<안전성·유효성 심사관련 제출자료목록>

○ 관련조항 : 의약품등의안전성·유효성심사에관한규정 (식품의약품안전청고시 제2003-17호, 2003.4.14.) 제2조제1항제1호

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	[별표1] 주5.에 따라 면제함.																		

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

○ 제출자료 목록

1. 기원 또는 발견 및 개발경위에 관한 자료

2. 구조결정·물리화학적 성질 및 생물학적 성질에 관한 자료(자사기준 및 시험방법 포함)

3. 안정성에 관한 자료

3.가. 장기보존시험 또는 가속시험자료

3.가.1. 36개월 장기보존시험자료

3.가.2. 24개월 중간시험자료

3.가.3 6개월 가속시험자료

3.나. 가혹시험자료

3.나.1. 광안정성시험자료

4. 독성에 관한 자료

4.가. 단회투여독성시험자료

4.가.1. R905-TX-001: Single oral dose toxicity study of YM905 in rats

4.가.2. R905-TX-002: Single oral dose toxicity study of YM905 in beagle dogs

4.가.3. R905-TX-045: Determination of plasma drug concentration from the study: Single oral dose toxicity study of YM905 in beagle dogs

4.나. 반복투여독성시험자료

4.나.1. R905-TX-003: Four-Week oral dose toxicity study of YM905 in rats

4.나.2 R905-TX-004: YM905 Toxicokinetics study by oral gavage administration to F344 rats for 4 weeks

4.나.3. R905-TX-005: YM905 Toxicity study by oral gavage administration to F344 rats for 26 Weeks followed by a 10 week recovery period

4.나.4. R905-TX-006: Four-Week oral toxicity study of YM905 in beagle dogs
4.나.5. R905-TX-007: YM905 Toxicity study by oral capsule administration to beagle dogs for 13 weeks
4.나.6. R905-TX-008: YM905 Toxicity study by oral capsule administration to beagle dogs for 52 weeks
4.나.7. R905-TX-009: YM905 Preliminary toxicity study by oral gavage administration to CD-1 mice for 2-weeks
4.나.8. R905-TX-010: YM905 Toxicity study by oral gavage administration to CD-1 mice for 13 weeks followed by a 5 week recovery period
4.나.9. R905-TX-026: 26-Week repeated oral dose toxicity study of YM905 in mice
4.나.10. R905-TX-035: YM905: Toxicity study by intravenous (bolus) administration to CD-1 mice for 2 weeks
4.나.11. R905-TX-036: 14 Day intravenous toxicity study with YM905 in dogs
4.나.12. R905-TX-041: Dose finding study for 2-week intravenous toxicity study of YM905 in beagle dogs
4.나.13. R905-TX-042: YM905: Dose Range findings toxicity study by intravenous (Bolus) administration to CD-1 mice 4 days
4.나.14. R905-TX-047: YM905: Statistical analysis of 4-week dog toxicity study

4.다. 생식발생독성시험자료

4.다.1. R905-TX-011: Effects of YM905 on fertility and early embryonic development to implantation in male rats by oral administration
4.다.2. R905-TX-012: Effects of YM905 on fertility and early embryonic development to implantation in female rats by oral administration
4.다.3. R905-TX-027: Effects of YM905 on fertility and early embryonic development to implantation in mice by oral administration
4.다.4. R905-TX-044: Determination of plasma drug concentration from the study: Effects of YM905 on fertility and early embryonic development to implantation in male rats by oral administration
4.다.5. R905-TX-046: Determination of plasma drug concentration from the study: Effects of YM905 on fertility and early embryonic development to implantation in female rats by oral administration
4.다.6. R905-TX-013: Effects of YM905 on embryo-fetal development in rats by oral administration - Dose range findings study
4.다.7. R905-TX-014: Effects of YM905 on embryo-fetal development in rats by oral administration
4.다.8. R905-TX-015: Preliminary oral teratology study of YM905 in rabbits
4.다.9. R905-TX-016: Effects of YM905 on embryo-fetal development in rabbits by oral administration
4.다.10. R905-TX-028: Effect of YM905 on embryo-fetal development in mice by oral administration -dose range finding study
4.다.11. R905-TX-029: Effects of YM905 on embryo-fetal development in mice by oral administration
4.다.12. R905-TX-030: YM905: Toxicokinetic study in pregnant New Zealand White rabbits
4.다.13. R905-TX-033: Investigational study for the fetal cleft palate in oral administration of YM905 to pregnant mice
4.다.14. R905-TX-034: Oral (gavage) toxicokinetic study of YM905 in presumed pregnant mice
4.다.15. R905-TX-032: Effect of YM905 on prenatal/postnatal development in mice by oral administration,

including maternal function

4.라. 유전독성시험자료

4.라.1. R905-TX-017: Reversion test of YM905 in bacteria

4.라.2. R905-TX-018: YM905: Induction of chromosome aberrations in cultured human peripheral blood lymphocytes

4.라.3. R905-TX-019: Micronucleus test of YM905 in rats

4.라.4. R905-TX-040: Plasma drug concentration of YM905 after single oral dosing to Fischer rats

4.마. 면역독성시험자료(항원성시험 및 기타 면역 독성시험자료)

4.마.1. R905-TX-039: Delayed type skin reaction test of YM905 in guinea pigs

4.바. 발암성시험자료

4.바.1. R905-TX-023: YM905: Carcinogenicity study by oral gavage administration to CD-1 mice for 104 weeks

4.바.2. R905-TX-024: 104-Week carcinogenicity gavage study with YM905 in rats

4.아. 국소독성시험자료

4.아.1. R905-TX-020: Acute skin irritation test of YM905 in rabbits

4.아.2. R905-TX-021: Acute eye irritation test of YM905 in rabbits

4.아.3. R905-TX-037: YM905: Intravenous, perivenous and intraarterial tolerance study in the New Zealand White rabbits

4.자. 기타독성시험자료

4.자.1. R905-TX-038: YM905 Haemocompatibility test: Method of Prieur et al

5. 약리작용에 관한 자료

5.가. 효력시험자료

5.가.1. R905-PH-001: Affinity of YM905 for human muscarinic M1, M2 and M3 receptor

5.가.2. R905-PH-002: Affinity of YM905 for various neurotransmitter receptors and ion channel

5.가.3. R905-PH-003: Ca2+ mobilization and activation of extracellular acidification by carbachol in acutely dispersed cells from guinea pig detrusor: Fura 2 fluorometry and microphysiometry using the Cytosensor

5.가.4. R905-PH-004: The effects of muscarinic antagonists on carbachol-induced intracellular calcium mobilization and activation of extracellular acidification in dispersed longitudinal smooth muscle cells from guinea pig colon

5.가.5. R905-PH-005: Effects of YM905, tolterodine and oxybutynin on M3 receptor-mediated cytosolic free Ca2+ mobilization in acutely dissociated cells from guinea pig urinary bladder smooth muscle and murine submandibular gland

5.가.6. R905-PH-006: Effects of YM905, oxybutynin and darifenacin on carbacholinduced intracellular calcium mobilization in dispersed longitudinal smooth muscle cells from guinea pig colon

5.가.7. R905-PH-007: Muscarinic M3 receptor antagonisticeffect of YM905 in isolated guinea pig urinary bladder

5.가.8. R905-PH-008: Muscarinic M3 receptor antagonistic effect of YM905 in the guinea pig colon

5.가.9. R905-PH-010: Effect of YM905 on response of urinary bladder and salivary gland to carbachol in

anesthetized mouse

5.가.10. R905-PH-011: Effects of YM-67905 on micturition reflex in anesthetized rats

5.가.11. R905-PH-018: Effect of M3 receptor antagonists on short-circuit current response in rat colonic mucosa

5.가.12. R905-PH-019: Effect of YM905 on cholera toxin-induced intestinal secretion in mice

5.가.13. R905-PH-020: Effect of chronic doses of YM905 on carbachol-induced salivary secretion in mice

5.가.14. R905-PH-022: Effect of darifenacin on carbachol-induced intracellular calcium mobilization in dispersed acinar cells from mouse submandibular gland

5.가.15. R905-PH-036: Affinity of solifenacin for the sodium channel site 2 and the sigma receptor

5.가.16. R905-PH-038: Cheng-Prusoff analysis for estimating YM905 affinity constants for muscarinic M3 receptors on dissociated smooth muscle cells from guinea pig bladder and colon

5.가.17. R905-PH-049: Effects of solifenacin succinate (YM905) on carbacholinduced intracellular Ca2+ mobilization in dispersed bladder smooth muscle and submandibular gland cells in monkeys

5.가.18. R905-PH-050: Effects of solifenacin succinate on carbachol-induced urinary bladder contraction and salivary secretion in anesthetized rats

5.가.19. R905-PH-051: Muscarinic M3 receptor antagonistic effect of solifenacin in isolated rat urinary bladder

5.가.20. R905-PH-052: Effects of solifenacin succinate on carbachol-induced intracellular Ca2+ mobilization in enzymatically-dispersed bladder smooth muscle and submandibular gland cells in rats

5.나. 일반약리시험자료

5.나.1. R905-PH-023: General pharmacology study of YM905

5.나.2. R905-PH-027: General pharmacology of YM-64250

5.나.3. R905-PH-029: Affinity of YM-64250 for various neurotransmitter-related receptors and ion channels

5.나.4. R905-PH-031: Effect of YM905 on action potential parameters in dog isolated cardiac Purkinje fibers

5.나.5. R905-PH-032: Effect of YM905 on 86Rb efflux from CHO cells stably expressing the human potassium channel HERG

5.나.6. R905-PH-033: Assessment of the Effect of YM905 Eyedrop on Normal Intraocular Pressure in Albino Rabbits

5.나.7. R905-PH-035: Evaluation of antimuscarinic effects of solifenacin hydrochloride (BY-235C) and its stereoisomers (BY-235B, BY-235D, BY-235E)

5.나.8. R905-PH-037: Effect of M2 and M5 on action potential parameters in dog isolated cardiac Purkinje fibers

5.나.9. R905-PH-039: Affinity of YM-277743 for various neurotransmitter-related receptors and ion channels

5.나.10. R905-PH-040: General Pharmacology of YM-277743

5.나.11. R905-PH-042: Effect of solifenacin and other antimuscarinics on 86Rb efflux from CHO cells

stably expressing the human potassium channel HERG

5.나.12. R905-PH-043: Affinity of YM-80264 and YM-270293 for various neurotransmitter-related receptors and ion channels

5.나.13. R905-PH-045: Effect of metabolites of solifenacin on 86Rb efflux from CHO cells stably expressing the human potassium channel HERG

5.나.14. R905-PH-046: Effect of DD01, an active metabolite of tolterodine, on 86Rb efflux from CHO cells stably expressing the human potassium channel HERG

5.나.15. R905-PH-048: The electrophysiological effects of solifenacin on cardiac action potential in isolated guinea pig papillary muscles

5.나.16. R905-PH-053: General Pharmacology of YM-80264 and YM-270293

5.나.17. R905-PH-054: Effect of M3 and M4 on action potential parameters in dog isolated cardiac Purkinje fibers

5.나.18. R905-PH-055: Effect of solifenacin, its metabolites, and other antimuscarinics on the HERG K+ currents stably expressed in CHO cells

5.나.19. R905-PH-058: Affinity of YM-80264 for human muscarinic receptors

5.다. 흡수, 분포, 대사 및 배설시험자료

[흡수]

5.다.1. R905-ME-001: Absorption, distribution, metabolism and excretion of radioactivity after oral administration of 14C-YM905 to rats

5.다.2. R905-ME-002: Plasma concentrations of the unchanged drug and its metabolite BY-348C after single intravenous

5.다.3. R905-ME-003: Plasma concentrations of the unchanged drug after single intravenous and oral administration of YM905 to dogs

5.다.4. R905-ME-004: Plasma concentrations of the unchanged drug after repeated oral administration of YM905 to dogs

5.다.5 R905-ME-005: Recovery study of the increased plasma concentrations after repeated oral administration of YM905 to dogs

5.다.6. R905-ME-006: Food effect study after single oral administration of YM905 to dogs

5.다.7. R905-ME-019: Plasma concentrations of the unchanged drug after single oral administration and in vitro plasma protein binding of YM905 in mice

5.다.8. R905-ME-030: Plasma concentrations of YM905 and YM-64250 after repeated oral administration of YM905 or single oral administration of YM-64250 to mice

5.다.9. R905-ME-031: ^{14}C-YM905 Absorption, Distribution, Excretion in the mouse after single oral administration

5.다.10. R905-ME-032: ^{14}C-YM905 Pharmacokinetic, excretion and biliary excretion in dog after single oral administration

5.다.11. R905-ME-033: ^{14}C-YM905 Tissue distribution in mouse after repeated oral administration

5.다.12. R905-ME-069: YM905 Plasma concentrations of the unchanged drug aftersingle intravenous and oral administration of YM905 to mice

[분포]

5.다.13. R905-ME-001: Absorption, distribution, metabolism and excretion of radioactivity after oral

administration of ^{14}C-YM905 to rats (중복자료: 5-다-① 흡수 참고)

5.다.14. R905-ME-002: Plasma concentrations of the unchanged drug and its metabolite BY-348C after single intravenous (중복자료: 5-다-① 흡수 참고)

5.다.15. R905-ME-003: Plasma concentrations of the unchanged drug after single intravenous and oral administration of YM905 to dogs (중복자료: 5-다-① 흡수 참고)

5.다.16. R905-ME-007: In vitro plasma protein binding of YM905

5.다.17. R905-ME-019: Plasma concentrations of the unchanged drug after single oral administration and in vitro plasma protein binding of YM905 in mice (중복자료: 5-다-① 흡수 참고)

5.다.18. R905-ME-031: ^{14}C-YM905 Absorption, Distribution and Excretion in the mouse after single oral administration (중복자료: 5-다-① 흡수 참고)

5.다.19. R905-ME-033: ^{14}C-YM905 Tissue distribution in mouse after repeated oral administration (중복자료: 5-다-① 흡수 참고)

5.다.20. R905-ME-034: ^{14}C-YM905 Placental transfer in the mouse after single oral administration

5.다.21. R905-ME-035: Pharmacokinetic study of YM905: Excretion into milk after single oral administration of 14C-YM905 to lactating mice

5.다.22. R905-ME-040: In vitro study for the transfer of YM905 into red blood cells

5.다.23. R905-ME-067: Distribution and metabolic fingerprinting in eye ball after oral administration of 14C-YM905 to pigmented mice

5.다.24. R905-ME-069: YM905 Plasma concentrations of the unchanged drug after single intravenous and oral administration of YM905 to mice (중복자료: 5-다-① 흡수 참고)

5.다.25. R905-ME-086: In vitro melanin binding of YM905

[대사]

5.다.26. R905-CH-007: Confirmation of conformation for mouse urinary metabolism of YM905

5.다.27. R905-ME-001: Absorption, distribution, metabolism and excretion of radioactivity after oral administration of 14C-YM905 to rats (중복자료: 5-다-① 흡수 참고)

5.다.28. R905-ME-002: Plasma concentrations of the unchanged drug and its metabolite BY-348C to rats (중복자료: 5-다-① 흡수 참고)

5.다.29. R905-ME-008: Characterization and structural elucidation of metabolites after oral administration of YM905 to rats

5.다.30. R905-ME-009: Comparison of in vitro metabolic patterns of YM905 among various species

5.다.31. R905-ME-021: Identification of in vitro metabolites of YM905 produced by dog liver microsomes

5.다.22. R905-ME-026: In Vitro Fingerprinting of ^{14}C-YM905 for Metabolism by Rat, Dog and Human Liver Slices and Microsomes

5.다.33. R905-ME-029: Absolute configuration of MU-1, N-oxide metabolite of YM905

5.다.34. R905-ME-030: Plasma concentrations of YM905 and YM-64250 after repeated oral administration of YM905 or single oral administration of YM-64250 to mice (중복자료: 5-다-① 흡수 참고)

5.다.35. R905-ME-042: In Vitro metabolism study of YM905 using cryopreserved mouse hepatocytes

5.다.36. R905-ME-043: YM905 Effects on hepatic enzyme activities in male mice following repeated oral administration for 7 days

5.다.37. R905-ME-044: Metabolic fingerprinting in plasma, urine, and bile, and quantitative analysis of

metabolites in urine after oral administration of 14C-YM905 to mice

5.다.38. R905-ME-045: Metabolic fingerprinting in plasma, urine, and bile, and quantitative analysis of metabolites in urine and bile after oral adminiatration of 14C-YM905 to dogs

5.다.39. R905-ME-059: Investigation on in vivo chiral inversion of the unchanged drug after oral administration of YM905 to dogs

5.다.40. R905-ME-061: Plasma concentrations of the unchanged drug and metabolites M2, M3, M4, and M5 after repeated oral administration of YM905 to dogs

5.다.41. R905-ME-063: Investigation on existence of glucuronide conjugate in plasma after oral administration of YM905 to dogs

5.다.42. R905-ME-065: Investigation on existence of glucuronide conjugate in plasma after oral administration of YM905 to mice

5.다.43. R905-ME-087: Investigation of YM905 metabolites formed with metabolic activation system used in the in vitro mutagenicity study of YM905

[배설]

5.다.44. R905-ME-001: Absorption, distribution, metabolism and excretion of radioactivity after oral administration of ^{14}C-YM905 to rats (중복자료: 5-다-① 흡수 참고)

5.다.45. R905-ME-031: ^{14}C-YM905 Absorption, Distribution and Excretion in the mouse after single oral administration (중복자료: 5-다-① 흡수 참고)

5.다.46. R905-ME-032: ^{14}C-YM905 Pharmacokinetic, excretion and biliary excretion studies in the dog after single oral administration (중복자료: 5-다-① 흡수 참고)

6. 임상시험성적에 관한 자료

6.가. 임상시험자료집

[생체이용률 시험]

6.1. R905-CL-003: An open two-period crossover study to assess the effect of food on the pharmacokinetics of a single dose of YM905 in healthy male volunteers

6.2. R905-CL-009: A single dose,open label,randomised,two-period crossover study in healthy male volunteers to assess the absolute bioavailability of YM905

[혈장단백결합 시험]

6.3. R905-ME-007: In vitro plasma protein binding of YM905 (중복자료: 5-다-② 분포 참고)

6.4. R905-ME-038: Estimation of the main human plasma binding protein for YM905

6.5. R905-ME-039: In vitro drug interaction for protein binding of YM905 in human plasma

6.6. R905-ME-040: In vitro study for the transfer of YM905 into red blood cells (중복자료: 5-다-② 분포 참고)

[간대사 및 약물상호작용 시험]

6.7. R905-ME-009: Comparison of in vitro metabolic patterns of YM905 among various species (중복자료: 5-다-③ 대사 참고)

6.8. R905-ME-010: Effect of YM905 on the metabolic activities of cytochrome P-450 isozymes

6.9. R905-ME-011: Identification of human liver CYP isoforms involved in the metabolism of YM905

6.10. R905-ME-020: Evaluation of the potential of drug-drug interactions with YM905

6.11. R905-ME-024: Evaluation of the potential of YM905 to inhibit the major human liver cytochrome

P450 isoenzymes

6.12. R905-ME-026: In vitro fingerprinting of 14C-YM905 for metabolism by rat,dog and human liver slices and microsomes (중복자료: 5-다-③ 대사 참고)

6.13. R905-ME-037: Investigation on in vivo chiral inversion of the unchanged drug after oral administration of YM905 to humans

6.14. R905-ME-046: Characterization and structural elucidation of YM905 metabolites in human plasma and urine

6.15. R905-ME-054: In vitro metabolism study of YM905 using cryopreserved human hepatocytes

6.16. R905-ME-055: Evaluation of the potential of YM-64250,the N-oxide metabolite of YM905 to inhibit the major human liver cytochrome P450 isoenzyme

6.17. R905-ME-060: Identification of human liver cytochrome P450 isoenzymes involved in the liver microsomal metabolism of YM905 as assessed via the formation of metabolites

6.18. R905-ME-062: Evaluation of the potential of YM-277743,the N-glucuronide of YM905, to inhibit the major human liver cytochrome P450 isoenzymes

6.19. R905-ME-066: Study on the metabolic pathways for the formation of M4 as a sequential metabolite of YM905

6.20. R905-ME-084: Evaluation of the potential of YM-80264, the 4R-hydroxy metabolite of YM905, and YM-27093, the 4R-hydroxy-N-oxide metabolite of YM905, to inhibit the major human liver cytochrome P450 isozymes

[기타 생체재료를 이용한 시험]

6.21. R905-ME-041: Investigation on involvement of MDR1 in transcellular transport of YM905 and inhibition of YM905 on digoxin transport mediated by MDR1

[건강한 피험자 약동학 및 초기 내약성 시험]

6.22. R905-CL-008: Open study to evaluate the pharmacokinetics of 14C-labelled YM905 after single oral administration of 10 mg YM905 in healthy male volunteers(YM905 mass balance study)

6.23. R905-CL-001: A placebo controlled dose-rising study in healthy male volunteers to evaluate safety,tolerability, pharmacodynamics and pharmacokinetics of single oral dosages of YM905

6.24. R905-CL-002: A double blind,randomised,placebo controlled dose rising study in healthy male volunteers to evaluate safety, tolerability and pharmacokinetics of multiple dosing with YM905

6.25. R905-CL-004: A double blind,randomised,placebo-controlled dose rising study in elderly healthy male and female volunteers to evaluate safety,tolerability and pharmacolkinetics of mutiple dosing with YM905

6.26. R905-CL-022 (part 1 of 2): Clinical pharmacology study to evaluate the effect on QTc of escalating multiple-doses of YM905 administered orally QD in male,premenopausal female,and postmenopausal female healthy volunteers

6.27. R905-CL-022 (part 2 of 2): Clinical pharmacology study to evaluate the effect on QTc of escalating multiple-doses of YM905 administered orally QD in male,premenopausal female,and postmenopausal female healthy volunteers

[내인성 인자에 대한 약동학 시험]

6.28. R905-CL-007: YM905 Phase Clinical Study:Clinical Report[Single oral administration study]

6.29. R905-CL-012: YM905 Phase Clinical Study-Repeated Oral Administration study-Clinical Study Report

6.30. R905-CL-021: An open-label study to investigate the pharmacokinetics, safety, and tolerability of YM905 in patients with mild, moderate, and severe renal disease compared to age and weight matched healthy subjects

6.31. R905-CL-026: An open-label, parallel study to investigate the safety, tolerability and pharmacokinetics of solifenacin succinate in patients with hepatic impairment compared to healthy subjects

6.32. R905-CL-029: An open label, two-period, crossover study to compare the steady state pharmacokinetics of 5 mg and 10 mg o.d. of solifenacin succinate between healthy elderly and young subjects

[외인성 인자에 대한 약동학 시험]

6.33. R905-CL-010: Effect of Multiple Doses of Ketoconazole on the Pharmacokinetics of a Single Doses of YM905 Administered Orally in Healthy Male and Female Volunteers[Ketoconazole study]

6.34. R905-CL-011: A Double-Blind, Placebo-Controlled, Cross-Over Pharmacokinetic Interaction Study of Steady State YM905 and Steady State of a Combined Oral Contraceptive (30 microg Ethinyl Estradiol and 150 micro g Levonorgestrel) in Healthy Female Volunteers

6.35. R905-CL-025: An open-label, one sequence crossover study to determine the effect of multiple doses of 10 mg solifenacin on the steady state

6.36. R905-CL-028: A double-Blind, randomised, placebo-controlled, crossover study to evaluate the effect of solifenacin succinate on the pharmacodynamics and pharmacokinetics of warfarin in healthy male subjects

6.37. R905-CL-036: Effect of steady state ketoconazole on the pharmacokinetics of single doses of YM905 administerted orally in healthy male and female volunteers

[집단약동학(Population Pharmacokinetics: Pop-PK) 시험]

6.38. Pop-PK 시험 (905-CL-013 및 905-CL-014): Population Pharmacokinetics of YM905 10 mg Administered Orally Once Daily Based on data of 2 Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Studies of the Efficacy and Safety Of Daily Oral Administration of 10 mg YM905 versus Placebo in Male And Female Subjects with Overactive Bladder (905-CL-013 and 905-CL-014)

[신청 적응증에 관한 대조 임상시험]

6.39. R905-CL-005: A randomised, double-blind, parallel group, dose-response study of YM905 in comparison with placebo and tolterodine in patients with symptomatic idiopathic detrusor instability

6.40. R905-CL-006: A randomized, double-blind, placebo-controlled, parallelgroup, fixed-dose,

dose-ranging study to assess the safety and efficacy of daily administration of a single oral dose of YM905 in male and female patients with urge urinary incontinence

6.41. R905-CL-013: A randomized, double-blind, placebo-controlled, parallel-group, fixed-dose, multicenter study to assess efficacy and safety of daily oral administration of 10mg YM905 (solifenacin succinate) versus placebo in male and female patients with overactive bladder

6.42. R905-CL-014: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study to Assess efficacy and Safety of Daily Oral Administration of 10mg YM905 (solifenacin succinate) versus Placebo in Male and Female patients with Overactive Bladder

6.43. R905-CL-015: A Raondomized, Double-blind, Parallel Group, Placebo and Active Controlled, Multi-center Study of Solifenacin Succinate 5 mg and 10mg in patients with Overactive Bladder

6.44. R905-CL-018: A randomized, double-blind, parallel group, placebo-controlled, multi-center study of solifenacin succinate 5 mg and 10 mg in patients with overactive bladder

[비대조 임상시험]

6.45. R905-CL-016: An Open-Label , Long-Term Tolerability study of daily oral Administration of 10mg YM905 (Solifenacin Succinate) in Male and Female Subjects with Overactive Bladder

6.46. R905-CL-019: An open-label, long-term safety and efficacy follow-up study of solifenacin succinate 5 mg and 10 mg in patients with overactive bladder-interim report

6.나. 가교자료

6.47. 과민성 방광을 가진 환자에 대한 숙신산솔리페나신5mg과 10mg의 유효성 및 안전성을 평가하기 위한 무작위배정, 이중맹검, 병행, 톨터로딘 대조, 다기관 임상시험

6.48. 가교자료설명서

7. 외국의 사용현황 등에 관한 자료

7.1. 영국의약품집

7.2. 미국의약품집

8. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료. 끝.