

非監視藥品執行國內BA/BE試驗統計表

112.1.31

試驗藥品 非監視新藥成分	BABE報告			
	准	不准	小計	
Acebutolol tab 400mg	1	0	1	
Acetaminophen tab 500mg	6	1	7	1件已註銷BE核備函
Acetaminophen ER tab 650mg	1	0	1	
Acetaminophen Injection 10mg/mL	1	0	1	
Acetaminophen/Tramadol HCl tab 325mg/37.5mg	2	0	2	
Acetylcysteine Effervescent tab 600mg	1	0	1	
Allopurinol tab 100mg	6	0	6	
Allopurinol tab 300mg	1	0	1	1件已註銷BE核備函
Amantadine tab 100mg	1	0	1	1件已註銷BE核備函
Amikacin inj 125mg/ml	2	0	2	
Amikacin inj 250mg/ml	1	1	2	
Amiodarone tab 200mg	1	0	1	
Amitriptyline SR cap 25mg	1	0	1	
Amoxicillin cap 250mg	0	1	1	
Amoxicillin cap 500mg	6	1	7	1件已註銷BE核備函
Amoxicillin susp 1.5g/60ml	1	0	1	
Amphotericin B liposome inj. 50mg	2	1	3	
Ampicillin cap 250mg	0	1	1	
Ampicillin/ Cloxacillin cap 250/250mg	0	1	1	
Arginine Vasopressin inj 20UI/ml	1	0	1	
Aspirin cap 100mg	1	0	1	1件已註銷BE核備函
Aspirin EM cap 100mg	3	1	4	
Aspirin tab 324mg	0	1	1	
Atenolol tab 50mg	6	3	9	
Atenolol tab 100mg	23	3	26	
Atenolol/ Chlorthalidone tab 100/25mg	4	1	5	
Baclofen tab 5mg	2	0	2	
Baclofen tab 10mg	1	1	2	
Benzbromarone cap 50mg	1	0	1	
Benzbromarone cap 100mg	1	0	1	
Benzbromarone tab 50mg	9	1	10	2件已註銷BE核備函
Benzbromarone tab 100mg	4	0	4	1件已註銷BE核備函
Bethanechol chloride tab 25mg	2	0	2	1件已註銷BE核備函
Bezafibrate retard tab 400mg	1	0	1	
Biperiden SR tab 4mg	1	1	2	
Biperiden tab 2mg	3	0	3	
Bromhexine tab 8mg	1	0	1	
Buflomedil tab 150mg	3	1	4	
Calcium para-aminosalicylate hydrate granules 1gm/g	1	0	1	
Carbamazepine CR tab 200mg	1	0	1	
Carbamazepine mixture 20mg/ml	1	0	1	
Carbamazepine SR tab 400mg	1	0	1	
Carbamazepine tab 200mg	4	0	4	

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Cefaclor cap 250mg	6	1	7	1件已註銷BE核備函
Cefaclor cap 500mg	1	0	1	
Cefaclor ER cap 375mg	1	0	1	
Cefaclor oral susp. 250mg/gm	1	0	1	
Cefadroxil cap 500mg	5	0	5	
Cefamandole inj 1g	1	0	1	
Cefazolin inj 500mg	1	0	1	
Cefazolin inj 1g	8	0	8	
Cefazolin inj 2g	2	0	2	
Cefmetazole inj 1g	1	0	1	
Cefoperazone inj 1g	3	0	3	
Cefotaxime inj 500mg	2	0	2	
Cefoxitin inj 1g	2	0	2	
Cephalexin cap 250mg	8	0	8	2件已註銷BE核備函
Cephalexin cap 500mg	10	0	10	2件已註銷BE核備函
Cephalothin inj 1g	1	0	1	
Cephapirin inj 1g	1	0	1	
Cephradine Arg inj 1g	4	0	4	
Cephradine cap 250mg	2	0	2	
Cephradine cap 500mg	6	0	6	
Cephradine inj 1gm	4	0	4	
Chlorpromazine tab 100mg	1	0	1	
Cimetidine tab 200mg	1	0	1	
Cimetidine tab 400mg	4	0	4	
Clindamycin cap 150mg	5	0	5	
Clindamycin cap 300mg	2	0	2	
Clindamycin inj 150mg/ml	4	0	4	
Clonazepam tab 0.5mg	1	0	1	
Clonazepam tab 2mg	1	0	1	
Colchicine tab 0.5mg	3	0	3	
Danazol cap 200mg	1	0	1	
Dextromethorphan SR tab 60mg	3	0	3	
Diazepam tab 2mg	1	0	1	
Diazepam tab 5mg	0	2	2	
Diclofenac Na EC tab 25mg	2	0	2	
DiclofenacNa EC tab 50mg	2	1	3	
Diclofenac Na EM cap 50mg	3	0	3	
Diclofenac Na SR cap 100mg	1	0	1	
Diclofenac Na SR tab 75mg	2	0	2	
Diclofenac Na SR tab 100mg	4	1	5	
Digoxin Elixir 0.05mg/ml	1	0	1	
Digoxin tab 0.25mg	0	1	1	
Diltiazem tab 5mg	0	1	1	

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試驗藥品 非監視新藥成分	BABE報告			
	准	不准	小計	
Diltiazem tab 30mg	7	0	7	
Diltiazem tab 60mg	2	1	3	
Diltiazem SR cap 120mg	1	0	1	
Diltiazem SR cap 180mg	1	0	1	
Diphenidol tab 25mg	5	0	5	2件已註銷BE核備函
Dipyridamole tab 25mg	8	2	10	1件已註銷BE核備函
Dipyridamole tab 50mg	1	0	1	
Dipyridamole tab 75mg	1	0	1	
Domperidone tab 10mg	4	0	4	
Estazolam tab 2mg	2	0	2	
Estradiol Patch 0.05mg	1	1	2	
Ethambutol HCl tab 400mg	2	0	2	
Fenoterol tab 2.5mg	1	1	2	
Flavoxate tab 200mg	1	0	1	1件已註銷BE核備函
Fludiazepam tab 0.25mg	3	0	3	
Flunarizine cap 5mg	1	0	1	
Flunarizine cap 10mg	1	0	1	
Flunarizine tab 5mg	1	1	2	
Flunitrazepam tab 1mg	1	0	1	
Flunitrazepam tab 2mg	1	0	1	
Flupentixol tab 3mg	1	0	1	
Flupentixol/Melitracen 0.5mg/10mg	2	0	2	1件已註銷BE核備函
Flurbiprofen tab 50mg	1	0	1	
Flurbiprofen tab 100mg	2	0	2	1件已註銷BE核備函
Furosemide inj 10mg/ml	2	0	2	
Furosemide tab 40mg	6	0	6	
Gentamicin inj 40mg/ml	8	0	8	
Gliclazide MR tab 30mg	11	0	11	
Gliclazide MR tab 60mg	2	1	3	
Gliclazide tab 80mg	7	2	9	
Glipizide tab 5mg	3	0	3	1件已註銷BE核備函
Glipizide ER tab 5mg	1	0	1	
Glipizide SR tab 10mg	1	0	1	
Glyburide tab 5mg	12	1	13	
Guaifenesin ER tab 600mg	1	0	1	
Haloperidol Decanoate inj 50mg/ml	1	0	1	
Haloperidol tab 5mg	2	0	2	
Haloperidol tab 10mg	1	1	2	
Hydroxychlorquine tab 200mg	2	0	2	
Ibuprofen MR Tablets 800mg	1	0	1	
Ibuprofen lysinate tab 500mg	1	0	1	
Ibuprofen supp 50mg	0	1	1	
Ibuprofen susp 20mg/ml	1	0	1	1件已註銷BE核備函

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	准	不准	小計	
Ibuprofen tab 400mg	2	0	2	
Imipramine tab 25mg	1	0	1	1件已註銷BE核備函
Indapamide tab 1.25mg	1	0	1	
Indapamide tab 2.5mg	3	0	3	
Indapamide SR tab 1.5mg	8	0	8	
Isoniazid tab 100mg	2	0	2	
Isoniazid/Rifampin/Pyrazinamide/Ethambutol tab 37.	1	0	1	
Isosorbide mononitrate tab 20mg	2	0	2	
Isosorbide mononitrate SR tab 40mg	1	0	1	
Isosorbide mononitrate CR tab 60mg	4	0	4	
Isosorbide dinitrate tab 10mg	1	0	1	
Ketoprofen cap 50mg	1	0	1	
Ketoprofen SR caps 200mg	1	0	1	
Labetalol tab 200mg	1	0	1	
Levonorgestrel tab 0.75mg	1	0	1	
Levonorgestrel tab 1.5mg	1	0	1	
Lidocaine Patch 700mg/patch	2	0	2	
Lorazepam tab 0.5mg	1	0	1	
Lorazepam tab 1mg	1	0	1	1件已註銷BE核備函
Lysine acetylsalicylate inj 900mg	1	1	2	
Mebeverine HCl SR cap 200mg	1	0	1	
Meclofenamic cap 100mg	2	0	2	
Megestrol Acetate Susp 40mg/ml	0	2	2	
Megestrol Acetate Susp 125mg/ml	0	1	1	
Mephenoxalone tab 200mg	6	1	7	2件已註銷BE核備函
Mequitazine tab 5mg	2	0	2	1件已註銷BE核備函
Metformin tab 500mg	10	0	10	4件已註銷BE核備函
Metformin tab 850mg	2	0	2	1件已註銷BE核備函
Metformin tab 1000mg	1	1	2	1件已註銷BE核備函
Metformin ER tab 500mg	4	0	4	
Metformin ER tab 750mg	1	0	1	
Metformin SR tab 500mg	1	0	1	
Metformin SR tab 750mg	1	0	1	
Metformin XR tab 500mg	1	0	1	
Metformin XR tab 750mg	1	0	1	
Methylphenidate cap 44mg	1	0	1	
Methylphenidate ER tab 36mg	2	0	2	
Methylprednisolone inj 40mg	1	0	1	
Methylprednisolone inj 500mg	1	0	1	
Methylprednisolone tab 4mg	4	0	4	
Methylprednisolone tab 8mg	1	0	1	
Metolazone tab 0.5mg	2	0	2	
Mexiletine cap 100mg	1	0	1	

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	准	不准	小計	
Minocycline cap 50mg	1	1	2	
Minocycline cap 100mg	3	0	3	
Morphine Sulfate continuous tab 30mg	1	0	1	
Naproxen EC tab 500mg	1	1	2	
Naproxen SR tab 750mg	4	0	4	
Naproxen suspension 25mg/ml	1	1	2	
Naproxen tab 250mg	1	0	1	
Naproxen tab 275mg	1	0	1	
Naproxen tab 500mg	1	0	1	
Nefopam tab 30mg	1	0	1	
Niacin ER tab 500mg	1	1	2	
Niacin SR tab 500mg	1	0	1	
Nicotinic Acid SR tab 500mg	1	0	1	
Nifedipine cap 5mg	2	0	2	
Nifedipine cap 10mg	17	4	21	
Nifedipine SR cap 20mg	1	1	2	
Nifedipine tab 10mg	0	1	1	
Nifedipine ER tab 30mg	1	0	1	
Nifedipine PR tab 30mg	1	0	1	
Nifedipine Retard tab 20mg	1	0	1	
Nifedipine SR tab 30mg	2	0	2	
Nimetazepam tab 5mg	1	0	1	
Orphenadrine ER tab 100mg	1	0	1	
Oxybutynin CR tab 5mg	0	1	1	
Oxybutynin ER tab 5mg	4	1	5	
Pentoxifylline Retard tab 400mg	1	0	1	
Pentoxifylline SR tab 100mg	1	0	1	
Pentoxifylline SR tab 400mg	9	0	9	
Pentoxifylline tab 100mg	1	0	1	
Phenylpropanolamine SR cap 75mg	3	0	3	
Pipoxolan tab 10mg	1	0	1	1件已註銷BE核備函
Piracetam oral soln 200mg/mL	1	0	1	
Piracetam granules for oral soln 2400mg	1	0	1	1件已註銷BE核備函
Piracetam cap 400mg	3	0	3	1件已註銷BE核備函
Piracetam tab 1200mg	5	0	5	2件已註銷BE核備函
Pirenoxine eye susp. 0.05mg/ml	0	1	1	
Piroxicam cap 10mg	3	1	4	
Piroxicam cap 20mg	1	0	1	
Piroxicam tab 20mg	2	0	2	
Prednisolone oral soln 10mg/ml	1	0	1	
Prednisolone Oral Solution 1.344mg/ml	1	0	1	
Propafenone tab 150mg	1	0	1	
Propranolol tab 10mg	0	1	1	

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非監視新藥成分	准	不准	小計	
Propranolol tab 40mg	1	0	1	
Pseudoephedrine SR tab 120mg	1	0	1	
Pyrazinamide tab 500mg	1	1	2	
Rifampin cap 300mg	8	1	9	
Rifampin cap 450mg	2	0	2	
Rifampin/Isoniazid cap 300/150mg	1	0	1	
Roxatidine cap 75mg	1	0	1	
Salbutamol CR tab 4mg	1	0	1	
Salmon calcitonin, syn inj 50 IU/ml	1	0	1	
Salmon calcitonin, Synth. nasal spray 550IU/ml	0	1	1	
Scopolamine Patch 1.5mg/3cm2	0	1	1	
Selegiline tab 5mg	1	1	2	1件已註銷BE核備函
Sulfasalazine tab 500mg	1	1	2	
Sulfinpyrazone tab 100mg	1	0	1	1件已註銷BE核備函
Sulindac tab 200mg	5	0	5	
Sulpiride tab 50mg	4	0	4	
Sulpiride tab 200mg	6	0	6	2件已註銷BE核備函
Sulpiride tab 400mg	1	0	1	
Tamoxifen tab 10mg	1	0	1	
Terbutaline tab 2.5mg	1	0	1	1件已註銷BE核備函
Theophylline SR tab 200mg	1	0	1	
Theophylline SR cap 250mg	1	0	1	
Theophylline SR tab 250mg	1	0	1	
Theophylline SR tab 400mg	0	1	1	
Tiaprofenic acid tab 200mg	2	0	2	1件已註銷BE核備函
Ticlopidine tab 100mg	2	0	2	1件已註銷BE核備函
Ticlopidine tab 250mg	1	1	2	
Tolperisone tab 150mg	1	0	1	1件已註銷BE核備函
Tranexamic acid cap 250mg	1	0	1	
Valproate sodium SR tab 500mg	1	0	1	
Valproate sodium/Valproic acid SR tab 333/145mg	4	0	4	
Verapamil SR cap 120mg	1	0	1	
Verapamil SR tab 240mg	1	0	1	
Warfarin tab 5mg	2	0	2	
總 計	558	68	626	
上表資料統計至112年1月31日止				
計算項目包含查驗登記用(含新藥)、上市後變更改用之類別。				
註銷BE核備函者仍列入計算，另於備註欄註明註銷之件數				
原案不准，申復通過者以"不准"及"准"各1件計算				
原案不准，申復亦不准者以"不准"1件計算				