

Revisions to USP 30–NF 25, First Supplement

Published February 2007

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Upcoming Revisions to USP 30–NF 25, First Supplement

Scientific Liaison

ALFADEX

USP 29–NF 24 p. 3268

PF 32(2) p. 395

Definition

Packaging and storage (add)

Loss on drying <731> (delete)

Water, Method I <921> (add)

Reducing sugars

Light-absorbing impurities

Organic volatile impurities, Method IV <467> (delete)

Residual solvents <467> (delete)

Assay

()

ALLOPURINOL

USP 29–NF 24 p. 75

PF 32(2) p. 302

Definition

Packaging and storage

USP Reference standards <11>

Chromatographic purity (Delete)

Related compounds (add)

Assay

()

Alumina, Magnesia, and Calcium Carbonate Tablets

USP 27, p. 75

PF29(6) p. 1835

Current Title (not to change until February 1, 2007)

PF29(6) p. 1836

New Title: Alumina, Magnesia, and Calcium Carbonate Chewable Tablets (to become official February 1, 2007)

Definition

Labeling

Identification

Disintegration

Uniformity of dosage units

Acid-neutralizing capacity

Assay for aluminum hydroxide

Assay for magnesium hydroxide

Assay for calcium carbonate

()

Alumina, Magnesia, and Simethicone Tablets

USP 27, p. 78

()

PF29(6) p. 1841

Current Title (not to change until February 1, 2007)

PF29(6) p. 1842

New Title: Alumina, Magnesia, and Simethicone Chewable Tablets (to become official February 1, 2007)

Definition

Packaging and storage

Labeling

USP Reference standards

Identification A, B, C

Uniformity of dosage units

Acid-neutralizing capacity

Defoaming activity

Sodium content

Assay for aluminum hydroxide

Assay for magnesium hydroxide

Assay for polydimethylsiloxane

Alumina, Magnesia, Calcium Carbonate, and Simethicone Tablets

()

USP 27, p. 75

PF29(6) p. 1837

Current Title (not to change until February 1, 2007)

PF29(6) p. 1837

New Title: Alumina, Magnesia, Calcium Carbonate, 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

Sodium content

Assay for aluminum hydroxide

Assay for magnesium hydroxide

Assay for calcium carbonate

Assay for polydimethylsiloxane

ALUMINUM SULFATE AND CALCIUM ACETATE FOR TOPICAL SOLUTION

()

PF 32(3) p. 755

Title

Definition

Packaging and storage

Identification A & B

pH <791>

Assay for aluminum sulfate

Assay for calcium acetate

Amino Methacrylate Copolymer (new)

()

PF 31(4) p. 1137

Title

Definition

Packaging and storage

USP Reference standards	
Color of solution	
Identification A, B; Viscosity	
Loss on drying	
Residue on ignition	
Limit of monomers	
Assay	
AMLODIPINE BESYLATE (new)	()
PF 32(3) p. 757	
Title	
Chemical Info	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A & B	
Optical rotation <781A>	
Water, Method I <921>	
Residue on ignition <281>	
Heavy metals, Method II <231>	
Related compounds	
Assay	
ATRACURIUM BESYLATE	()
USP 29–NF 24 p. 216	
PF 32(2) p. 305	
Chromatographic purity	
Assay	
AZITHROMYCIN	()
USP 29–NF 24 p. 227	
PF 32(2) p. 306	
Labeling	
USP Reference standards <11>	
Limit of related substances	
Bismuth Subsalicylate Oral Suspension (new)	()
PF 31(4) p. 1035	
Microbial limits	
Bismuth Subsalicylate Oral Suspension (new)	()
PF 31(4) p. 1035	
Title	
Definition	
Identification A, B	
pH	
Assay	
Bismuth Subsalicylate Tablets (new)	()
PF 31(3), p. 741	()
Disintegration	
Bismuth Subsalicylate Tablets (new)	()
PF 31(3), p. 741	
Title	
Definition	

Labeling	
Identification A, B	
Assay	
BISOCTRIZOLE (new)	()
PF 32(2) p. 309	
Title	
Chemical Info	
Definition	
Packaging and storage	
USP Reference standards <11>	
Identification A, B	
Heavy metals	
Limit of bisoctrizole related compound A and the bisoctrizole isomer	
Related compounds	
Limit of residual solvents	
Assay	
Budesonide (new)	()
PF 30(6), p. 1978	
Microbial limits	
Budesonide (new)	()
PF 30(6), p. 1978	
Title	
Chemical formula	
Molecular weight	
Chemical names	
CAS number	
Definition	
Packaging and storage	
USP Reference standards	
Identification A, B	
Loss on drying	
Organic volatile impurities	
Limit of methanol	
Limit of 21-acetate of budesonide	
Limit of 11-ketobudesonide	
Related compounds	
Assay	
BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS	()
USP 29–NF 24 p. 322	()
PF 32(2) p. 312	
Drug release <724>	
Dissolution <711>	
Calcium Carbonate, Magnesia, and Simethicone Tablets	()
USP 27, p. 302	
PF29(6) p. 1853	
Current Title (not to change until February 1, 2007)	
PF29(6) p. 1854	
New Title: Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets (to become official February 1, 2007)	
Definition	

Packaging and storage	
Labeling	
USP Reference standards	
Identification A, B, C	
Uniformity of dosage units	
Acid-neutralizing capacity	
Defoaming activity	
Sodium content	
Assay for polydimethylsiloxane	
Assay for calcium carbonate and magnesium hydroxide	
Calcium Silicate	()
NF23 p. 2970	
PF 31(5) p. 1417	
Definition	
pH	
Limit of fluoride	
Assay for silicon dioxide	
Assay for calcium oxide	
CEFADROXIL FOR ORAL SUSPENSION	()
USP 29–NF 24 2S p. 3715	()
PF 32(2) p. 315	
Dissolution <711> (add)	
CEFEPIME HYDROCHLORIDE	()
USP 29–NF 24 p. 409	
PF 32(2) p. 316	
Limit of N-methylpyrrolidine	
CEFEPIME HYDROCHLORIDE	()
USP 29–NF 24 p. 409	
PF 32(2) p. 316	
Related compounds	
CHLORHEXIDINE GLUCONATE ORAL RINSE	()
USP 29–NF 24 p. 476	
PF 32(3) p. 768	
Assay	
CHLORHEXIDINE GLUCONATE SOLUTION	()
USP 29–NF 24 p. 477	
PF 32(3) p. 768	
Assay	
CHLOROPHYLLIN COPPER COMPLEX SODIUM	()
USP 29–NF 24 p. 478	
PF 32(3) p. 769	
Content of total copper	
CHOLESTYRAMINE RESIN	()
USP 29–NF 24 p. 503	
PF 32(2) p. 320	
Dialyzable quaternary amines	
CIMETIDINE	()
USP 29–NF 24 p. 512	

PF 32(3) p. 769 Identification A Chromatographic purity	
CIPROFLOXACIN AND DEXAMETHASONE OTIC SUSPENSION (new) PF 32(2) p. 321 Sterility <71>	()
CIPROFLOXACIN AND DEXAMETHASONE OTIC SUSPENSION (new) PF 32(2) p. 321 Title Definition Packaging and storage USP Reference standards <11> Identification A, B pH <791> Particle size Osmolality <785> Limit of ciprofloxacin formamide Ciprofloxacin related compounds Dexamethasone related compounds Assay for ciprofloxacin Assay for dexamethasone	()
CIPROFLOXACIN HYDROCHLORIDE USP 29–NF 24 p. 517 PF 32(2) p. 325 Chromatographic purity Assay	()
CIPROFLOXACIN INJECTION USP 29–NF 24 p. 518 PF 32(2) p. 326 Limit of ciprofloxacin ethylenediamine analog Assay	()
CIPROFLOXACIN USP 29–NF 24 p. 516 PF 32(2) p. 320 Chromatographic purity Assay	()
COCONUT OIL (new) PF 32(2) p. 397 Title Chemical Info Definition Packaging and storage Identification Melting range <741> Acid value <401> Peroxide value <401> Unsaponifiable matter <401> Fatty acid composition Water, Method I <921> Arsenic, Method II <211>	()

Alkaline impurities

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