

**PROTOKOL TRANSFER METODE ANALISIS
PENETAPAN KADAR DAN CEMARAN BAHAN
BAKU TRIMETOPRIM
TRANSFER PROTOCOL ANALYTICAL
METHOD FOR ASSAY AND ORGANIC
IMPURITY OF TRIMETOPRIM RAW
MATERIALS**

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- 7.2.5. **Pembuatan Larutan Induk Trimetoprim (Konsentrasi 1 mg/ mL)**
Preparation of Trimetoprim main active solution (Concentration 1 mg/ mL)
- 7.2.5.1. Timbang seksama 25 mg Trimetoprim, masukkan ke dalam labu ukur 25 mL.
Weight 25 mg Trimethoprim, put into 25 mL volumetric flask.
- 7.2.5.2. Tambahkan 10 mL fase gerak, sonikasi 15 menit.
Add 10 mL mobile phase, sonicate 15 minutes.
- 7.2.5.3. Tambahkan fase gerak sampai tanda batas, kocok sampai homogen.
Add mobile phase up to volume, shake until homogenous.
- 7.2.6. **Pembuatan Larutan Induk Diaveridin (Konsentrasi 0.1 mg/ mL)**
Preparation of Diaveridin main active solution (Concentration 0.1 mg/ mL)
- 7.2.6.1. Timbang seksama 2.5 mg Diaveridin, masukkan ke dalam labu ukur 25 mL.
Weight 2.5 mg Diaveridin, put into 25 mL volumetric flask.
- 7.2.6.2. Tambahkan 2 mL DMSO, sonikasi 15 menit.
Add 2 mL DMSO, sonicate 15 minutes.
- 7.2.6.3. Tambahkan fase gerak sampai tanda batas, kocok sampai homogen.
Add mobile phase up to volume, shake until homogenous.
- 7.2.7. **Pembuatan Larutan Resolusi (Konsentrasi masing-masing 0.01 mg/ mL dan 0.005 mg/ mL)**
Preparation of resolution solution (Concentration 0.01 mg/ mL and 0.005 mg/mL)
- 7.2.7.1. Pipet 1 mL larutan induk Trimetoprim, masukkan ke dalam labu ukur 100 mL.
Pipette 1 mL Trimethoprim main active solution, put into 100 mL volumetric flask.
- 7.2.7.2. Pipet 5 mL larutan induk Diaveridin, masukkan ke dalam labu ukur 100 mL.
Pipette 5 mL Diaveridin main active solution, put into 100 mL volumetric flask.
- 7.2.7.3. Tambahkan fase gerak sampai tanda batas, kocok sampai homogen.
Add mobile phase up to volume, shake until homogenous.
- 7.2.7.4. Masukkan masing-masing konsentrasi ke dalam vial HPLC.
Put each concentration into HPLC vial.
- 7.2.8. **Larutan sampel [Triheksifenidil Hidroklorida 2 mg/mL]**
Sample solution [Trihexyphenidyl Hydrochloride 2 mg/mL]
- 7.2.8.1. Timbang seksama 25 mg Trimethoprim.
Weigh accurately 25 mg Trimethoprim.
- 7.2.8.2. Masukkan ke dalam labu ukur 25 mL.
Put into 25 mL volumetric flask.
- 7.2.8.3. Tambahkan 10 mL fase gerak, sonikasi 15 menit.
Add 10 mL mobile phase, sonicate 15 minutes.
- 7.2.8.4. Tambahkan fase gerak sampai tanda batas, kocok sampai homogen.
Add mobile phase up to the volume, shake until homogeneous.
- 7.2.8.5. Saring larutan menggunakan syringe filter PTFE 0.45 µm.
Filter the solution using PTFE 0.45 µm syringe filter.
- 7.2.8.6. Masukkan ke dalam vial HPLC.
Put into HPLC vial.
- 7.2.9. **Prosedur**
Procedure
- Suntikkan secara terpisah larutan resolusi dan larutan sampel ke dalam sistem HPLC, ukur respons puncak utama dengan urutan sebagai berikut :
- Separately inject resolution solution and sample solution into the HPLC system, determine the main peak response with the following order :*



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 of Drug %
1181506	Active	Diacetylated Monoglycerides (200 mg)	Reference Standard		R209F0	R024D1 (31-JUL-2024)	8029-92-3	N/A	\$337.00	MY	Plant		200	mg	2915900090		AMPUL E	No	No		
1182000	Active	Diacetylfluorescein (200 mg)	Reference Standard	Fluorescein	R197G0	I0L140 (29-FEB-2024)	596-09-8	N/A	\$265.00	IN	Chemical Synthesis		200	mg	2932992100		VIAL	No	No		
1184005	Active	Diatrizoic Acid (100 mg)	Reference Standard	Diatrizoic Acid	R070E0	H0E084 (31-MAY-2018)	50978-11-5	N/A	\$257.00	ES	Chemical Synthesis		100	mg	2924296000		VIAL	No	No		
1184027	Active	Diatrizoic Acid Related Compound A (50 mg) (5-Acetamido-3-amino-2,4,6-triodobenzoic Acid)	Reference Standard	Diatrizoic Acid	R186C0	J0J206 (31-MAR-2025)	1713-07-1	N/A	\$838.00	CN	Chemical Synthesis		50	mg	2924296000		VIAL	No	No		
1184118	Active	Diaverdine (25 mg) (5-(3,4-Dimethoxybenzyl)pyrrolidine-2,4-diamine)	Reference Standard	Sulfamethoxazole	F03831	F03830 (31-MAR-2021)	5355-16-8	N/A	\$323.00	CN	Chemical Synthesis		25	mg	2933599550		VIAL	No	No		
1185008	Active	Diazepam CIV (100 mg)	Reference Standard	Diazepam	R138G0	R079N0 (31-MAY-2022)	439-14-5	00216 04040 3	\$414.00	IT	Chemical Synthesis	UN2811	100	mg	2933910000	Controlled	VIAL	No	No	DIAZEPAM	100
1185020	Active	Diazepam Related Compound A (25 mg) (2-methylamino-5-chlorobenzophenone)	Reference Standard	Diazepam	R164J0	R083U0 (31-AUG-2024)	1022-13-5	N/A	\$903.00	CN	Chemical Synthesis		25	mg	2922390000		VIAL	No	No		
1185063	Active	Diazepam Related Compound E (25 mg) (6-Chloro-1-methyl-4-phenylquinazolin-2(1H)-one)	Reference Standard	Diazepam	F114A0		20927-53-1	N/A	\$903.00	IN	Chemical Synthesis		25	mg	2933998350		VIAL	No	No		
1186000	Active	Diazoxide (200 mg)	Reference Standard	Diazoxide	R155T0	H0F314 (30-SEP-2022)	364-98-7	N/A	\$275.00	IT	Chemical Synthesis		200	mg	2934990005		VIAL	No	No		
1187003	Active	Dibucaine Hydrochloride (500 mg)	Reference Standard	Dibucaine	R150U0	J0I022 (31-JAN-2023)	61-12-1	N/A	\$297.00	FR	Chemical Synthesis	UN2811	500	mg	2933492250		VIAL	No	No		
1187080	Active	Dibutyl Phthalate (200 mg)	Reference Standard		R240H0	R127E0 (28-FEB-2026)	84-74-2	N/A	\$289.00	US	Chemical Synthesis	UN3082	200	mg	2917340110		AMPUL E	No	No		
1187091	Active	Dibutyl Sebacate (1 mL)	Reference Standard		R116S0	R03810 (31-AUG-2021)	109-43-3	N/A	\$301.00	FR	Plant - Synthetic		1	mL	2917130000		AMPUL E	No	No		
1187229	Active	Dichloroaniline (15 mg) (3,4-Dichloroaniline)	Reference Standard	Dichloroaniline	F181J0		95-76-1	N/A	\$630.00	CA	Chemical Synthesis	UN3442	15	mg	2921420000		VIAL	No	No		

Kebutuhan RS Diaveridin

No	Description	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Grand Total
1	Trimetoprim	-	-	-	-	1	-	-	1

No	Nama Bahan Baku	RS	Proses	Kebutuhan (mg)	Batch 2026	Total Kebutuhan
1	Trimetoprim	Diaveridin ex USP Cat No 1184118	Cemaran Organik	2,5	1	2,5
Total (mL)						2,5
Worstcase (+30%)						3,25

Oleh karena itu, dibutuhkan Diaveridin ex USP Cat No 1184118 sebanyak 1 vial @ 25 mg

Jumlah pemesanan dapat bertambah jika terdapat perubahan rencana kedatangan bahan baku/ada transfer metode yang menggunakan RS tersebut