

Bagian : QC

Due Date : 28-Jul-26

ANALISA PERMINTAAN BARANG

Tanggal : 12-Jun-26

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	RGN00051	Ranitidine Related Compound C	mg	0	100	-100	0	100	0	0

Catatan :

Ranitidine Related Compound C, cat.no : 1598700 ex. USP (1 vial @50 mg)

- Digunakan Sebagai baku pembanding dalam larutan uji kesesuaian sistem pada prosedur penetapan kadar Ranitidine 150 Tablet dan Rancus 150 Tablet
- Digunakan Setiap kali analisa Ranitidine 150 Tablet dan Rancus 150 Tablet
- Pemesanan pertama kali Dept. QC

Latar Belakang :

- Sehubungan dengan adanya update Metode Pengujian Obat Jadi Ranitidine 150 Tablet dan Rancus 150 Tablet, serta telah berhasil dilakukan transfer metode. Oleh karena itu perlu dilakukan pengadaan Ranitidine Related Compound C untuk kebutuhan analisa rutin.
- RS sudah dilakukan validasi metode, tidak bisa diberikan alternatif karena harus validasi ulang.

Terlampir metode analisa, penawaran harga dan rencana kebutuhan.

Dibuat

 12/26
SRS/06

Mengetahui

 12/26
HUBO/06



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**PROTOKOL TRANSFER METODE ANALISA
PENETAPAN KADAR RANITIDINE DALAM
RANITIDINE 150 TABLET SALUT SELAPUT
SECARA KCKT
TRANSFER PROTOCOL FOR METHOD ANALYSIS
ASSAY OF RANITIDINE IN RANITIDINE 150 FILM
COATED TABLETS BY HPLC**

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No. Dokumen	: RD.02-PTP/088.00
Document Number	
Tanggal Dokumen Disetujui	:
Document Approved Date	
Menggantikan No.	: -
Replaces No.	

7.5.4.8. Syringe filter PTFE 0.45 μ m
PTFE syringe filter 0.45 μ m

7.5.4.9. Vial HPLC
HPLC vials

7.5.5. Bahan
Materials

7.5.5.1. *Ammonium Acetate*
Ex. Smartlab Cat. No. A-2001

7.5.5.2. *Methanol*
Ex. Thermo Fisher Cat. No. A452-4

7.5.5.3. *Ranitidine Related Compound C*
Ex. USP Cat. No. 1598700

7.5.5.4. *Ranitidine HCl Working Standard*

7.5.6. Pembuatan Larutan
Preparation of Solution

7.5.6.1. Pembuatan Larutan Amonium Asetat 0.1 M
Preparation of Ammonium Acetate 0.1 M Solution

- Timbang saksama 7.708 g Amonium asetat.
Weigh carefully 7.708 g of Ammonium Acetate.
- Masukkan ke dalam gelas ukur 1000 mL.
Put into 1000 mL beaker glass.
- Tambahkan 1000 mL air murni, kocok sampai homogen.
Add 1000 mL purified water, shake until homogenous.

7.5.6.2. Larutan Induk Senyawa Sejenis C Ranitidin (0.1 mg/mL)
Ranitidine Related Compound C Main Solution (0.1 mg/mL)

- Timbang saksama 5 mg Senyawa Sejenis C Ranitidine.
Weigh carefully 5 mg of Ranitidine Related Compound C.
- Masukkan ke dalam labu ukur 50 mL.
Put into 50 mL volumetric flask.
- Tambahkan pelarut sampa tanda batas, kocok sampai homogen.
Add solvent solution up to the limit mark, shake until homogenous.

7.5.6.3. Larutan Induk Standar (1.0 mg/mL)
Standard Main Solution (1.0 mg/mL)

- Timbang saksama 11.2 mg Ranitidine HCl WS setara dengan 10 mg Ranitidine ke dalam labu ukur 10 mL.
Weigh carefully 11.2 mg Ranitidine HCl WS equivalent to 10 mg Ranitidine, put into 10 mL volumetric flask.
- Tambahkan pelarut sampai tanda batas, sonikasikan selama 10 menit.
Add solvent up to the limit mark, sonicate 10 minutes.

7.5.6.4. Larutan Standar (0,1 mg/mL)
Standard Solution (0.1 mg/mL)

- Pipet 1.0 mL larutan induk standar, masukkan ke dalam labu ukur 10 mL.
Pipette 1.0 mL standard main solution, put into 10 mL volumetric flask.
- Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
Add solvent up to volume, shake until homogeneous.

Kebutuhan Senyawa Sejenis C Ranitidine

Description	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Grand Total
Rancus 150 Tablet	2	2	2	3	2	2	2	15

No	Nama Produk Jadi	Reagen	Proses	Kebutuhan (mg)	Total Batch	Total Kebutuhan
1	Rancus 150 Tablet	Ranitidine Related Compound C ex USP Cat No 1598700 CAS Number 73851-70-4	Penetapan Kadar	5	15	75
Total (mg)						75
Worstcase (+30%)						97,5

Oleh karena itu, dibutuhkan Ranitidine Related Compound C ex USP Cat No 1598700 CAS Number 73851-70-4 sebanyak 2 botol @ 50 mg. Kebutuhan tersebut dapat berubah sewaktu-waktu jika ada perubahan rencana produksi Rancus 150 TSS atau Ranitidine 150 TSS.



Last Updated On: June 7, 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 %
		carboxylic acid)																			
1598323	Active	Ramipril Related Compound B (20 mg) ((2S,3aS,6aS)-1-(((S)-1-Methoxy-1-oxo-4-phenylbutan-2-yl)-L-alanyl)octahydrocyclopenta[b]pyrrole-2-carboxylic acid)	Reference Standard	Ramipril	R172P0	F0F151 (31-MAY-2024)	295328-72-2	N/A	\$885.00	DE	Chemical Synthesis		20	mg	2933998350		VIAL	No	No		
1598336	Active	Ramipril Related Compound C (20 mg) ((2S,3aS,6aS)-1-(((S)-4-Cyclohexyl-1-ethoxy-1-oxobutan-2-yl)-L-alanyl)octahydrocyclopenta[b]pyrrole-2-carboxylic acid hydrochloride)	Reference Standard	Ramipril	R172H0	F0E157 (31-MAY-2024)	885516-61-0	N/A	\$880.00	DE	Chemical Synthesis		20	mg	2933999552		VIAL	No	No		
1598347	Active	Ramipril Related Compound D (20 mg) (Ethyl (S)-2-[(3S,5aS,8aS,9aS)-3-methyl-1,4-dioxodecahydro-2H-cyclopenta[4,5]pyrrolo[1,2-a]pyrazin-2-yl]-4-phenylbutanoate)	Reference Standard	Ramipril	R161B0	R002S0 (31-JAN-2024)	108731-95-9	N/A	\$838.00	DE	Chemical Synthesis		20	mg	2933998350		VIAL	No	No		
1598405	Active	Ranitidine Hydrochloride (200 mg)	Reference Standard	Ranitidine	R127X0	H1G103 (30-JUN-2022)	66357-59-3	N/A	\$297.00	ES	Chemical Synthesis		200	mg	2932190002		VIAL	No	No		
1598450	Active	Ranitidine Resolution Mixture (20 mg)	Reference Standard	Ranitidine	R135A0	R075B0 (28-FEB-2023)	N/A	N/A	\$1,705.00	IN	Chemical Synthesis		20	mg	3822190000		VIAL	No	No		
1598507	Active	Ranitidine Related Compound A (50 mg) (5-[[[2-Aminoethyl]thio]methyl]-N,N-dimethyl-2-furanmethanamine hemifumarate)	Reference Standard	Ranitidine	R06290	I0L576 (30-SEP-2018)	256948-32-0	N/A	\$903.00	IN	Chemical Synthesis		50	mg	2932190002		VIAL	No	No		
1598509	Active	Ranitidine Related Compound B (50 mg) (N,N'-bis[2-[[[5-[[dimethylamino]methyl]-2-furanyl]methyl]thio]ethyl]-2-nitro-1,1-ethenediamine)	Reference Standard	Ranitidine	G1D347	G (31-MAR-2006)	72126-78-4	N/A	\$863.00	US	Chemical Synthesis		50	mg	2932190002		VIAL	No	No		
1598700	Active	Ranitidine Related Compound C (50 mg) (N-[2-[[[5-	Reference Standard	Ranitidine	R04740	I2G232 (30-SEP-2017)	73851-70-4	N/A	\$855.00	IN	Chemical Synthesis		50	mg	2932190002		VIAL	No	No		