	독성에 관한 자료 제7조제5항에 의거 면제																		

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

○ 제출자료 목록

1. 기원 및 개발경위에 관한 자료

3. 안정성에 관한 자료
3.1. 12개월 장기보존시험자료
3.2. 6개월 가속시험자료

4. 독성에 관한 자료 : 제7조제5항에 따라 면제

5. 약리작용에 관한 자료
5.1. 효력시험자료
5.1.1. Effect of dietary supplementation of 1,25(OH)2D3 to control or tibial dyschondroplasia-inducing diets on performance and incidence of tibial dyschondroplasia in 3-week-old and 6-week-old male broiler chickens (F-92-17)
5.1.2. Effect of dietary supplementation of 1,25(OH)2D3 to control, intermediate or tibial dyschondroplasia-inducing diets on performance and incidence of tibial dyschondroplasia in 3-week-old male broiler chickens (F-92-18, F-93-01)
5.1.3. Vitamin D metabolites prevent vertebral osteopenia in ovariectomized rats. Calcif Tissue Int, 1992, 50:228-36.
5.1.4. The advantage of alfacalcidol over vitamin D in the treatment of osteoprorosis. Calcif Tissue Int, 1999, 65:311-6.

5.1.5. Prevention of bone loss in ovariectomized rats by combined treatment with risedronate and 1α, 25-dihydroxyvitamin D3. J Bone Miner Res, 2002, 17(8):1498-511.

5.1.6. The Bisphosphonate aledronate inhibits bone loss due to ovariectomized in rats J. Bone Miner Res, 1991, 6(4):.

5.1.7. MRL Preclinical report: Pharmacology of MK-217, MSDRL,

6. 임상시험성적에 관한 자료

[임상약리시험]

6.1. MRL clinical study, single study: An open, randomized, 2-period, crossover, pilot study to investigate the influence of vitamin D3 on the oral absorption of alendronate (protocol 183)

6.2. An open-label, randomized, 3-period, crossover, pilot study to examine the relative bioavailability of alendronate and the pharmacokinetics of vitamin D3 in an alendronate/vitamin D3 combination tablet (protocol 220)

6.3. A 2-part, open-label, randomized, crossover study to evaluate the bioequivalence of the 70-mg alendronate/2800 IU vitamin D3 final-market combination tablet to a 70-mg alendronate marketed tablet, and the relative bioavailability of vitamin D3 (protocol 226)

[치료적확증시험]

6.4. A 15-week, double-blind, randomized, active-controlled, multicenter study with 24-week extension to evaluate the safety, tolerability, and efficacy of alendronate 70-mg plus vitamin D3 2800IU combination tablet in men and postmenopausal women with osteoporosis (protocol 227)

7. 외국의 사용현황 등에 관한 자료

8. 국내 유사제품과의 비교검토에 관한 자료