Resource Summary Report

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PSTC Nephrotoxicity Biomarkers

RRID:SCR_003709
Type: Tool

Proper Citation

PSTC Nephrotoxicity Biomarkers (RRID:SCR_003709)

Resource Information

URL: http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualifica

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Description: Urinary kidney biomarkers (KIM-1, albumin, total protein, 2-microglobulin, cystatin C, clusterin and trefoil factor-3) that are considered acceptable biomarkers for the detection of acute drug-induced nephrotoxicity in rats and can be included along with traditional clinical chemistry markers and histopathology in toxicology studies. These biomarkers may be used voluntarily as additional evidence of nephrotoxicity in nonclinical safety assessment studies to complement the standard data (BUN and sCr). In ROC analyses, some of these biomarkers showed better sensitivity and specificity than BUN and sCr relative to histopathological alterations considered to be the gold standard when tested with a limited number of nephrotoxicant and control compounds.

Abbreviations: PSTC Nephrotoxicity Biomarkers

Synonyms: Predictive Safety and Testing Consortium Drug-induced Nephrotoxicity Biomarkers, PSTC NWG Drug-induced Nephrotoxicity Biomarkers

Resource Type: data or information resource, narrative resource, standard specification

Keywords: biomarker, drug development, drug, urinary, urinary biomarker, gold standard, kim-1, albumin, total protein, beta2-microglobulin, cystatin c, clusterin, trefoil factor-3, kidney, nonclinical

Related Condition: Nephrotoxicity, Drug-induced nephrotoxicity

Availability: Public

Resource Name: PSTC Nephrotoxicity Biomarkers

Resource ID: SCR_003709

Alternate IDs: nlx_157890

Record Creation Time: 20220129T080220+0000

Record Last Update: 20260919T195023+0000

Ratings and Alerts

No rating or validation information has been found for PSTC Nephrotoxicity Biomarkers.

No alerts have been found for PSTC Nephrotoxicity Biomarkers.

Data and Source Information

Source: SciCrunch Registry

Usage and Citation Metrics

We have not found any literature mentions for this resource.