

国立医薬品食品衛生研究所報告第143号キーワード索引（アルファベット順）

A

absolute purity 164, 247
Absorption 176
Accumulation 176
ACE2 decoy 208
acetamide 221
Acetamiprid 213
acetone 22
acrylamide formation 170
actinorhodin 169
active pharmaceutical ingredient 193
Acute exacerbations 198
acute lung injury 199
acute lymphoblastic leukemia 202
acute toxicity 41
acylation 197
ADRA (amino acid derivative reactivity assay) 227
advanced therapies 234
Adverse event 216
adverse outcome pathway (AOP) 228, 265
Aerobic plate count 183
aflatoxin 186
Alignment 215
allergic contact dermatitis 167
Alpha-glycosyl isoquercitrin 176
alternative DNA repair 194
Ames mutagenicity 224
amino acid 175
analytical method 166, 249
angiotensin receptor 210
annotation 162
annual committed effective dose 249
anti-malarial activity 164
Antibody 189
antibody-drug conjugates 144
Antimicrobial resistance 177
antimicrobial resistance 177
antioxidant 1 copper chaperone 204
antiplasmodial activity 164
antisense oligonucleotide 155
Anura 207
APG IV 147
Apotheker 249
applied microbiology 142

Artemisia capillaris 151
ascidian 143
Asparagi radix 149
Aspergillus 186
Assessment II for human health effects 230
asthma 185
astrocyte differentiation 208
astrocytes 218
atmospheric pressure chemical ionization 171
atomic force microscopy 223, 252
attenuated total reflection 140
autoinduction 201
automated sample preparation 143

B

ball-on-flat test 160
Bandrowski's base 227
Bayesian estimation 172
BBB 217, 218
Beef carcass 182, 183
beni-koji 1, 147
berberine-baicalin complex 147
biased agonist 210
biepitopic antibody 141
binucleated hepatocyte 221
bioanalysis 201, 241, 242
biochemical analysis 187
biodistribution 152
Biomarker 198
biomarker 136, 263
biosynthesis gene 185
biparatopic antibody 141
bis(2,3-dibromopropyl)phosphate 167
Blackwellomyces cardinalis 185
blood-brain barrier (BBB) 217
BMDL₁₀ 266
Bone metastasis 198
borderline tumor 199
boronic acid 174
Bortezomib 200
botanical origin 149
bovine coronavirus 181
BR (borderline range) 227
Brain microvascular endothelial cells 217

buckling load 160
busulfan 204

C

C(sp³)-H difluoroalkylation 191
Ca(2+) dynamics 211
cancer 266
cannabinoids 197
Cannabis sativa L. 148
caprolactam 175
Carbapenemase 179
carcinogenesis 220
carcinogenicity study 259, 260
Cardiac 216
Cardiac methods 216
cardiogenic shock 160
Cardiomyocyte 215
carrier gas 171
Case-control study 204
Castration-resistant prostate cancer 198
Catharanthus roseus 164
causal network 228
cause of death 175
CD30 receptor 141
CD44 219
Cell culture 257
Cell penetrating peptide 200
cell therapy products 154
cell-based assays 237
Cell-penetrating peptides 190
cellular and gene therapies 234
cellular uptake 158
central and peripheral area of testes 204
CHANGE 254
characteristics 144
chemical leukoderma 197
Chemical Substances Control Law (CSCL) 230
Chemical tool 192
Chicken meat 177
chicken meat 177
chromosomal rearrangement 220
chromosome aberration 220
chronic toxicity in *Daphnia* 230
ciguatera poisoning 180, 250
ciguatoxin 180, 250
ciprofloxacin 139

circadian rhythm 208
cisplatin 205, 207, 208
clastogen 261
Clostridium perfringens 183
clustered DNA damage 223
CMC 240
CNS barrier 217
Coculture 218
collagen I microfiber (CMF) 217
composite food 173
comprehensive analysis 147
containers and packaging 175
Contamination 183
contamination 183
continuous manufacturing 235
Contractility 215
copper 204
corrosion 41
corticosterone 255
COVID-19 10, 146, 157, 214, 228
COVID-19 vaccine 145
CQA 151
CRISPR/Cas 194
critical control point (CCP) 168
cross-contamination 178
CTD mock-up 235
Cutaneous adverse drug reaction 204
cyanogenic compounds 168
Cyclic peptide 200
cyclophosphamide hydrate 247
cyclosporine 219
CYP2C19 201
CYP2D6 203
cytochrome P450 137

D

DASH for SaMD 245
data-independent acquisition 199
database 230
DDI-Associated transporters 200
ddPCR 152
DDS 190
Decontamination 182
decoy 190
dehumidification tube 166
deleterious substance 41

Der 1 185
 derivatization 174
 detection limit 181
 detection sensitivity 153
 Developmental Neurotoxicity 213
 developmental neurotoxicity (DNT) 209
 developmental toxicity 256
 Developmental toxicity test 255
 Diastolic dysfunction 211
 diffuse alveolar damage 199
 Discoloration 182
 distribution 196
 DLK1 221
 DNA barcoding 149
 DNA double-strand break 226
 DNA double-strand break repair 222
 DNA polymerase 195
 DNA/RNA heteroduplex 190
 DNT *in vitro* test battery (DNT-IVB) 209
 dog 175
 drinking water 248
 droplet digital PCR 153
 drug delivery system 251
 drug interaction 137
 drug shortage 234
 Drug-induced hypersensitivity syndrome 204
 drug-induced kidney injury 221
 drug-target orthologs 230
 dry powder formulation 208
 DX 240

E

early life stress 255
 ecotoxicological QSAR 230
 edible insects 180
 EDXR 236
 EFE 150
 egg protein 172
 electrocardiogram 206
 electrochemical oxidation 191
 elemental impurities analysis 236
 endocrine disruptor 219
 endosomal escape 158
 Endosomal escape domain 190
 endotoxin 182
 Engineered heart tissues 218

Enteritidis 188
 environmental water 187
 Ephedra Herb 146
 epi-genotoxicity 222
 EpiSensA (epidermal sensitization assay) 227
 epithelial-mesenchymal transition (EMT) 228
 error-corrected sequencing 225
Escherichia albertii 187
 estimated daily intake 172
 European Union (EU) 265
 existing chemical substance 34
 exosome 142, 145
 exposure assessment 173
 expression systems 142
 extracellular vesicles 142, 143, 145, 153, 236
 eyelash serum 166

F

FADCC 249
 Family name 147
 fatigue 160
 fatigue test 163
 fertilization 143
 field flow fractionation 159
 field investigations 149
 flavoring agent 205, 220
 floor wax 22
 flow-through cell system 138
 foldamer 251
 food 183, 187
 food additive 175
 food allergy 172
 food chemical 26
 food ingredient 173
 food interactions 137
 food safety 180, 253
 Food safety information 26
 Food utensils 175
 foodborne pathogens 180
 freeze concentration 138
 french fries 170
 friction coefficient 163
 friction test 162
 Fukushima Daiichi Nuclear Power Station Accident 170
 fumonisin 180
 fungal count 185

fungal resistance 186
furan 221

G

GalNAc 190
Gardenia blue 176
gastric cancer (GC) 228
gastrointestinal tumor 266
gene expression profiling 264
generic drugs 234
genetic disease 260
genetic risk 202
genetic toxicology 261
genetical analysis 187
genetically modified 196
genetically modified papaya 195
genome-wide association study 145
genome-wide mutation 194
genotoxic marker gene 225
genotoxicity 263
genotoxicity biomarker 264
germ - line mutation 260
germinated soybean 172
Gilteritinib 193
glass bead size 138
glass filter 181
glyphosate 168
GM papaya 195
Good Cell Culture Practice 257
Gut microbiota 176

H

HACCP 252
health hazard 147
Heart failure 212, 214
heart weight 229
heat-killed *Staphylococcus aureus* 181, 182
Helical peptides 190
Hematopoietic prostaglandin D synthase 191
henna 165
HifSA 174
high-resolution X-ray computed tomography 151
high-speed measurement 140
histopathology 175, 219
homologous recombination 222

HPLC 166, 175, 188, 192
Human induced pluripotent stem cell-derived cardiomyocyte sheets 211
hyaluronic acid 138
hydrates 141
hydrodynamics 138

I

ICH 259, 260
ICH Q5C 239
ICH-S6 255
IDATEN 245
illegal herbal product 148
immunogenicity 145, 237, 241, 242
immunotoxicity 226
impurity 157
Impurity analysis 191
In silico molecular design 191
in silico prediction 230
in vitro assay 154, 221
In vitro tumorigenicity assay 154
indoor air 165, 166
indoor air quality 22
infant food 170
Inflammatory cytokines 151
inhibition 137
innate immunity 155
insecticide 165
interleukin-6 181, 182
international harmonization 188, 192
Interstitial lung disease 198
interstitial lung disease 199
intraoperative imaging devices 158
iPSC-derived cell therapies 233
ISO IDMP 253
Isolation 183
isopropyl cloprostenate 166
IUCLID 34

J

JaCVAM 263
Japanese children 202
Japanese pharmacopoeia 147, 188, 192
JECDB 34
juzentaihoto 205

K

key event (KE) 228
key neurodevelopmental processes (KNDP) 209
Kidney 176
kidney 184, 219
Kineothrix alysoides 176

L

labeling 172
laboratory performance study 195
lactonization 169
LBA 237
LC-high resolution MS 165
LC-MS 201
LC-MS/MS 173, 180, 250
ligand binding assay 239
lime plaster 186
linalool oxide 220
lipid nanoparticle 252
Lipidomics 200
lipidomics 136
liposome 139, 252
Live-cell reporter assay 255
liver microsomes 197
LSD 193

M

machine learning 162
male reproductive system 255
marine biotoxin 250
mass spectrometry 181
matrix profile algorithm 206
MAVS 253
maximum residue limit 249
maximum specific activity 224
mechanical circulatory support 160
medical device cleanliness 161
medium-sized drug 191
melanin-producing cells 194
membrane permeability 137, 189
membrane-active peptide 252
Mentha arvensis var. *piperascens* 150
Mentha canadensis 150
Mentha haplocalyx Briq. 150

menthoxypropanediol 167
mesenchymal stromal cells 232
metabolic flux 169
metalloprotease 143
microcrystal electron diffraction 193
microglia 213, 218
microneedle 138
micronucleus 221
microphysiological system (MPS) 217
Microphysiological systems 218, 258
microsampling 136
migration testing 175
Mini-Review 243
MiPLA 193
Mitochondria 214
MLR assay 151
Molecular epidemiology 179
molecular mechanism 266
Monascus pilosus 1
moniliformin 184
monoclonal antibody 143
monocyte-activation test 181, 182
monolith column 159
mouse 136, 180, 184
mRNA vaccine 10
MSPC 235
multi-angle light scattering 143, 153
multi-attribute method 143
Multidrug-resistant *Acinetobacter baumannii* 179
Multiple myeloma 200
multisite experiments 153
Multisite study 154
mutational signature 225

N

N-(*tert*-butyldimethylsilyl)-*N*-methyl trifluoroacetamide 168
N-nitrosamine 224
NAMs 212, 257
nanomaterial 226
nanoparticle 159
nanoparticle density 159
near-infrared spectroscopy 140
nephrotoxicity 208
neural differentiation 208
neuronal development 206
Neuropathic pain 150

New approach methodologies 258
new approach methodologies 258
New Approach Methodologies (NAMs) 256
new approach methodology 261
New Approach Methods (NAMs) 254, 261
next generation risk assessment 227, 261
next generation sequencing 225
ninhydrin 175
nitrenium ion 224
Nitrosamine 191
NMR 193
nocturnal enuresis 179
non-endotoxin pyrogen 181, 182
non-rodent 175
nonhomologous end joining 222
nonhuman primate 175
novel food 253
Nrf2 197
Nucleic acid amplification test 157
nucleic acid amplification test 10

O

Odor 182
OECD 263
oligonucleotide therapeutics 156, 157, 158, 201
Onco-cardiology 214
oosporein 185
open TG-GATE 225
oral toxicity study 229
orengedokuto 147
organic compound 166
organozinc alkylation 191
ortho-quinone 194
ovarian cancer 199

P

p-Cymene 205
Paclitaxel 150
Panax ginseng C.A. Meyer 243
particle density 139
Penicillium adametzioides 1
peptide marker 173
Peptides 189
per and polyfluoroalkyl substances (PFAS) 248
Peracetic acid 182

performance assessment 10
period 1 204
peripheral blood mononuclear cells 182
pesticide 171, 173, 249
pharmaceutical excipient 137
pharmacogenetics 203
pharmacokinetic modeling 203
Pharmacology 212
Photocleavable linker 192
physicochemical property 173
physiologically based kinetic (PBK) modeling 230
physiologically based pharmacokinetic modeling 201
Plantago asiatica 151
Pluripotent stem cell 257
podoplanin 144
poisonous and deleterious substances control law 41
poisonous substance 41
polished rice 186
Poly-Lys 159
polyamide 175
positive control 181
potency 239
Prader-Willi syndrome 206
primary aromatic amine 224
processing factor 173
profiling 159
Propionimicrobium lymphophilum 179
PROTAC 189, 191, 192, 193
PROTACs 190
protein binding 156
protein residue quantification 161
proteolysis-targeting chimera 189
pseudo-polymorphism 140
psoriasis 180
pterostilbene 194
puberulic acid 1
pufferfish 174

Q

qNMR 174, 249
qPCR 152
QSAR 224
qualitative evidence synthesis 158
quality 236
quality assessment 10
quality by design (QbD) 234

quality control 160
 quality evaluation 157
 quantitative ^{19}F -NMR 164
 quantitative ^{31}P -NMR 247
 quantitative analysis 235
 quantitative assessment of non-threshold carcinogenicity 266
 quantum mechanics 174

R

radioactive cesium 170, 249
 radiomimetic drug 226
 Raman spectroscopy 139
 Rana 207
 randomized comparative trial 146
 ranitidine hydrochloride 193
 rat 199
 raw material plant 165
 real-time PCR 195
 real-time PCR assay 187
 regenerative medicine 233
 regulation 242, 253
 regulatory frameworks 234
 Regulatory science 191, 258
 regulatory toxicology 254, 261
 renal injury 205
 reporter assay 222
 reproductive toxicity 256
 residual agricultural chemicals 172
 Residual pluripotent stem cell 154
 retraining 162
 retrovirus-derived genes 206
 reversed-phase HPLC-UV 174
 rheumatoid arthritis 136
 rigorous solution 162
 risk assessment 172, 260
 RMS 249
 rolling revision 248
 Ruhemann's purple 175

S

S-protein 214
 safety 232, 236
Salmonella 177, 178
Salmonella prevalence 177
 SaMD 245

SARS-CoV-2 157, 208, 214
 secondary structure 191
 semi-synthetic cannabinoid 148
 semi-volatile organic compound 165
 serum tumor marker 199
 Siglec-7 ligand 144
 Signal disruption dynamics 255
 single seed 172
 single-needle compression 160
 siRNA 253
 site-specific conjugation 144
 size-exclusion chromatography 143, 153
 skin care product 167
 skin sensitization 227
 Slaughter house 183
 sliding friction 163
 Society for the Advancement of AOPs Knowledgebase Interest Group (SKIG) 265
 solid formulation 235
 solid-phase analytical derivatization 168
 solid-phase extraction 173
 SOX9 221
 soybean 196
 spermatogenesis disorder 204
 spheroid 221
 ssRNA-seq 172
 stainless steel surface analysis 161
 Stanton's formula 162
 stapled peptide 251
 Stapling structures 190
 STEC 183
 stem cell therapy 232
 subchronic toxicity 220
 sugar-modified nucleotide 155
 suppression effect 170
 surface 163
 sweetened bean paste 168
 synthetic biology 142

T

Targeted protein degradation 193
 taste evaluation 147
 TD_{50} 266
 TDM 232
 terahertz frequency-domain spectroscopy 141
 terahertz spectroscopy 140

testicular toxicity 207
testis organ culture 207
tetramethylammonium hydroxide (TMAH, CAS No. 75-59-2) 229, 230
tetrodotoxin 174
textile 167
TFPI2 199
the cost of goods (COGs) 233
thematic analysis 158
Third-generation cephalosporin resistance 178
THP-1 cell 226
thyroid grand 219
time-stretch spectroscopy 140
tissue distribution 156
TK gene 222
TK6 cell 223
Total diet study 249
total diet study 172
toxicity 136, 175, 205
toxicogenomics 225
toxicological assessment 34
transcript profiling 263
transcriptomics 264
transformed cells 154
tri-sialylated T antigen 144
trimeric monoterpenoid indole alkaloid 164
tris(2,3-dibromopropyl)phosphate 167
TRV027 210
tumorigenicity 154
Typhimurium 188
tyrosinase 197
tyrosyl-DNA phosphodiesterase 226

U

ubiquitin-proteasome system 189
UBR protein 189
UHPLC/MS/MS 175
unconformity contact 160
urinary microbiome 179
urobiome 179

V

vaccine 239, 241
validation study 175, 186
veno-arterial extracorporeal membrane oxygenation 160

vertebral column 207
viral detection 181
viral respiratory infection 181
vital signs 206
vitamin D 208
volatile organic compound 166
volume measurement 139
voriconazole 164

W

Washing 182
water quality analysis 248
water quality standard 248
water quality testing 166
water vapor 141
wearable sensor 163
weight of evidence 259, 260

X

X-ray computed tomography 139
X-ray CT 235
X-ray CT imaging 163
X-Ray fluorescence spectrometry 236

16S rRNA 176
16s rRNA methyltransferase 179
2-step enrichment method 187
2-thiouracil 171
3-spirooxindole 164
3次元培養ヒト皮膚モデル 246
4-thiouracil 171
6-methyl-2-thiouracil 171

AIを活用したプログラム医療機器 246
Codex食品添加物部会 250
Codex分析・サンプリング法部会 252
Codex文書 252
DNA抽出精製 194
mRNA医薬 244, 245
PMDA科学委員会 246
 β -Catenin 189

- Δ⁸-tetrahydrocannabinol (Δ⁸-THC) analog 148
- Δ⁹-tetrahydrocannabinol (Δ⁹-THC) analog 148
- アフラトキシン 251
- 安全性 212, 257
- 安全性確認 196
- 安全性評価 245, 255
- 安全性薬理試験 258
- 安定性 239
- 異種間伝播 251
- 遺伝子組換え食品 194, 252
- 遺伝子パネル検査 244
- 遺伝毒性 264
- 意図的混入有害物質 238
- 医薬品 232, 247
- 医薬品安全性監視活動 253
- 医薬品コード 253
- 医薬品識別情報 253
- 医療DX 253
- 医療費 246
- ウイルス安全性 244
- 牛伝染性リンパ腫ウイルス 251
- 液状チオグリコール酸培地 187, 188
- エクソソーム 239
- 欧州食品安全機関 249
- オフターゲット変異 245
- オランダ 249
- 改正 252
- ガイドライン 245
- 開発動向 240
- 化学物質 247
- 核酸医薬 244, 245
- 拡散経路 251
- 加工食品 249, 250
- 加水分解コムギ 247
- 環境疾患 265
- 環境保護 246
- 監視指導 252
- 乾燥コウタケ 170
- 管理戦略 238
- 機械学習 246
- 起源 251
- 規制 244, 245
- 規制整備 245
- 逆フィルター 163
- 球形吸着炭 234
- 形質転換細胞 244
- 系統進化 251
- 化粧品 262
- ゲノム編集 244, 245
- ゲノム編集技術応用食品 251
- ゲノム編集食品 196
- 健康被害 246
- 検査法 252
- 検出感度 187, 188
- 高圧処理 250
- 抗がん薬 212, 256
- 抗体薬 255
- 国際標準 247
- 国際標準化機構 253
- 国際分類 245
- 骨シンチグラム 163
- コンパニオン診断薬 244
- 再生医療等製品 233
- サイトカイン 259
- 細胞外小胞 256
- 差周波 235
- 殺菌効果検証 250
- サプリメント 250
- サルモネラ症 188
- シアン化合物 169
- ジェネリック医薬品 232
- 閾値 264
- 試験法 248
- 脂質ナノ粒子 (LNP) 236
- 市場流通品 234
- 次世代医療機器 245
- 次世代医療機器・再生医療等製品評価指標作成事業 243
- 次世代シーケンス 244
- 次世代シーケンシング技術 244
- 事前相談 196
- 事前相談・届出制度 251
- 疾患メカニズム 265
- 室内空気 248
- 室内濃度指針値 247
- 重量変化率 170
- 小規模食品事業者 252
- 条件及び期限付き製造販売承認 233
- 承認審査 243
- 承認申請 245
- 食事性ばく露量 249
- 食品汚染 251

- 食品中の食品添加物分析法 249
食品テロ 169
食品添加物 249, 250
食品添加物公定書 249
食品添加物指定等相談センター 250
食品添加物条項 250
食品添加物に関する一般規格 250
食品媒介リステリア症 250
食物アレルギー 252
除湿管 248
除湿剤 248
新規手法 265
人獣共通感染症 250
深層学習 163
心毒性 258
水分分析 252
ステージゲート 250
製造工程管理戦略 238
製造施設の衛生管理 250
製造販売後調査 233
生物活性試験 238
清涼飲料水 250
ソイビーン・カゼイン・ダイジェスト培地 187, 188
造腫瘍性細胞検出試験法 244
相対モル感度 249
代替 254
脱アミド化 247
妥当性確認ガイドライン 249
単回使用医療機器 246
定量NMR 247
デジタル技術 241
テラヘルツ分光法 235
動物実験代替法 263
毒性 256
特性解析 239
内在性レトロウイルス 244
日本薬局方 187, 188, 232, 234, 238
ネオエビトープ 247
農薬 248
バイオ医薬品 238, 239, 240, 241
白斑 246
発達神経毒性試験 258
バンコマイシン 232
ヒトiPS細胞 258
ヒトiPS細胞由来心筋細胞 212, 256, 258
ヒトiPS心筋 212, 257
ヒト血液 169
ヒト細胞加工製品 243
非ヒト霊長類 (NHP) 254
皮膚感作性 246, 262
皮膚刺激性 246
病院薬剤師 249
評価指標 245
表示 252
表示制度 252
標準化 253
微量不純物検出 235
非臨床安全性評価 254
品質・安全性評価 245
品質確保 234
品質管理 234, 241
品質管理戦略 239
品質評価 236, 244, 245
品質リスクマネジメント 238
フェロトーシス 253
豚肉 250
豚レンサ球菌 250
物理化学的特性 234
プベールル酸 250
フローサイトメトリー 238
分析法規格 252
粉乳 252
紅麹 250
放射性セシウム検査 170
マイコトキシン 251
ミトコンドリア 212, 256
未分化多能性幹細胞 244
民族差 232
無菌試験法 187, 188
薬剤師 240
薬剤反応性 232
薬用化粧品 246
有害物質含有家庭用品規制法 248
有害物質等 248
輸出拡大実行戦略 250
要請書 250
リアルタイム PCR 194
リスク 245
リスク管理 248
リスク評価 262, 264
リステリア・モノサイトゲネス 250
臨床試験 244
レギュラトリーサイエンス 232, 247, 248
老化 259