

Revisions to USP 30–NF 25, First Supplement

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Upcoming Revisions to USP 30–NF 25, First Supplement

Scientific Liaison

DANTROLENE SODIUM (new)

()

PF 32(2) p. 327

Title

Chemical Info

Definition

Packaging and storage

USP Reference standards <11>

Identification A, B, C

Water, Method Ia <921>

Heavy metals, Method II <231>

Limit of dantrolene related compound A

Related compounds

Assay

DANTROLENE SODIUM FOR INJECTION (new)

()

PF 32(3) p. 779

Bacterial endotoxins <85>

Sterility <71>

DANTROLENE SODIUM FOR INJECTION (new)

()

PF 32(3) p. 779

Title

Definition

Packaging and storage

USP Reference standards <11>

Identification A & B

Uniformity of dosage units <905>

pH <791>

Water, Method Ia <921>

Related compounds

Other requirements

Assay

Desmopressin Acetate (new)

()

PF 31(4) p. 1052

Microbial limits

Desmopressin Acetate (new)

()

PF 31(4) p. 1052

Title

Chemical structure

Chemical formulas

Molecular weight
Chemical names
CAS numbers
Definition
Packaging and storage
Labeling
USP Reference standards
Identification A, B, C
Specific rotation
Water
Amino acid content
Limit of acetic acid
Chromatographic purity
Assay

DESMOPRESSIN ACETATE INJECTION ()

Title
Definition
Packaging and storage
Labeling
USP Reference standards
Identification
pH
Particulate matter
Other requirements
Assay

DESMOPRESSIN INJECTION (new) ()

PF 31(4) p. 1057
Bacterial endotoxins
Sterility

DESOGESTREL AND ETHINYL ESTRADIOL TABLETS (new) ()

PF 30(5), p. 1604 ()
Dissolution

DESOGESTREL AND ETHINYL ESTRADIOL TABLETS (new) ()

PF 30(5), p. 1604
Title
Definition
Packaging and storage
Labeling
USP Reference standards
Thin-layer chromatographic identification test
Identification B
Uniformity of dosage units
Loss on drying
Water
Assay

DIAZEPAM EXTENDED-RELEASE CAPSULES ()

USP 29–NF 24 p. 674
PF 32(2) p. 330
USP Reference standards <11>
Assay

DIDANOSINE (new) ()
PF 32(3) p. 781
Title
Chemical info
Definition
Packaging and storage
USP Reference standards <11>
Identification A & B
Water, Method I <921>
Residue on ignition <281>
Specific rotation <781S>

Assay

Didanosine for Oral Solution (new) ()
PF 31(5) p. 1357
Title
Definition
Packaging and storage
Labeling
USP Reference standards
Identification A, B
Water
Deliverable volume
Related Compounds
Assay

Dihydroxyaluminum Sodium Carbonate Tablets ()
USP 27, p. 624
PF29(6) p. 1873
Current Title (not to change until February 1, 2007)
PF29(6) p. 1873
New Title: Dihydroxyaluminum Sodium Carbonate Chewable Tablets (to become official February 1, 2007)
Definition
Packaging and storage
Labeling
Identification
Uniformity of dosage units
Acid-neutralizing capacity
Assay

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE ORAL SOLUTION ()
USP29 p. 732
PF 31(6) p. 1612
Identification
Assay for diphenoxylate hydrochloride (delete)
Assay for atropine sulfate (delete)
Assay (add)

DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE TABLETS ()
USP29 p. 733
PF 31(6) p. 1614
Identification
Assay for diphenoxylate hydrochloride (delete)

Assay for atropine sulfate (delete)	
Assay (add)	
DOXAZOSIN TABLETS (new)	()
PF29(1) p. 64	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification	
Uniformity of dosage units	
Assay	
DOXEPIN HYDROCHLORIDE	()
USP 29–NF 24 p. 758	
PF 32(2) p. 330	
USP Reference standards <11>	
Identification B	
Melting range (delete)	
Chloride content (delete)	
Related compounds (add)	
DRONABINOL	()
USP 29–NF 24 Pg. 769	
PF 32(1) Pg. 86	
USP Reference standards (USP Exo-tetrahydrocannabinol RS (add), USP delta-8-Tetrahydrocannabinol RS (delete))	
Identification A, B	
Limit of delta-8-tetrahydrocannabinol (delete)	
Related compounds (add)	
Assay	
DROSPIRENONE (new)	()
PF 32(3) p. 787	
Title	
Chemical info	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A & B	
Melting range, Class I <741>	
Specific rotation <781S>	
Water, Method I <921>	
Residue on ignition <281>	
Heavy Metals, Method II <231>	
Organic volatile impurities, Method IV <467>	
Limit of 1,2-dimethoxyethane and diisopropyl ether	
Chromatographic purity	
Assay	
ERYTHRITOL (new)	()
PF 31(5) p. 1422	
Microbial limits	
ERYTHRITOL (new)	()
PF 31(5) p. 1422	

Title
Chemical structure
Chemical formula
Molecular weight
Chemical names
CAS number
Definition
Packaging and storage
USP Reference standards
Identification A, B
Loss on drying
Water
Conductivity
Residue on ignition
Limit of lead
Related compounds
Assay

ESTRADIOL AND NORETHINDRONE ACETATE TABLETS (new) ()
PF 31(5) p. 1364

Title
Definition
Packaging and storage
USP Reference standards
Identification A, B
Loss on drying
Chromatographic purity
Assay

ETHOTOIN TABLETS ()

USP 29 p. 870
PF 32(2) p. 332
USP Reference standards <11>
Assay

ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER Dispersion (new) ()

PF 31(4) p. 1141
Microbial limits

ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER DISPERSION (new) ()

PF 31(4) p. 1141
Title
CAS number
Definition
Packaging and storage
Labeling
USP Reference standards
Identification
Viscosity
pH
Loss on drying
Residue on ignition
Limit of monomers
Coagulum content

FAMOTIDINE INJECTION (new)	()
PF 32(2) p. 333	
Bacterial endotoxins <85>	
Sterility <71>	
FAMOTIDINE INJECTION (new)	()
PF 32(2) p. 333	
Title	
Definition	
Packaging and storage	
Labeling	
USP Reference standards <11>	
Identification	
pH <791>	
Particulate matter <788>	
Related compounds	
Content of benzyl alcohol (if present)	
Other requirements	
Assay	
FEXOFENADINE HYDROCHLORIDE TABLETS (new)	()
PF 30(6), p. 1997	()
Dissolution	
FEXOFENADINE HYDROCHLORIDE TABLETS (new)	()
PF 30(6), p. 1997	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Uniformity of dosage units	
Water	
Related compounds	
Assay	
FLUCONAZOLE	()
USP 29–NF 24 2S p. 3719	
PF 32(2) p. 335	
Related compounds	
FLUMAZENIL	()
USP 29–NF 24 Pg. 919	
PF 32(1) Pg. 94	
USP Reference standards (USP Flumazenil Related Compound B RS, USP Flumazenil Related Compound C RS)	
Related compounds	
Assay	
FLUOROMETHOLONE ACETATE (new)	()
PF 31(5) p. 1371	
Title	
Chemical formula	
Molecular weight	
Definition	
Packaging and storage	

USP Reference standards	
Identification A, B, C	
Specific rotation	
Loss on drying	
Chromatographic purity	
Residual solvents	
Assay	
FLUTICASONE PROPIONATE	()
USP 29–NF 24 2S p. 3720	
PF 32(2) p. 337	
Definition	
Bromofluoromethane content (delete)	
FLUVOXAMINE MALEATE TABLETS (new)	()
PF 30(5), p. 1622	
Related compounds	
FLUVOXAMINE MALEATE	()
USP 29–NF 24 p. 964	
PF 32(2) p. 344	
Maleic acid (delete)	
Assay	
FOSINOPRIL SODIUM (new)	()
PF 32(3) p. 789	
Related compounds	
FOSINOPRIL SODIUM (new)	()
PF 32(3) p. 789	
Title	
Chemical info	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification	
Water, Method I <921>	
Heavy metals, Method II <231>	
Residual solvents	
Assay	
FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE TABLETS (new)	()
PF 30(6), p. 2006	()
Dissolution	
FOSINOPRIL SODIUM AND HYDROCHLOROTHIAZIDE TABLETS (new)	()
PF 30(6), p. 2006	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Uniformity of dosage units	
Related compounds	
Assay for fosinopril sodium	
Assay for hydrochlorothiazide	

FOSINOPRIL SODIUM TABLETS (new)	()
PF 30(6), p. 2004	()
Dissolution	
FOSINOPRIL SODIUM TABLETS (new)	()
PF 30(6), p. 2004	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Uniformity of dosage units	
Limit of related compound A	
Assay	
GONADORELIN ACETATE (new)	()
PF 30(4), p. 1250	
Title	
Chemical structure	
Chemical formula	
Molecular weight	
Chemical name	
CAS number	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Specific rotation	
Water	
Limit of fluoride	
Acetic acid and trifluoroacetic acid	
Related compounds	
Amino acid analysis	
Assay	
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE TABLETS	()
(new)	
PF 30(3), p. 853	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Uniformity of dosage units	
Limit of dihydrocodeine bitartrate, hydrocodone diol, and related substances	
Limit of homatropine hydrobromide and related substances	
Limit of tropine	
Assay	
HYDROCODONE BITARTRATE	()
USP 28, p. 956	
PF 30(5), p. 1628	
USP Reference standards	
[USP Hydrocodone Bitartrate Related Compound A]	
Ordinary impurities (delete)	

IBUPROFEN ORAL SUSPENSION	()
USP 29–NF 24 p. 1101	
PF 32(3) p. 796	
USP Reference standards <11>	
Limit of 4-isobutylacetophenone	
Assay	
IBUPROFEN TABLETS	()
USP 29–NF 24 2S p. 3725	
PF 32(3) p. 798	
USP Reference standards <11>	
Limit of 4-isobutylacetophenone	
Assay	
IBUPROFEN	()
USP 29–NF 24 p. 1100	
PF 32(3) p. 796	
USP Reference standards <11>	
Limit of 4-isobutylacetophenone	
Assay	
INDINAVIR SULFATE	()
USP 29–NF 24 p. 1118	
PF 32(2) p. 345	
Heavy metals (delete)	
Heavy metals <231> (add)	
Chromatographic purity	
Assay	
HUMAN INSULIN ISOPHANE SUSPENSION AND HUMAN INSULIN INJECTION (new)	()
PF 31(4) p. 1032	
Title	
Definition	
Packaging and storage	
Labeling	
USP Reference standards	
Identification	
pH	
Zinc content	
Limit of high molecular weight proteins	
Soluble insulin human content	
Assay	
HUMAN INSULIN ISOPHANE SUSPENSION AND HUMAN INSULIN INJECTION	()
PF 31(4) p. 1032	
Bacterial endotoxins	
Sterility	
IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS (new)	()
PF29(4), p. 1036	()
Dissolution	
IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS (new)	()
PF29(4), p. 1036	

Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification	
Uniformity of dosage units	
Assay	
IRBESARTAN TABLETS (new)	()
PF 32(3) p. 799	()
Dissolution <711>	
IRBESARTAN TABLETS (new)	()
PF 32(3) p. 799	
Title	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A & B	
Uniformity of dosage units <905>	
Related compounds	
Assay	
IRBESARTAN	()
USP 29–NF 24 p. 1177	
PF 32(3) p. 799	
Related compounds (Test solution)	
IRBESARTAN	()
USP 29–NF 24 Pg. 1177	
PF 32(1) Pg. 115	
Limit of azide (Chromatographic system)	
ISOSORBIDE MONONITRATE TABLETS (new)	()
PF29(5), p. 1513	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Uniformity of dosage units	
Related compounds	
Assay	
LAMIVUDINE	()
USP 29–NF 24 p. 1225	
PF 32(2) p. 346	
Assay	
LEUPROLIDE ACETATE (new)	()
PF 30(3), p. 882	
Bacterial endotoxins	
LEUPROLIDE ACETATE (new)	()
PF 30(3), p. 882	
Title	

Chemical structure	
Chemical formula	
Molecular weight	
Chemical names	
CAS number	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Specific rotation	
Water	
Residue on ignition	
Chromatographic purity	
Content of acetic acid	
Amino acid content	
Assay	
LIDOCAINE AND PRILOCAINE CREAM (new)	()
PF 31(4) p. 1087	
Microbial limits	
LIDOCAINE AND PRILOCAINE CREAM (new)	()
PF 31(4) p. 1087	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification	
Microbial limits	
Minimum fill	
pH	
Assay	
LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION	()
USP 29–NF 24 p. 1269	
PF 32(2) p. 353	
Assay	
MAGALDRATE AND SIMETHICONE TABLETS	()
USP 27, p. 1118	
PF29(6) p. 1918	
Current Title (not to change until February 1, 2007)	
PF29(6) p. 1919	
New Title: Magaldrate and Simethicone Chewable Tablets (to become official February 1, 2007)	
Definition	
Packaging and storage	
Labeling	
USP Reference standards	
Identification A, B	
Microbial limits	
Uniformity of dosage units	
Acid-neutralizing capacity	
Defoaming activity	
Magnesium hydroxide content	
Aluminum hydroxide content	

Assay for magaldrate
Assay for polydimethylsiloxane

MELOXICAM (new) ()
PF 31(1), p. 57
Title
Chemical structure
Chemical formula
Molecular weight
Chemical name
CAS number
Definition
Packaging and storage
Labeling
USP Reference standards
Identification A, B
Loss on drying
Residue on ignition
Heavy metals
Related compounds
Assay

METHYLDOPA ORAL SUSPENSION ()
USP 29–NF 24 p. 1396
PF 32(2) p. 354
USP Reference standards <11>
Limit of methyldopa-glucose reaction product (delete)

METHYLPREDNISOLONE ()
USP 29–NF 24 p. 1406
PF 32(2) p. 354
Chromatographic purity

METHYLSULFONYLMETHANE (new) ()
PF 32(3) p. 826
Chromatographic purity and limit of dimethyl sulfoxide

METHYLSULFONYLMETHANE (new) ()
PF 32(3) p. 826
Microbial enumeration <2021>

METHYLSULFONYLMETHANE (new) ()
PF 32(3) p. 826
Title
Chemical Info
Definition
Packaging and storage
USP Reference standards <11>
Identification A & B
Melting range <741>
Heavy metals, Method I <231>
Assay

METHYLSULFONYLMETHANE (new) ()
PF 32(3) p. 826
Water, Method I <921>

METHYLSULFONYLMETHANE TABLETS (new) PF 32(3) p. 827 Disintegration and dissolution <2040>	()
METHYLSULFONYLMETHANE TABLETS (new) PF 32(3) p. 827 Title Definition Packaging and storage USP Reference standards <11> Identification Weight variation <2091> Assay	()
MILK OF MAGNESIA USP 29–NF 24 p. 1291 PF 32(2) p. 353 Limit of calcium (delete)	()
MITOXANTRONE INJECTION USP 29–NF 24 p. 1447 PF 32(2) p. 355 Packaging and storage	()
MORANTEL TARTRATE USP 29 p. 1455 PF 32(2) p. 355 pH <791>	()
MUPIROCIN CALCIUM (new) PF 31(2), p. 430 Title Chemical structure Chemical formula Molecular weight Chemical names CAS number Definition Packaging and storage USP Reference standards Identification A, B, C Specific rotation Water Chloride Related compounds Assay	()
MUPIROCIN CREAM (new) PF 31(2), p. 432 Title Definition Packaging and storage Labeling USP Reference standards Identification	()

Minimum fill	
pH	
Related compounds	
Assay	
NEFAZODONE HYDROCHLORIDE TABLETS (new)	()
PF 32(3) p. 804	
Title	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A, B	
Uniformity of dosage units <905>	
Related compounds	
Assay	
NEFAZODONE HYDROCHLORIDE TABLETS (new)	()
PF 31(4) p. 1096	()
Dissolution	
NEVIRAPINE TABLETS (new)	()
PF 32(3) p. 807	()
Dissolution <711>	
NEVIRAPINE TABLETS (new)	()
PF 32(3) p. 807	
Title	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A & B	
Uniformity of dosage units <905>	
Chromatographic purity	
Assay	
NIMODIPINE	()
USP 29–NF 24 p. 1535	
PF 32(2) p. 360	
Identification	
Related compounds	
NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS (new)	()
PF29(1) p. 87	()
Disintegration	
Dissolution	
NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS (new)	()
PF29(1) p. 87	
Title	
Definition	
Packaging and storage	
USP Reference standards	
Identification	
Uniformity of dosage units	
Chromatographic purity	
Assay	

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