

ANALISA PERMINTAAN BARANG

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IBS00062	Lorazepam	mg	0	30	-30	0	30	0	0
2	IBS00288	Lorazepam Related Compound D	mg	0	75	-75	0	75	0	0
3	IBS00450	Zolpidem Related Compound D	mg	0	90	-90	0	90	0	0

Catatan :

1. Lorazepam Ex. EDQM, order code : L0750500, Sebagai baku pembanding untuk pembuatan larutan standar pada analisa pembakuan Working Standar Lorazepam

- Saat ini stok sudah habis, perlu dilakukan pengadaan untuk analisa pembakuan pada bulan Februari 2027
- Packing Size : 1 Vial @15 mg
- Pemesanan terakhir kali 2024 (PR148183)

2. Lorazepam Related Compound D Ex. USP Cat.no : 1370350, Sebagai baku pembanding untuk pembuatan larutan standar pada analisa cemaran organik bahan baku Lorazepam, produk jadi Lorazepam tablet dan Lorazepam Injeksi

- Saat ini stok di QC sudah habis, perlu dilakukan pengadaan kembali untuk analisa rutin baku Lorazepam dan produk jadi Lorazepam tablet
- Packing Size : 1 Vial @25 mg
- Pemesanan terakhir kali tahun 2024 (PR148347)

3. Zolpidem Related Compound A Ex. USP Cat.no : 1724918, Sebagai baku pembanding untuk pembuatan larutan standar pada analisa cemaran organik bahan baku Zolpidem Tartrate, produk jadi Zolpidem Tablet

- Saat ini stok yang ada di QC hanya cukup untuk analisa bahan baku, perlu dilakukan pengadaan untuk persiapan analisa produk baru Zolpidem Tablet (Valpro, Stabilita, dll)
- Packing size : 1 Vial @15 mg
- Pemesanan terakhir kali tahun 2026 (RQ000224)

Latar Belakang Permintaan :

- Stok saat ini sudah habis, sehingga diperlukan pengadaan lagi untuk memenuhi kebutuhan analisa rutin.

Terlampir rencana kebutuhan,dan metode pengujian bahan awal

Dibuat


Si: 29/26
SOS/og

Mengetahui



RENCANA KEBUTUHAN REFERENCE STANDARD UNTUK PENGUJIAN RUTIN

Lorazepam

No.	Produk Jadi	Kebutuhan/Batch	Jumlah Batch	Kebutuhan/Tahun	Kebutuhan (Vial)
1	Pembakuan Lorazepam	15 mg	2	30 mg	2 1,00 vial

2 1,00 vial

20/26
09

Lorazepam Related Compound D

No.	Analisa	Kebutuhan/Batch	Jumlah Batch	Kebutuhan/Tahun	Kebutuhan (Vial)
1	Bahan Baku Lorazepam	2,5 mg	4	10 mg	0,40 vial
2	Lorazepam Tablet	2,5 mg	12	30 mg	1,20 vial
3	Lorazepam Injeksi	2,5 mg	3	7,5 mg	0,30 vial
4	Stabilita Lorazepam	2,5 mg	2	5 mg	0,20 vial
5	Validasi dan Transfer Metode	2,5 mg	4	10 mg	0,40 vial

2,50 vial

~ 3 vial

Zolpidem Related Compound A

No.	Analisa	Kebutuhan/Batch	Jumlah Batch	Kebutuhan/Tahun	Kebutuhan (Vial)
1	Zolpidem Tablet	5 mg	6	30 mg	2,00 vial
2	Transfer Metode Analisa	5 mg	5	25 mg	1,67 vial
3	Validasi Proses	5 mg	3	15 mg	1,00 vial
4	Bahan Baku Zolpidem	5 mg	2	10 mg	0,67 vial

5,33 vial

~ 6 vial

28/26
09



Last Updated On: September 27, 2026

USP Catalog

Catalog #	Status	Product Name	Product Type	Associated Drug Substance	Current Lot	Previous Lot (VUD)	CAS #	NDC #	Unit Price	Co. Of Origin	Material Origin	UN #	Net Weight	Unit Of Measure	Commodity Codes (HS Codes)*	Special Restriction	Pkg. Type	USMCA Eligible	KORUS Eligible	Base Control Drug	Base Control Drug %
		stearate and zinc palmitate)																			
1724769	Active	Zinc Sulfate (1 g)	Reference Standard	Zinc	R162K0	R096J0 (31-OCT-2023)	7446-19-7	N/A	\$285.00	IN	Chemical Synthesis	UN3077	1	g	2833294500		VIAL	No	No		
1724772	Active	Ziziphus Jujuba Sphosa Seed Dry Extract (750 mg)	Reference Standard		F129D0		N/A	N/A	\$491.00	CN	Plant		750	mg	1302190200		VIAL	No	No		
1724780	Active	Zinc Undecylenate (200 mg)	Reference Standard	Zinc	F137K0		557-08-4	N/A	\$341.00	IN	Chemical Synthesis		200	mg	2916196000		VIAL	No	No		
1724791	Active	Ziziphus jujuba Fruit Dry Extract (1.5 g)	Reference Standard		F189D0		N/A	N/A	\$857.00	CN	Plant		1.5	g	1302190200		VIAL	No	No		
1724805	Active	Zolazepam Hydrochloride (500 mg)	Reference Standard	Zolazepam	R168G0	R067K0 (28-FEB-2023)	33754-49-3	N/A	\$294.00	FR	Chemical Synthesis		500	mg	2933996500		VIAL	No	No	Zolazepam	89
1724827	Active	Zoledronic Acid (150 mg)	Reference Standard	Zoledronic Acid	R118M0	R05911 (31-MAR-2023)	165800-06-6 (Monohydrate)	N/A	\$297.00	CH	Chemical Synthesis	UN3077	150	mg	2933290000		VIAL	No	No		
1724838	Active	Zoledronic Acid Related Compound A (30 mg) (2-(1H-Imidazol-1-yl)acetic acid)	Reference Standard	Zoledronic Acid	R118D0	R006D0 (30-JUN-2020)	22884-10-2	N/A	\$903.00	CN	Chemical Synthesis		30	mg	2933290000		VIAL	No	No		
1724849	Active	Zoledronic Acid Related Compound B (COLD SHIPMENT REQUIRED) (30 mg) (1-Hydroxy-2-[1-(2-hydroxy-2,2-diphosphonoethyl)-1H-imidazol-3-ium-3-yl]-1-phosphonoethylphosphonate)	Reference Standard	Zoledronic Acid	F120S0		1627731-61-6	N/A	\$1,015.00	CH	Chemical Synthesis		30	mg	2933290000	Cold Shipment Required	VIAL	No	No		
1724883	Active	Zolpidem CIV (10 mg)	Reference Standard	Zolpidem	F01064		82626-48-0	00216 27830 1	\$249.00	FR	Chemical Synthesis	UN3077	10	mg	2933996500	Controlled	VIAL	No	No	ZOLPIDEM	100
1724907	Active	Zolpidem Tartrate CIV (200 mg) (COLD SHIPMENT REQUIRED)	Reference Standard	Zolpidem	R141E0	R003V0 (31-OCT-2021)	99294-93-6	00216 27850 1	\$419.00	FR	Chemical Synthesis		200	mg	2933996500	Controlled - Cold Shipment Required	VIAL	No	No	ZOLPIDEM	80.2
1724918	Active	Zolpidem Related Compound A (15 mg) (N,N-Dimethyl-2-[7-methyl-2-p-tolylimidazo[1,2-	Reference Standard	Zolpidem	R20960	R100U0 (31-DEC-2025)	1346600-85-8	N/A	\$921.00	FR	Chemical Synthesis		15	mg	2933997500		VIAL	No	No	ZOLPIDEM	100

Order Code	Reference Standard	Batch n°	Quantity per vial	Sale Unit	Information	Monograph	Storage	Shipping group	Price
Y0001505	LOPINAVIR FOR SYSTEM SUITABILITY CRS	1	10 MG	1		2615	+5°C+/-3°C	A1A	90 €
Y0000688	LORATADINE CRS	4	60 MG	1		2124	+5°C+/-3°C	A1A	90 €
Y0000603	LORATADINE FOR SYSTEM SUITABILITY CRS	3	15 MG	1		2124	+5°C+/-3°C	A1A	90 €
Y0000604	LORATADINE IMPURITY F CRS	2	10 MG	1		2124	+5°C+/-3°C	A1A	90 €
Y0000605	LORATADINE IMPURITY H CRS	3	60 MG	1		2124	+5°C+/-3°C	A1A	90 €
L0750500	LORAZEPAM CRS - * PSY	2	15 MG	1	We require your original import permit to proceed with the shipment (allow 2-3 weeks). For your import permit, you have to apply for 15 mg of Lorazepam, PER VIAL. Your import permit must be valid for at least 3 months. Please specify your preferred airport for parcel pickup in your next communication.	1121	+5°C+/-3°C	A2A	90 €
Y0000576	LORAZEPAM FOR SYSTEM SUITABILITY CRS - * PSY (LORAZEPAM)	4	0.8 MG	1	We require your original import permit to apply for an export licence from the French authorities (allow 2-3 weeks). Your permit must be valid for at least 3 months. Please indicate your preferred airport. You should apply for your import permit, per vial, 0,8 mg of Lorazepam on your import permit.	1121	+5°C+/-3°C	A2A	90 €
Y0000718	LORAZEPAM IMPURITY D CRS	3	15 MG	1		1121	+5°C+/-3°C	A1A	90 €
Y0001076	LOSARTAN FOR SYSTEM SUITABILITY CRS	4	0.002 MG	1		2232	+5°C+/-3°C	A1A	90 €
Y0001072	LOSARTAN IMPURITY D CRS	4	10 MG	1		2232	+5°C+/-3°C	A1A	90 €
Y0001062	LOSARTAN POTASSIUM CRS	3	50 MG	1		2232	+5°C+/-3°C	A1A	90 €
L0790000	LOVASTATIN CRS	4	60 MG	1		1538	-20°C +/-5°C	C1A	90 €
Y0001136	LOVASTATIN FOR PEAK IDENTIFICATION CRS	1	20 MG	1		1538	-20°C +/-5°C	C1A	90 €
Y0001798	LOW-SUBSTITUTED HYDROXYPROPYLCELLULOSE CRS	2	50 MG	1		2083	+5°C+/-3°C	A1A	90 €
Y0001284	LUFENURON CRS	1	140 MG	1		2177	+5°C+/-3°C	A1A	90 €
Y0001261	LUFENURON FOR PEAK IDENTIFICATION CRS	1	0.4028 MG	1		2177	+5°C+/-3°C	A1A	90 €
Y0001265	LUFENURON IMPURITY G CRS	1	15 MG	1		2177	+5°C+/-3°C	A1A	90 €
L0800000	LYNESTRENOL CRS	2	50 MG	1		0558	+5°C+/-3°C	A1A	90 €
Y0001034	LYNESTRENOL FOR PEAK IDENTIFICATION CRS	1	20 MG	1		0558	+5°C+/-3°C	A1A	90 €
Y0000397	LYSINE ACETATE CRS	2	60 MG	1		2114	+5°C+/-3°C	A1A	90 €
L0900000	LYSINE HYDROCHLORIDE CRS	4	50 MG	1		0930, 1654	+5°C+/-3°C	A1A	90 €
Y0001904	LYSOPHOSPHATIDYLCHOLINE FROM EGG YOLK CRS	2	200 MG	1		2315	-20°C +/-5°C	C1A	90 €
Y0001952	LYSOPHOSPHATIDYLCHOLINE FROM SOYA BEAN CRS	2	200 MG	1		2316	-20°C +/-5°C	C1A	90 €



Last Updated On: September 27, 2026

USP Catalog

Catalog #	Status	Product Name	Product Type	Associated Drug Substance	Current Lot	Previous Lot (VUD)	CAS #	NDC #	Unit Price	Co. Of Origin	Material Origin	UN #	Net Weight	Unit Of Measure	Commodity Codes (HS Codes)*	Special Restriction	Pkg. Type	USMCA Eligible	KORUS Eligible	Base Control Drug	Base Control Drug %
1370269	Active	Loratadine Related Compound C (15 mg) (8-Chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one)	Reference Standard	Loratadine	R124D0	F1J365 (31-MAY-2022)	31251-41-9	N/A	\$863.00	IE	Chemical Synthesis		15	mg	2933998350		VIAL	No	No		
1370270	Active	Loratadine (200 mg)	Reference Standard	Loratadine	R125E0	R052U0 (30-APR-2021)	79794-75-5	N/A	\$474.00	IE	Chemical Synthesis	UN3077	200	mg	2933399065		VIAL	No	No		
1370280	Active	Loratadine Related Compound A (15 mg) (8-Chloro-5,6-dihydro-11-(piperidin-4-ylidene)-11H-benzo[5,6]cyclohepta[1,2-b]pyridine)	Reference Standard	Loratadine	R108Q0	R023T0 (30-APR-2021)	100643-71-8	N/A	\$855.00	IN	Chemical Synthesis		15	mg	2933399065		VIAL	No	No		
1370291	Active	Loratadine Related Compound B (15 mg) (8-Chloro-5,6-dihydro-11-(N-methylpiperidin-4-ylidene)-11H-benzo[5,6]cyclohepta[1,2-b]pyridine)	Reference Standard	Loratadine	R234B0	R08820 (31-AUG-2026)	38092-89-6	N/A	\$1,015.00	IN	Chemical Synthesis		15	mg	2933399065		VIAL	No	No		
1370305	Active	Lorazepam CIV (200 mg)	Reference Standard	Lorazepam	R114V0	J01304 (31-JAN-2021)	846-49-1	00216 28850 5	\$414.00	IT	Chemical Synthesis		200	mg	2933910000	Controlled	VIAL	No	No	LORAZEPAM	100
1370327	Active	Lorazepam Related Compound A (25 mg) (7-Chloro-5-(o-chlorophenyl)-1,3-dihydro-3-acetoxy-2H-1,4-benzodiazepin-2-one)	Reference Standard	Lorazepam	R141D0	R013M0 (30-NOV-2021)	2848-96-6	N/A	\$1,029.00	IN	Chemical Synthesis		25	mg	2933997500		VIAL	No	No		
1370338	Active	Lorazepam Related Compound B (25 mg) (2-Amino-2',5'-dichlorobenzophenone)	Reference Standard	Lorazepam	R226X0	R054Q0 (31-AUG-2025)	2958-36-3	N/A	\$838.00	CN	Chemical Synthesis		25	mg	2922390000		VIAL	No	No		
1370349	Active	Lorazepam Related Compound C (25 mg) (6-Chloro-4-(o-chlorophenyl)-2-quinazolinecarboxaldehyde)	Reference Standard	Lorazepam	R09830	R011F0 (31-MAR-2020)	93955-15-8	N/A	\$838.00	IN	Chemical Synthesis		25	mg	2933997500		VIAL	No	No		
1370350	Active	Lorazepam Related Compound D (25 mg) (6-Chloro-4-(o-chlorophenyl)-2-quinazolinecarboxylic Acid)	Reference Standard	Lorazepam	R084F0	J0L024 (31-DEC-2019)	54643-79-7	N/A	\$1,029.00	IN	Chemical Synthesis		25	mg	2933997500		VIAL	No	No		



PT MERSIFARMA TM,
DIVISI MANUFACTURING
SUKABUMI-INDONESIA

METODE PENGUJIAN BAHAN AWAL LORAZEPAM

Halaman 5 dari 6
Nomor Dokumen :
RD.02-MBA/068.01
Tanggal berlaku :
31 Agustus 2023

DEPARTEMEN
RESEARCH AND DEVELOPMENT

SEKSI
ANALYTICAL DEVELOPMENT

Disusun Oleh :

Diperiksa Oleh :

Ditetujui Oleh :

Inas Kanina

AD Staff

Tanggal : 07/08/23

Reza Aulia Gusli

AD Supervisor

Tanggal : 08/08/23

Rustam Wiraya

R&D Manager

Tanggal : 09/08/23

Selvi

QA Manager

Tanggal : 10/08/23

Pengganti No :

RD.02-MBA/068.00

Tanggal :

10 April 2023

2. Aliran pompa : 1.0 mL / menit
3. Panjang gelombang detektor : 230 nm
4. Volume penyuntikkan : 20 μ L
5. Suhu kolom : 11 $^{\circ}$ C
6. Suhu sampel : 11 $^{\circ}$ C
7. Pelarut : Methanol : Purified Water (75 : 25)
8. Fase gerak : Purified water : asam asetat glasial :
asetonitril (50 : 1.2 : 50)

Uji kesesuaian sistem

1. Suntikkan larutan standar ke dalam sistem HPLC sebanyak 5 kali.
2. Ukur respons dan hitung RSD dari hasil perhitungan alat.
Kriteria keberterimaan : RSD luas area $\leq$ 2.0%.
: RSD waktu retensi $\leq$ 2.0%.

Faktor Ikutan

Kriteria penerimaan : $\leq$ 2.0

Larutan standar

1. Timbang seksama 20.0 mg Lorazepam WS, masukkan ke dalam labu ukur 100 mL.
2. Tambahkan 25 mL pelarut, sonikasikan $\pm$ 10 menit.
3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
4. Pipet 1.0 mL larutan, masukkan ke dalam labu ukur 20 mL.
5. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
6. Saring menggunakan syringe filter 0.45 μ m.
7. Masukkan ke dalam vial HPLC.

Larutan sampel

1. Timbang seksama 20.0 mg sampel, masukkan ke dalam labu ukur 100 mL.
2. Tambahkan 25 mL pelarut, sonikasikan $\pm$ 10 menit.
3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
4. Pipet 1.0 mL larutan, masukkan ke dalam labu ukur 20 mL.
5. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
6. Saring menggunakan syringe filter 0.45 μ m.
7. Masukkan ke dalam vial HPLC.

Prosedur

Suntikkan secara terpisah larutan standar dan larutan uji ke dalam sistem HPLC, ukur respons puncak utama.



PT. MERSIFARMA TM
DIVISI MANUFACTURING
SUKABUMI - INDONESIA

METODE ANALISA PRODUK
LORAZEPAM 2 TABLET SALUT SELAPUT
PRODUCT ANALYSIS METHOD OF
LORAZEPAM 2 FILM COATED TABLET

Page 19 of 24
Document No. :
MPOJ/00065.00
Valid Date :
10 DEC 2024

DEPARTMENT
RESEARCH AND DEVELOPMENT

SECTION
ANALYTICAL DEVELOPMENT

Arranged By :

Checked By :

Approved By :

Soia Neriyan

AD act Supervisor

Date : 24/10/24

Reza Aulia Gusli

AD Manager

Date : 24/10/24

Rustam Wijaya

Head of R&D

Date : 25/10/24

Selvi

QA Manager

Date : 25/10/24

Replace No. :
RD.02-MOJ/052.01
Date :
January 27th 2023

13.4.1.3. Atur pH larutan hingga 5.0 ± 0.05 menggunakan Asam asetat glasial.

Adjust pH of solution until 5.0 ± 0.05 with Acetic Acid glacial.

13.4.1.4. Tambahkan purified water hingga 1000 mL, aduk sampai homogen.

Add purified water until 1000 mL, stir until homogeneous.

13.5. Uji kesesuaian sistem

System Suitability Test

13.5.1. Suntikkan larutan standar ke dalam sistem HPLC sebanyak 6 kali.

Inject the standard solution to the HPLC system for 6 times

13.5.2. Ukur respons dan hitung RSD dari hasil perhitungan alat.

Measure response and calculate RSD from tool calculation result.

Kriteria keberterimaan : RSD luas area $\leq 5.0\%$.

Acceptant Criteria : RSD area $\leq 5.0\%$.

: RSD waktu retensi $\leq 5.0\%$.

: RSD retention time $\leq 5.0\%$.

13.5.3. Faktor Ikutan

Tailing factor

Kriteria penerimaan : ≤ 2.0

Acceptant Criteria : ≤ 2.0

13.5.4. Resolusi

Resolution

Kriteria keberterimaan : ≥ 1.2 antara senyawa sejenis A lorazepam dan senyawa sejenis E lorazepam

Acceptant Criteria : ≥ 1.2 between related compound A Lorazepam and related compound E Lorazepam

13.6. Penetapan kadar cemaran organik

Determination of organic impurities assay

13.6.1. Pembuatan Larutan Identifikasi

Identification solution making

13.6.1.1. Larutan Senyawa Sejenis A, B, C, D, dan E Lorazepam.

Lorazepam Related Substance A, B, C, D, and E Solution

a. Timbang seksama masing-masing Senyawa Sejenis A, B, C, D, dan E Lorazepam WS sebanyak 3.2 mg, masukkan ke dalam labu ukur 50 mL.

Weigh accurately 3.2 mg each related substance A, B, C, D, E Lorazepam, put into 50 mL volumetric flask.

b. Tambahkan 25 mL pelarut, sonikasikan ± 10 menit.

Add 25 mL solvent, sonicate for ± 10 minutes.

c. Tambahkan pelarut sampai tanda batas, kocok sampai homogen.

Add solvent up to volume, shake until homogeneous.

C_s = concentration of USP Zolpidem Tartrate RS in the Standard solution (mg/mL)
 L = label claim (mg/Tablet)
 V = volume of Medium, 900 mL_A (USP 1-Aug-2020)

Tolerances: NLT 80% (Q) of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2.

Medium: 0.1 N hydrochloric acid VS; 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Standard solution: $(L/900)$ mg/mL of USP Zolpidem Tartrate RS in Medium, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

Mode: UV

Analytical wavelength: 295 nm

Blank: Medium

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the Sample solution

A_S = absorbance of the Standard solution

C_S = concentration of USP Zolpidem Tartrate RS in the Standard solution (mg/mL)

L = label claim (mg/Tablet)

V = volume of Medium, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ is dissolved.

Test 3: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 3.

Medium: 0.01 N hydrochloric acid TS; 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Standard solution: $(L/900)$ mg/mL of USP Zolpidem Tartrate RS in Medium, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Instrumental conditions

Mode: UV

Analytical wavelength: 295 nm

Blank: Medium

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the Sample solution

A_S = absorbance of the Standard solution

C_S = concentration of USP Zolpidem Tartrate RS in the Standard solution (mg/mL)

L = label claim (mg/Tablet)

V = volume of Medium, 900 mL

Tolerances: NLT 85% (Q) of the labeled amount of zolpidem tartrate $[(C_{19}H_{21}N_3O)_2 \cdot C_4H_6O_6]$ is dissolved.

• **UNIFORMITY OF DOSAGE UNITS** (905): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 3.3 mL/L of phosphoric acid in water, adjusted with triethylamine to a pH of 6.0

Solution B: Acetonitrile

Solution C: Methanol

Mobile phase: See Table 1.

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	76	14	10
35.0	48	16	36
36.5	48	16	36
37.5	76	14	10
42.0	76	14	10

Diluent: Solution B, Solution C, and Solution A (15:10:75)

System suitability solution: 0.5 mg/mL of USP Zolpidem Tartrate RS and 0.0008 mg/mL of USP Zolpidem Related Compound A RS in Diluent

Standard solution: 0.005 mg/mL of USP Zolpidem Tartrate RS in Diluent

Sample solution: Nominally equivalent to 0.5 mg/mL of zolpidem tartrate in Diluent from NLT 10 Tablets, prepared as follows. Transfer the Tablets to a suitable volumetric flask, add 70% of the flask volume of Diluent, and stir for 30 min. Dilute with Diluent to volume. Centrifuge a portion of the solution and use the clear supernatant.

Chromatographic system

(See Chromatography <621>, System Suitability.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm $\times$ 15-cm; 4- μ m packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

System suitability

Samples: System suitability solution and Standard solution

Suitability requirements

Resolution: NLT 2.0 between zolpidem and zolpidem related compound A, System suitability solution

Relative standard deviation: NMT 5.0%, Standard solution

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of each degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each degradation product from the Sample solution

r_S = peak response of zolpidem from the Standard solution

C_S = concentration of USP Zolpidem Tartrate RS in the Standard solution (mg/mL)

C_U = nominal concentration of zolpidem tartrate in the Sample solution (mg/mL)

F = relative response factor (see Table 2)

Acceptance criteria: See Table 2.