<안전성·유효성 심사관련 제출자료목록>

○ 관련규정 : 의약품등의안전성·유효성심사에관한규정 (식품의약품안전청고시 제2003-17호, 2003.4.14.) 제2조제1항제1호 [별표1] 1. 화학구조 또는 본질조성이 전혀 새로운 신물질 의약품

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	X	X	X	X	△	△	○	○	X	○	○
2. 제출여부	○	○	○	○	○	X	X	X	X	X	X	X	○	X	○	○	X	○	○
3. 면제사유																			

○ 제출자료목록

1. 기원 또는 발견 및 개발경위에 관한 자료
2. 구조결정·물리화학적 성질 및 생물학적 성질(생물학적제제, 유전자재조합의약품, 세포배양의약품, 세포치료제 등에 한함)에 관한 자료(자사기준 및 시험방법 포함)
3. 안정성에 관한 자료
   가. 장기보존시험 또는 가속시험자료 : 제조 후 6시간
   나. 가혹시험자료 : 제조 후 6시간
4. 독성에 관한 자료
   가. 단회투여독성시험자료
      1) 3'-데옥시-3'-플루오로티미딘의 랫드를 이용한 단회 정맥내 투여 독성시험
      2) 3'-데옥시-3'-플루오로티미딘의 Beagle 견을 이용한 단회 정맥내 투여 독성시험
5. 약리작용에 관한 자료
   가. 효력시험자료
      1) Basis of FLT as a cell proliferation marker : comparative uptake studies with [^{3}H]thymidine and [^{3}H]arabinothymidine, and cell-analysis in 22 asynchronously growing tumor cell lines
      2) Validation of FLT uptake as a Measure of Thymidine Kinase-1 Activity in A549 Carcinoma Cells
      3) Evaluation of pyrimidine metabolising enzymes and in vitro uptake of 3'-[18F]fluoro-3'-deoxythymidine([18F]FLT) in pancreatic cancer cell lines
      4) Early changes in [18F]FLT uptake after chemotherapy : an experimental study
   나. 일반약리시험자료
   다. 흡수, 분포, 대사 및 배설시험자료
      1) 에프엘티주사(3'-데옥시-3'-플루오로티미딘[^{18}F])의 대사 및 체내동태 연구

6. 임상시험성적에 관한 자료

가. 임상시험자료집

1) Imaging proliferation in vivo with [F-18]FLT and positron emission tomography
2) 3‘-[^{18}F]Fluoro-3’-Deoxythymidine([^{18}F]-FLT) as Positron Emission Tomography Tracer for Imaging Proliferation in a Murine B-Cell Lymphoma Model and in the Human Disease
3) Kinetic Analysis of 3'-Deoxy-3'-Fluorothymidine PET Studies : Validation Studies in Patients with Lung Cancer
4) [^{18}F]Fluorothymidine Radiation Dosimetry in Human PET Imaging Studies
5) 3-Deoxy-3-[^{18}F]Fluorothymidine-Position Emission Tomography for Noninvasive Assement of Proliferation in Pulmonary Nodules
6) In Vivo Validation of 3'deoxy-3'[^{18}F]fluorothymidine([^{18}F]FLT) as a Proliferation Imaging Tracer in Humans: Correlation of [^{18}F]FLT Uptake by Positron Emission Tomography with Ki-67 Immunohistochemistry and Flow Cytometry in Human Lung Tumors
7) Imaging Proliferation in Lung Tumors with PET: ^{18}F-FLT Versus ^{18}F-FDG
8) [^{18}F]3’-Deoxy-3’-Fluorothymidine-PET in NHL Patients: Whole-Body Biodistribution and Imaging of Lymphoma Manifestation - a Pilot Study
9) Quantification of Cellular Proliferation in Tumor and Normal Tissues of Patients with Breast Cancer by [^{18}F]Fluorothymidine-Positron Emission Tomography Imaging: Evaluation of Analytical Methods
10) In vivo Imaging cellular proliferation in colorectal cancer using position emission tomography
11) Detection and Grading of Soft Tissue Sarcomas of the Extremities with ^{18}F-3'-Fluoro-3'-Deoxy-L-Thymidine
12) Imaging Proliferation in Brain Tumors with ^{18}F-FLT PET: Comparison with ^{18}F-FDG
13) 18F-fluorodeoxythymidine PET for evaluating the response to hyperthermic isolated limb perfusion for locally advanced soft-tissue sarcomas.
14) (18)F-fluorothymidine kinetics of malignant brain tumors.
15) 3'-Deoxy-3'-[F-18]fluorothymidine positron emission tomography in patients with recurrent glioblastoma multiforme: comparison with Gd-DTPA enhanced magnetic resonance imaging.
16) Evaluation of primary brain tumors with FLT-PET: usefulness and limitations.
17) Usefulness of 3'-[F-18]fluoro-3'-deoxythymidine with positron emission tomography in predicting breast cancer response to therapy.
18) Molecular imaging of proliferation in malignant lymphoma.
19) Positron emission tomography in patients with breast cancer using (18)F-3'-deoxy-3'-fluoro-l-thymidine ((18)F-FLT)-a pilot study.

20) 18F-FLT PET in hematologic disorders: a novel technique to analyze the bone marrow compartment.

21) PET with [18F]fluorothymidine for imaging of primary breast cancer: a pilot study.

22) 18F-FLT PET for visualization of laryngeal cancer: comparison with 18F-FDG PET.

23) [18F]FLT PET for diagnosis and staging of thoracic tumours.

24) 3'-18F-fluoro-3'-deoxy-L-thymidine: a new tracer for staging metastatic melanoma?

나. 국내임상시험결과보고서

1) 폐종양환자에서 에프엘티주사(3'-데옥시-3'-플루오로티미딘[^{18}F]) Positron Emission Tomography를 이용한 종양세포증식도 생체측정을 위한 단일기관, 비무작위배정, 제3상 임상시험

7. 외국의 사용현황 등에 관한 자료

8. 국내 유사제품과의 비교검토 및 당해 의약품등의 특성에 관한 자료