

<별지2>

<안전성·유효성 심사관련 제출자료목록>

○ 관련규정 : 의약품등의품목허가·신고·심사규정(식약청고시 제2008-56호, 2008.8.14.) 제2조제8호 [별표1] II. 자료제출의약품 2. 새로운 효능군 의약품, 4. 새로운 투여경로 의약품 (기타), 5. 새로운 용법·용량 의약품, 제28조제2항

구분	자료번호		3		4					5		6		7	8						
			가	나	가	나	다	라	마	바	(1)	(2)	(3)	가	나						
	1)	2)	1)	2)																	
1. 제출자료	○	×	×	×	○	×	△	△	×	△	×	△	△	△	○	△	○	○	×	○	○
2. 제출여부	○	×	×	×	○	×	×	×	×	×	×	×	×	×	×	○	×	○	○	○	○
3. 면제사유																					

○ 제출자료목록

1. 기원 또는 발견 및 개발경위에 관한 자료

3. 안정성에 관한 자료

3.나. 완제의약품에 관한 자료

3.나.1) 장기보존시험 또는 가속시험자료

3.나.1.1. 장기보존시험자료 (60개월)

3.나.1.2. 가속시험자료 (6개월)

6. 임상시험성적에 관한 자료

6.가. 임상시험자료집

6.가.1. Assay of beclomethasone 17,21-dipropionate (BDP), beclomethasone 17-monopropionate (BMP) and beclomethasone alcohol (BOH) by combined HPLC/MICL/MS to evaluate systemic absorption in young healthy volunteers following 2 single rectal administrations (enemas and suppositories) and a single oral dosing as enteric coated tablets

6.가.2. The in-vivo behaviour of a colonic delivery system

6.가.3. Recovery of beclomethasone 17,21-dipropionate (BDP), beclomethasone 17-monopropionate (BMP), and beclomethasone alcohol (BOH) in ileostomy effluents of patients who had undergone previously a terminal ileostomy (since 3 months at least) following single oral administration of two different 5mg BDP tablets : enteric-coated or core (non

enteric-coated) tablets

- 6.가.4. Evaluation of the systemic exposure to beclomethasone dipropionate and its active metabolite beclomethasone 17 monopropionate and the effects on cortisok 24-hour urinary excretion after single and repeated administration of BDP enteric coated tablets in 12 ulcerative colitis disease patients
- 6.가.5. Randomised, double-blind, parallel group, controlled clinical study, in open-label with 5-aminosalicylic acid (5-ASA), to assess the efficacy and tolerability of two dose levels (5mg/day and 10mg/day) of beclometasone dipropionate in the treatment of active mild to moderate ulcerative colitis
- 6.가.6. Mulyticentre double blind randomised, balanced parrallel group, controlled, dose range finding study of 5mg every 2 days, 5mg, and 10mg of beclomethasone dipropionate enteric coated tablets versus placebo in mild to moderate extensive ulcerative colitis patients under oral aminosalicylated (like mesalazine, sulfasalazine) preventive therapy
- 6.가.7. Evaluation of the efficacy and safety of beclometasone dipropionate (BDP), 5mg tablets, in the treatment of ulcerative colitis
- 6.가.8. Beclometasone dipropionate in the treatment of active mild to moderate ulcerative colitis. Multicentre, randomised, parrallel-study, double-blind, placebo-controlled study

7. 외국의 사용현황 등에 관한 자료

8. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료