Information about Columns for Japanese Pharmacopoeia Draft Monographs (Chemical Drug)

Pharmaceuticals and Medical Devices Agency
Office of Review Management
December 1, 2023

In accordance with the policy for “Disclosure of Information about Columns for Japanese Pharmacopoeia Draft Monographs (by Division of Pharmacopoeia and Standards for Drugs, Office of Standards and Guidelines Development, Pharmaceuticals and Medical Devices Agency, dated March 1, 2016)” (see Annex), the information about the columns that were used for acquisition of the data that were referred in the preparation of the drafts for public comments is as follows:

Posting Date	Monograph	Test	Brand Name
December 1, 2023	Camostat Mesilate Tablets	Uniformity of dosage units	Finepak SIL C18S
		Assay	Finepak SIL C18S
December 1, 2023	Pranlukast Capsules	Uniformity of dosage units	Develosil C8-HG-5
		Assay	Develosil C8-HG-5
December 1, 2023	Pranlukast for Syrup	Uniformity of dosage units	YMC-Pack C8 or Develosil C8-HG-5
		Assay	YMC-Pack C8 or Develosil C8-HG-5
September 1, 2023	Indocyanine Green	Purity (2) Related substances	YMC-Pack ODS AM
March 1, 2023	Aripiprazole	Purity Related substances, Assay	YMC-Pack Pro C18
March 1, 2023	Febuxostat	Purity Related substances(i), Assay	TSKgel ODS-80Ts
		Purity Related substances(ii)	Develosil C-30-UG-3
March 1, 2023	Febuxostat Tablets	Identification, Purity Related substances, Uniformity of dosage units, Assay	TSKgel ODS-80Ts
March 1, 2023	Gefitinib Tablets	Assay	Inertsil ODS-3
March 1, 2023	Goserelin Acetate	Acetic Acid	Spherisorb ODS
		Purity	XTerra MS C18
		Assay	XTerra MS C18
March 1, 2023	Lornoxicam	Purity Related substances	L-column 2 ODS
		Assay	CAPCELL PAK C18 MGII

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Posting Date	Monograph	Test	Brand Name
March 1, 2023	Lornoxicam Tablets	Purity Related substances, Uniformity of dosage units, Dissolution, Assay	TSKgel ODS-80TM
March 1, 2023	Oxaliplatin	Purity(2) Oxalic acid, Purity(3) Related substance A	Hypersil BDS-C18
		Purity(4) Other related substances, Assay	Hypersil ODS
		Purity(5) Enantiomer	Chiralcel OC-H
March 1, 2023	Oxaliplatin Injection	Purity(1) Related substances, Purity(2) Oxalic acid	Hypersil BDS-C18
		Assay	Hypersil ODS
March 1, 2023	Tolvaptan	Purity Related substances	TSKgel ODS-100V 3μm
		Assay	YMC-Pack ODS-A or YMC-Pack ODS-AM
March 1, 2023	Tolvaptan tablets	Identification, Uniformity of dosage units, Assay	YMC-Pack ODS-A or YMC-Pack ODS-AM
September 1, 2021	Anastrozole Tablets	Uniformity of dosage unit, Dissolution, Assay	Hicrom RPB
September 1, 2021	Bicalutamide Tablets	Assay	Spherisorb ODS2
June 1, 2021	Voglibose Orally Disintegrating Tablets	Uniformity of dosage unit, Dissolution, Assay	YMC-Pack Polyamine Ⅱ
March 1, 2021	Budesonide	Purity (2) Related substances, Isomer ratio, Assay	Hypersil ODS C18 or Discovery HS C18

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Posting Date	Monograph	Test	Brand Name
September 1, 2020	Temozolomide	Purity (2) Related substances, Assay	Spherisorb ODS2 5μm 150mm x 4.6mm
		Purity (3) Acetonitrile	J&W DB-WAX, 30m x 0.53mm fused silica, 1.0μm film thickness
September 1, 2020	Temozolomide Capsules	Identification, Purity Related substances, Uniformity of dosage units, Assay	Spherisorb ODS2 5μm 150mm x 4.6mm
September 1, 2020	Temozolomide for Injection	Identification, Purity Related substances, Assay	Spherisorb ODS2 5μm 150mm x 4.6mm
June 1, 2020	Anastrozole	Purity (2) Related substances, Assay	Hichrom RPB
March 2, 2020	Oxybutynin Hydrochloride	Purity (2) Related substances	Symmetry C8
September 30, 2019	Cloperastine Fendizoate	Purity (3) 4-Chlorobenzophenone	L-column ODS
September 30, 2019	Cloperastine Fendizoate Tablets	Uniformity of dosage units, Assay	L-column ODS
		Dissolution	TSKgel ODS-80Ts
September 30, 2019	Eribulin Mesilate	Identification (2), Assay (2) Methanesulfonic acid	Zorbax NH2 5μm 4.6mmX25cm
		Purity (2) Related substance, Assay (1) Eribulin mesilate	ACE 3 C18 3μm 3.0mmX15cm
September 30, 2019	Phenobarbital Tablets	Uniformity of dosage units, Assay	Mightysil RP-18 GP-Ⅱ
September 30, 2019	Pitavastatin Calcium Orally Disintegrating Tablets	Purity, Uniformity of dosage units, Assay	L-column ODS
		Dissolution	L-column2 ODS

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Posting Date	Monograph	Test	Brand Name
September 30, 2019	Silodosin Orally Disintegrating Tablets	Identification, Purity Relsted substance, Uniformity of dosage units, Dissolution, Assay	Inertsil ODS-3
September 2, 2019	Bicalutamide	Purity (2) Related substances, Assay	Kromasil C18
September 2, 2019	Celecoxib	Purity (2) Related substances, Assay	SUPELCOSIL LC-DP
September 2, 2019	Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution	Identification (1), Purity (1) Related substances 1, Assay (1) Dorzolamide Hydrochloride	Zorbax Rx-C8 5μm 4.6mm X25cm
		Identification (2), Purity (2) Related substances 2, Assay (2) Timolol Maleate	Inertsil ODS-2 5μm 4.6mmX25cm
September 2, 2019	Ethyl Loflazepate	Purity (4) Related substances	TSKgel ODS-80TM
		Assay	Develosil ODS-7
September 2, 2019	Ethyl Loflazepate Tablets	Unifomity of dosage units, Dissolution, Assay	Inertsil ODS-3
September 2, 2019	Fenofibrate	Purity (2) Related substances, Assay	YMC-Pack Pro C18
September 2, 2019	Fenofibrate Tablets	Purity Related substances	CAPCELL PAK C18 UG80
		Unifomity of dosage units, Dissolution, Assay	YMC-Pack ODS-AM
September 2, 2019	Gefitinib	Purity (2) Related substances, Assay	Inertsil ODS-3 C18
September 2, 2019	Glucagon (Genetical Recombination)	Identification (1)	Lichrospher 100 RP18
		Identification (2), Purity, Assay	ACE 3 C18
September 2, 2019	Irinotecan Hydrochloride Injection	Purity Related substances, Assay	Inertsil ODS-2

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Posting Date	Monograph	Test	Brand Name
September 2, 2019	Rilmazafone Hydrochloride Hydrate	Purity (2) Related substances	L-column ODS 5μm 4.6X250 mm
		Assay	L-column ODS 5μm 4.6X150 mm
September 2, 2019	Rilmazafone Hydrochloride Tablets	Uniformity of dosage units, Dissolution, Assay	L-column ODS 5μm 4.6X150 mm
September 2, 2019	Rosuvastatin Calcium	Purity (3) Related substances, Assay	Inertsil ODS-3 C18 3μm 100Å
		Purity (4) Enantiomer	CHIRALCEL OJ-RH
September 2, 2019	Rosuvastatin Calcium Tablets	Purity Related substances, Assay	Columbus 5μ C18 110A
		Dissolution	Spherisorb S5 ODS2
June 3, 2019	Copovidone	Purity (4)	Inertsil ODS-4
		Purity (7)	Inertsil ODS-3
June 3, 2019	Telmisartan and Amlodipine Besylate Tablets	Uniformity of dosage units, Dissolution, Assay	Inertsil C8-3 (5μm 3.0×75mm)
September 3, 2018	Fludiazepam Tablets	Uniformity of dosage units, Assay	YMC-Pack ODS-AM
		Dissolution	μ BONDASPHERE 5μ C18-100A
June 1, 2018	Miglitol Tablets	Uniformity of dosage units, Dissolution, Assay	Asahipak NH2P-50 4D
March 1, 2018	Bromfenac Sodium Hydrate	Purity (2) Related substances, Assay	YMC-Pack ODS-A
March 1, 2018	Bromfenac Sodium Ophthalmic Solution	Assay	CAPCELL PAK C18 SG120Å
March 1, 2018	Cefixime Fine Granules	Purity Related substances, Uniformity of dosage unit, Dissolution, Assay	Inertsil ODS-3

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Posting Date	Monograph	Test	Brand Name
March 1, 2018	Doripenem Hydrate	Purity (3) Related substances（ⅰ）, Assay	L-column ODS
		Purity (3) Related substances（ⅱ）	Kaseisorb LC ODS-SAX Super
		Purity (3) Related substances（ⅲ）	Cadenza CD-C18
March 1, 2018	Doripenem for Injection	Purity (2) Related substances（ⅰ）, Assay	L-column ODS
		Purity (2) Related substances（ⅱ）	Kaseisorb LC ODS-SAX Super
March 1, 2018	Felodipine	Purity (2) Related substances	L-Column ODS
March 1, 2018	Felodipine Tablets	Uniformity of dosage unit, Dissolution, Assay	L-Column ODS
March 1, 2018	Irinotecan Hydrochloride Hydrate	Purity Related substances	Inertsil ODS-2
March 1, 2018	Polaprezinc	Purity Related substances, Assay	Mightysil RP18GP L-Column ODS
March 1, 2018	Polaprezinc Granules	Uniformity of dosage unit, Assay	L-Column ODS Symmetry C18
March 1, 2018	Sodium Valproate Extended-release Tablets A	Uniformity of dosage unit, Dissolution, Assay	Develosil ODS-UG-5
March 1, 2018	Sodium Valproate Extended-release Tablets B	Uniformity of dosage unit, Dissolution, Assay	Develosil ODS-UG-5

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Posting Date	Monograph	Test	Brand Name
March 1, 2018	Telmisartan and Hydrochlorothiazide Tablets	Idendification (1)(2), Uniformity of dosage unit (1)(2), Dissolution (1)(2), Assay (1)(2), Purity Related substances	Inertsil C8-3
March 1, 2018	Valsartan and Hydrochlorothiazide Tablets	Uniformity of dosage unit (1)(2), Dissolution (1)(2), Assay (1)(2)	Nucleosil 100-5 C18
December 1, 2017	Ethylcellulose	Assay	HP-1, Rtx-1
December 1, 2017	Gatifloxacin Hydrate	Purity (3) Related substances, Assay	Inertsil ODS-2
December 1, 2017	Gatifloxacin Ophthalmic Solution	Purity Related substances, Assay	Inertsil ODS-2
December 1, 2017	Hydroxyethylcellulose	Assay	HP-1, Rtx-1
December 1, 2017	Lanoconazole	Purity Related substances, Assay	Inertsil ODS-2
December 1, 2017	Lanoconazole Cream	Assay	Inertsil ODS-2
December 1, 2017	Lanoconazole Cutaneous Solution	Assay	Inertsil ODS-2
December 1, 2017	Lanoconazole Ointment	Assay	Inertsil ODS-2
December 1, 2017	Sitagliptin Phosphate Hydrate	Purity (1) Related substances, Assay	Supelco Discovery Cyano
		Purity (2) Enantiomer	Diacel AD-H
December 1, 2017	Sitagliptin Phosphate Tablets	Identification (2), Purity Related substances, Uniformity of dosage unit, Dissolution, Assay	Supelco Discovery Cyano
December 1, 2017	Verapamil Hydrochloride Injection	Assay	Mightysil RP-18GP
September 1, 2017	Cefalotin Sodium for Injection	Purity (2) Related substances, Assay	Inertsil ODS-3
September 1, 2017	Dexamethasone Sodium Phosphate	Purity (5) Related substances, Assay	Waters, Symmetry C18 Column, 100Å

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Posting Date	Monograph	Test	Brand Name
September 1, 2017	Diclofenac Sodium Suppositories	Assay	NUCLEOSIL 5C18 LICHROSPHER PR18-5
September 1, 2017	Ritodrine Hydrochloride Injection	Assay	YMC-Pack Pro C8
September 1, 2016	Acarbose	Purity (3) Related substances, Assay	APS-2 Hypersil
September 1, 2016	Acarbose Tablets	Purity Related substances, Uniformity of dosage units, Assay	APS-2 Hypersil
		Dissolution	Develosil ODS-T
September 1, 2016	Clomipramine Hydrochloride Tablets	Uniformity of dosage units, Assay	Wakosil 10C18
September 1, 2016	Entacapone	Purity (2) Related substances, Assay	XTerra Phenyl, YMC-Pack Ph
September 1, 2016	Entacapone Tablets	Uniformity of dosage units, Assay	XTerra Phenyl
September 1, 2016	Irbesartan Tablets	Uniformity of dosage units, Assay	YMC-Pack ODS-A
September 1, 2016	Pazufloxacin Mesilate Injection	Assay	Nucleosil 100-10C_{18}
September 1, 2016	Tramadol Hydrochloride	Purity (3) Related substances(ii)	LiChrospher 60 RP-select B
June 1, 2016	Azosemide Tablets	Uniformity of dosage units, Assay	SunFire C18
June 1, 2016	Purified Glucose	Identification (2), Purity (3) Related substances, Assay	BIORAD Aminex HPX-87C
June 1, 2016	Glucose Hydrate	Identification (2), Purity (3) Related substances, Assay	BIORAD Aminex HPX-87C
June 1, 2016	Irbesartan and Amlodipine Besilate Tablets	Dissolution, Identification(1)(2), Uniformity of dosage units(1)(2), Assay(1)(2)	Shim-pack XR-ODS Ⅱ

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Posting Date	Monograph	Test	Brand Name
March 1, 2016	Pazufloxacin Mesilate	Purity (2) Related substances	Inertsil ODS-2
		Assay	Nucleosil 100-10C_{18}
March 1, 2016	Pentobarbital Calcium Tablets	Uniformity of dosage unit, Assay	L-Column ODS, Inertsil ODS-3
March 1, 2016	Zonisamide	Purity (4) Related substances, Assay	Develosil ODS-5

Annex

March 1, 2016

Disclosure of Information about Columns for Japanese Pharmacopoeia Draft Monographs

Division of Pharmacopoeia and Standards for Drugs,
Office of Standards and Guidelines Development,
Pharmaceuticals and Medical Devices Agency

Please be notified that the division of Pharmacopoeia and Standards for Drugs, Office of Standards and Guidelines Development, Pharmaceuticals and Medical Devices Agency (PMDA) starts to take a measure to in principle disclose the information about columns, such as the name (model number) of columns, for Japanese Pharmacopoeia (JP) draft monographs (hereinafter excluding the draft monographs for crude drugs) under the following rules:

1. Concerning tests as a whole using columns in the draft monographs, while further ensuring of transparency of the JP revision process is required, the measure mentioned above is to post the information about the columns that were used for acquisition of the data that were referred in the preparation of the drafts on the PMDA website by PMDA at the start of publication of the relevant drafts for public comments.

2. This disclosure is principally provided for ensuring of enhancement of public comments by wide sharing of the information 1 above with stakeholders other than the manufacturers who prepared the drafts at the time of publication for public comments. Thus, addition of information about other alternative columns or update of information associated with technological innovation is in principle not to be done.

3. The columns to be disclosed have not been confirmed as applicable to all the samples that could be the subjects to application to the monographs of the relevant drafts.

4. The information about columns are released only when cooperation is provided by the manufactures who prepared the drafts.