

USP Small Molecules Priority Monographs

Last updated: 20 Dec 2024

This list includes APIs and Drug Products for which USP is **seeking the donation of information and materials** to support the development of a new official monograph (or to modernize an official monograph).

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Monograph Name	Monograph Type
ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE TABLETS	New
ABALOPARATIDE INJECTION	New
ABEMACICLIB	New
ABEMACICLIB TABLETS	New
ACALABRUTINIB MALEATE	New
ACALABRUTINIB TABLETS	New
AFATINIB TABLETS	New
ALOGLIPTIN AND METFORMIN HYDROCHLORIDE TABLETS	New
ALOGLIPTIN AND PIOGLITAZONE TABLETS	New
ALPELISIB	New
ALPELISIB TABLETS	New
AMINOLEVULINIC ACID HYDROCHLORIDE	Modernization
ANIDULAFUNGIN	New
ANIDULAFUNGIN FOR INJECTION	New
APALUTAMIDE	New
APALUTAMIDE TABLETS	New
ARIPIRAZOLE LAUROXIL	New
ARIPIRAZOLE LAUROXIL EXTENDED-RELEASE INJECTABLE SUSPENSION	New
ATOGEPAANT	New
ATOGEPAANT TABLETS	New
AVIBACTAM SODIUM	New
AZILSARTAN MEDOXOMIL	New
AZILSARTAN MEDOXOMIL AND CHLORTHALIDONE TABLETS	New
AZILSARTAN MEDOXOMIL TABLETS	New
BARICITINIB	New
BARICITINIB TABLETS	New
BECLOMETHASONE DIPROPIONATE INHALATION AEROSOL	New
BEMPEDOIC ACID	New
BEMPEDOIC ACID AND EZETIMIBE TABLETS	New
BEMPEDOIC ACID TABLETS	New
BENDAMUSTINE HYDROCHLORIDE INJECTION	New
BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE TABLETS	New
BICTEGRAVIR SODIUM	New

Monograph Name	Monograph Type
BINIMETINIB	New
BINIMETINIB TABLETS	New
BUPROPION HYDROBROMIDE	New
CABOTEGRAVIR	New
CABOTEGRAVIR AND RILPIVIRINE EXTENDED-RELEASE SUSPENSION	New
CABOZANTINIB CAPSULES	New
CABOZANTINIB S-MALATE	New
CABOZANTINIB TABLETS	New
CALCIPOTRIENE	Modernization
CASPOFUNGIN ACETATE	New
CASPOFUNGIN FOR INJECTION	New
CEFTAZIDIME AND AVIBACTAM FOR INJECTION	New
CERITINIB TABLETS	New
CLADRIBINE TABLETS	New
COBICISTAT TABLETS	New
CRISABOROLE	New
CRISABOROLE OINTMENT	New
CRIZOTINIB	New
CRIZOTINIB CAPSULES	New
CYCLOPENTOLATE HYDROCHLORIDE	Modernization
CYCLOSPORINE OPHTHALMIC SOLUTION	New
DABRAFENIB CAPSULES	New
DABRAFENIB MESYLATE	New
DABRAFENIB TABLETS	New
DALBAVANCIN HYDROCHLORIDE	New
DALBAVANCIN HYDROCHLORIDE FOR INJECTION	New
DARUNAVIR AND COBICISTAT TABLETS	New
DEUTETRABENAZINE	New
DEUTETRABENAZINE EXTENDED-RELEASE TABLETS	New
DEUTETRABENAZINE TABLETS	New
DEXLANSOPRAZOLE DELAYED-RELEASE CAPSULES	New
DEXRAZOXANE HYDROCHLORIDE	New
DIROXIMEL FUMARATE	New
DIROXIMEL FUMARATE DELAYED-RELEASE CAPSULES	New
EDOXABAN TABLETS	New
ELAGOLIX TABLETS	New
ELBASVIR	New
ELBASVIR AND GRAZOPREVIR TABLETS	New
ELEXACAFTOR	New
ELEXACAFTOR, TEZACAFTOR AND IVACAFTOR TABLETS	New
ELTROMBOPAG FOR ORAL SUSPENSION	New

Monograph Name	Monograph Type
ELTROMBOPAG TABLETS	New
ELVITEGRAVIR	New
ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE FUMARATE TABLETS	New
EMPAGLIFLOZIN, LINAGLIPTIN, AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS	New
EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS	New
EMTRICITABINE ORAL SOLUTION	New
ENCORAFENIB	New
ENCORAFENIB CAPSULES	New
ENZALUTAMIDE TABLETS	New
ESKETAMINE HYDROCHLORIDE	New
ESKETAMINE NASAL SPRAY	New
ETONOGESTREL IMPLANT	New
FERRIC CARBOXYMALTOSE	New
FERRIC CARBOXYMALTOSE INJECTION	New
FERRIC CITRATE	New
FERRIC CITRATE TABLETS	New
FIDAXOMICIN	New
FIDAXOMICIN FOR ORAL SUSPENSION	New
FIDAXOMICIN TABLETS	New
FINASTERIDE	Modernization
FINERENONE	New
FINERENONE TABLETS	New
FLUTICASONE FUROATE	New
FLUTICASONE FUROATE, UMECLIDINIUM, AND VILANTEROL INHALATION POWDER	New
FLUTICASONE FUROATE AND VILANTEROL TRIFENATATE INHALATION POWDER	New
FLUTICASONE FUROATE INHALATION POWDER	New
FLUTICASONE FUROATE NASAL SPRAY	New
FOSTEMSAVIR TROMETHAMINE	New
FOSTEMSAVIR TROMETHAMINE EXTENDED-RELEASE TABLETS	New
GADOBENATE DIMEGLUMINE	New
GADOBENATE DIMEGLUMINE INJECTION	New
GADOBUTROL INJECTION	New
GADOXETATE DISODIUM	New
GADOXETATE DISODIUM INJECTION	New
GLECAPREVIR	New
GLECAPREVIR AND PIBRENTASVIR TABLETS	New
GRAZOPREVIR	New

Monograph Name	Monograph Type
HYDROCORTISONE BUTYRATE CREAM	Modernization
HYDROCORTISONE ORAL SOLUTION	New
HYDROCORTISONE SODIUM SUCCINATE	Modernization
HYDROXYUREA	Modernization
HYDROXYUREA CAPSULES	Modernization
IPRATROPIUM BROMIDE INHALATION AEROSOL	New
ISAVUCONAZONIUM SULFATE	New
ISAVUCONAZONIUM SULFATE CAPSULES	New
ISAVUCONAZONIUM SULFATE FOR INJECTION	New
IVACAFTOR GRANULES	New
IVACAFTOR TABLETS	New
IXAZOMIB CAPSULES	New
KETAMINE HYDROCHLORIDE	Modernization
LEDIPASVIR	New
LEDIPASVIR AND SOFOSBUVIR PELLETS	New
LEDIPASVIR AND SOFOSBUVIR TABLETS	New
LETERMOVIR INJECTION	New
LEVONORGESTREL AND ETHINYL ESTRADIOL TABLETS	Modernization
LINAGLIPTIN AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS	New
LUBIPROSTONE CAPSULES	New
LUMACAFTOR	New
LUMACAFTOR AND IVACAFTOR TABLETS	New
MELENGESTROL ACETATE	Modernization
METHIMAZOLE TABLETS	Modernization
METHIMAZOLE TABLETS	Modernization
MIDOSTAURIN CAPSULES	New
MIFEPRISTONE TABLETS	New
MOMETASONE FUROATE AND FORMOTEROL FUMARATE INHALATION AEROSOL	New
MORPHINE SULFATE	Modernization
MORPHINE SULFATE	Modernization
NALOXONE NASAL SPRAY	New
NALTREXONE AND BUPROPION HYDROCHLORIDES EXTENDED-RELEASE TABLETS	New
NAPROXEN AND ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE TABLETS	New
NELFINAVIR MESYLATE	New
NELFINAVIR TABLETS	New
NITAZOXANIDE	New
NITAZOXANIDE TABLETS	New
NORELGESTROMIN AND ETHINYL ESTRADIOL TRANSDERMAL SYSTEM	New

Monograph Name	Monograph Type
OLODATEROL HYDROCHLORIDE	New
OLODATEROL INHALATION SPRAY	New
OLSALAZINE SODIUM	New
OLSALAZINE SODIUM CAPSULES	New
ORITAVANCIN FOR INJECTION	New
OZENOXACIN CREAM	New
PALBOCICLIB	New
PATIROMER FOR ORAL SUSPENSION	New
PATIROMER SORBITEX CALCIUM	New
PEMETREXED	New
PEMETREXED INJECTION	New
PERINDOPRIL ARGININE	New
PERINDOPRIL ARGININE AND AMLODIPINE TABLETS	New
PIBRENTASVIR	New
PILOCARPINE HYDROCHLORIDE	Modernization
PIMAVANSERIN CAPSULES	New
PIMAVANSERIN TABLETS	New
PIMAVANSERIN TARTRATE	New
PIPERACILLIN AND TAZOBACTAM INJECTION	New
PITOLISANT HYDROCHLORIDE	New
PITOLISANT TABLETS	New
POMALIDOMIDE	New
POMALIDOMIDE CAPSULES	New
PONATINIB HYDROCHLORIDE	New
PONATINIB TABLETS	New
POSACONAZOLE DELAYED-RELEASE TABLETS	New
PRASTERONE	New
PRASTERONE VAGINAL INSERTS	New
PROCHLORPERAZINE	Modernization
PROPYLTHIOURACIL TABLETS	Modernization
PRUCALOPRIDE TABLETS	New
QUINIDINE GLUCONATE	Modernization
QUINIDINE GLUCONATE EXTENDED-RELEASE TABLETS	Modernization
RELUGOLIX	New
RELUGOLIX TABLETS	New
REMDESIVIR	New
REMDESIVIR FOR INJECTION	New
REMDESIVIR INJECTION	New
REMIFENTANIL FOR INJECTION	New
REMIFENTANIL HYDROCHLORIDE	New
RIBOCICLIB AND LETROZOLE TABLETS	New

Monograph Name	Monograph Type
RIBOCICLIB SUCCINATE	New
RIBOCICLIB TABLETS	New
RIFAPENTINE	New
RIFAPENTINE TABLETS	New
RIFAXIMIN TABLETS	New
RILPIVIRINE TABLETS	New
RIMEGEPANT ORALLY DISINTEGRATING TABLETS	New
RIMEGEPANT SULFATE	New
RISPERIDONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION	New
RUXOLITINIB CREAM	New
RUXOLITINIB TABLETS	New
SECNIDAZOLE	New
SECNIDAZOLE ORAL GRANULES	New
SELPERCATINIB	New
SELPERCATINIB CAPSULES	New
SELPERCATINIB TABLETS	New
SELUMETINIB SULFATE	New
SELUMETINIB SULFATE CAPSULES	New
SILVER SULFADIAZINE CREAM	Modernization
SODIUM OXYBATE	New
SODIUM OXYBATE ORAL SOLUTION	New
SOFOSBUVIR AND VELPATASVIR TABLETS	New
SOFOSBUVIR TABLETS	New
SUCRALFATE	Modernization
SULFASALAZINE	Modernization
SULFASALAZINE TABLETS	Modernization
SUVOREXANT	New
SUVOREXANT TABLETS	New
TACROLIMUS EXTENDED RELEASE TABLETS	New
TAFAMIDIS	New
TAFAMIDIS CAPSULES	New
TAFAMIDIS MEGLUMINE	New
TAFAMIDIS MEGLUMINE CAPSULES	New
TAPENTADOL EXTENDED-RELEASE TABLETS	New
TAPENTADOL TABLETS	New
TENOFOVIR ALAFENAMIDE FUMARATE	New
TENOFOVIR ALAFENAMIDE FUMARATE TABLETS	New
TENOFOVIR ALAFENAMIDE TABLETS	New
TEZACAFTOR	New
TEZACAFTOR AND IVACAFTOR TABLETS	New
TIOTROPIUM AND OLODATEROL INHALATION SPRAY	New

Monograph Name	Monograph Type
TIRZEPATIDE	New
TIRZEPATIDE INJECTION	New
TRAMETINIB DIMETHYL SULFOXIDE	New
TRAMETINIB ORAL SOLUTION	New
TRAMETINIB TABLETS	New
TREPROSTINIL EXTENDED-RELEASE TABLETS	New
TREPROSTINIL INHALATION SOLUTION	New
TREPROSTINIL INJECTION	New
TRIFAROTENE	New
TRIFAROTENE CREAM	New
UBROGEPANT	New
UBROGEPANT TABLETS	New
UMECLIDINIUM AND VILANTEROL INHALATION POWDER	New
UMECLIDINIUM BROMIDE	New
UMECLIDINIUM INHALATION POWDER	New
UPADACITINIB	New
UPADACITINIB EXTENDED-RELEASE TABLETS	New
VELPATASVIR	New
VENETOCLAX	New
VENETOCLAX TABLETS	New
VIBEGRON	New
VIBEGRON TABLETS	New
VILANTEROL TRIFENATATE	New
VONOPRAZAN FUMARATE	New
VONOPRAZAN FUMARATE TABLETS	New

Monographs removed since August 2024

ACETAMINOPHEN INJECTION
ALENDRONATE SODIUM AND
CHOLECALCIFEROL TABLETS
AMISULPRIDE INJECTION
AMLODIPINE BENZOATE
AMLODIPINE BENZOATE ORAL SUSPENSION
APOMORPHINE HYDROCHLORIDE INJECTION
APRACLONIDINE HYDROCHLORIDE
APRACLONIDINE OPHTHALMIC SOLUTION
BEMOTRIZINOL
BUPROPION HYDROBROMIDE EXTENDED-
RELEASE TABLETS
CEFEPIME INJECTION
CERITINIB
CLASCOTERONE CREAM
CLINDAMYCIN PHOSPHATE AND TRETINOIN
GEL
CROTAMITON LOTION
DEXTROAMPHETAMINE SULFATE EXTENDED-
RELEASE CAPSULES
DICLOFENAC SODIUM OPHTHALMIC SOLUTION
ELTROMBOPAG OLAMINE
ENZALUTAMIDE CAPSULES
ERTUGLIFLOZIN AND METFORMIN
HYDROCHLORIDE TABLETS
ERTUGLIFLOZIN AND SITAGLIPTIN TABLETS
EZETIMIBE AND ATORVASTATIN TABLETS
FOSFOMYCIN FOR ORAL SOLUTION
GLYCOPYRRONIUM TOPICAL SOLUTION
GLYCOPYRRONIUM TOSYLATE
HALOBETASOL PROPIONATE OINTMENT
LENVATINIB CAPSULES
LENVATINIB MESYLATE
LEVALBUTEROL TARTRATE
LEVALBUTEROL TARTRATE METERED-DOSE
INHALATION AEROSOL
LEVOLEUCOVORIN FOR INJECTION
LEVOthyroxine SODIUM CAPSULES
LEVOthyroxine SODIUM FOR INJECTION
LIDOCAINE TRANSDERMAL SYSTEM
LISDEXAMFETAMINE DIMESYLATE CHEWABLE
TABLETS

LOPERAMIDE HYDROCHLORIDE CAPSULES
LULICONAZOLE
LULICONAZOLE CREAM
MESALAMINE DELAYED-RELEASE CAPSULES
METFORMIN HYDROCHLORIDE ORAL
SOLUTION
MIDOSTAURIN
MISOPROSTOL TABLETS
MOMETASONE FUROATE NASAL SPRAY
NELARABINE
NELARABINE INJECTION
NEPAFENAC
OZENOXACIN
PALIPERIDONE PALMITATE EXTENDED-RELEASE
INJECTABLE SUSPENSION
PENCICLOVIR CREAM
PERAMPANEL ORAL SUSPENSION
PREDNISONE DELAYED-RELEASE TABLETS
PROCHLORPERAZINE EDISYLATE
RITONAVIR ORAL POWDER
SELEXIPAG
SERTACONAZOLE NITRATE
SERTACONAZOLE NITRATE CREAM
TAPENTADOL HYDROCHLORIDE
TAZAROTENE CREAM
TAZAROTENE TOPICAL GEL
TERBINAFINE HYDROCHLORIDE TOPICAL SPRAY
TIOPRONIN
TIOPRONIN DELAYED-RELEASE TABLETS
TIOPRONIN TABLETS
TIPIRACIL HYDROCHLORIDE
TOREMIFENE CITRATE
TOREMIFENE TABLETS
TREPASTINIL
TRIFLURIDINE AND TIPIRACIL TABLETS
TRIMETHOBENZAMIDE HYDROCHLORIDE
TRIMETHOBENZAMIDE HYDROCHLORIDE
CAPSULES
VALBENZAZINE CAPSULES
VALBENZAZINE TOSYLATE
ZILEUTON EXTENDED-RELEASE TABLETS

Monographs added since 01Jul2024

ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE TABLETS
ACETAMINOPHEN INJECTION
AMINOLEVULINIC ACID HYDROCHLORIDE
ARIPIRAZOLE LAUROXIL
ARIPIRAZOLE LAUROXIL EXTENDED-RELEASE INJECTABLE SUSPENSION
ARSENIC TRIOXIDE
ARSENIC TRIOXIDE INJECTION
BEMOTRIZINOL
BEMPEDOIC ACID
BEMPEDOIC ACID AND EZETIMIBE TABLETS
BEMPEDOIC ACID TABLETS
BENDAMUSTINE HYDROCHLORIDE INJECTION
CABOTEGRAVIR
CABOTEGRAVIR AND RILPIVIRINE EXTENDED-RELEASE SUSPENSION
CASPOFUNGIN ACETATE
CASPOFUNGIN FOR INJECTION
CERITINIB TABLETS
CLADRIBINE TABLETS
CRIZOTINIB
CRIZOTINIB CAPSULES
CYCLOPENTOLATE HYDROCHLORIDE
CYCLOSPORINE OPHTHALMIC SOLUTION
DARUNAVIR AND COBICISTAT TABLETS
DEUTETRABENAZINE EXTENDED-RELEASE TABLETS
DOXEPIN TABLETS
EDOXABAN TABLETS
ETONOGESTREL IMPLANT
EZETIMIBE AND ATORVASTATIN TABLETS
FINERENONE
FINERENONE TABLETS
FLUTICASONE FUROATE NASAL SPRAY
FOSFOMYCIN FOR ORAL SOLUTION
FOSTEMSAVIR TROMETHAMINE
FOSTEMSAVIR TROMETHAMINE EXTENDED-RELEASE TABLETS
GADOBUTROL INJECTION
HYDROCORTISONE ORAL SOLUTION
IXAZOMIB CAPSULES
LEVOTHYROXINE SODIUM FOR INJECTION
LIDOCAINE TRANSDERMAL SYSTEM

MIDOSTAURIN
MIDOSTAURIN CAPSULES
MOMETASONE FUROATE AND FORMOTEROL FUMARATE INHALATION AEROSOL
MOMETASONE FUROATE NASAL SPRAY
MORPHINE SULFATE
NALOXONE NASAL SPRAY
NALTREXONE AND BUPROPION HYDROCHLORIDES EXTENDED-RELEASE TABLETS
NAPROXEN AND ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE TABLETS
NELARABINE
NELARABINE INJECTION
NORELGESTROMIN AND ETHINYL ESTRADIOL TRANSDERMAL SYSTEM
OZENOXACIN
OZENOXACIN CREAM
PATIROMER FOR ORAL SUSPENSION
PATIROMER SORBITE CALCIUM
PEMETREXED
PEMETREXED INJECTION
PIMAVANSERIN CAPSULES
PIMAVANSERIN TABLETS
PIMAVANSERIN TARTRATE
PITOLISANT HYDROCHLORIDE
PITOLISANT TABLETS
POMALIDOMIDE
POMALIDOMIDE CAPSULES
POSACONAZOLE DELAYED-RELEASE TABLETS
PRASTERONE
PRASTERONE VAGINAL INSERTS
RELUGOLIX
RELUGOLIX TABLETS
SELPERCATINIB
SELPERCATINIB CAPSULES
SELPERCATINIB TABLETS
TACROLIMUS EXTENDED RELEASE TABLETS
TENOFIVIR ALAFENAMIDE FUMARATE
TERBINAFINE HYDROCHLORIDE TOPICAL SPRAY
TIPIRACIL HYDROCHLORIDE
TREPROSTINIL EXTENDED-RELEASE TABLETS
TREPROSTINIL INHALATION SOLUTION
TRIFAROTENE



TRIFAROTENE CREAM
TRIFLURIDINE AND TIPIRACIL TABLETS
UMECLIDINIUM AND VILANTEROL INHALATION
POWDER

UMECLIDINIUM INHALATION POWDER
VONOPRAZAN FUMARATE
VONOPRAZAN FUMARATE TABLETS

For questions/inquiries, please contact donations@usp.org