

503A Compliance Assessment

Russell Fortney

Acting Branch Chief

Compounding & Pharmacy Practices Branch

Office of Unapproved Drugs and Labeling Compliance



Section 503A - Exemptions

- 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring:
 - FDA approval prior to marketing (section 505)
 - Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); and
 - Labeling with adequate directions for use (section 502(f)(1))
- Pharmacies that qualify for the exemptions are still subject to other Federal requirements, including those regarding preparing, packing or holding drug products under insanitary conditions



Section 503A - Conditions

- Conditions that must be met for compounded drug products to qualify for the exemptions under section 503A include:
 - Receipt of valid prescriptions for individually-identified patients
 - Bulk drug substances (active ingredients) used in compounding must:
 - Comply with applicable monograph standards;
 - Be components of approved drugs; or
 - Be on a list of bulk drugs developed by FDA of bulk drug substances acceptable for compounding



Evidence Review

- Prescription log
- Individual prescriptions
- Batch records



Prescription Log

LOG OF SCRIPTS COMBINED PRESCRIPTIONS Schedule: ALL

1 line report

Printed 3/16/2016

Page 1 Prescriptions filled between 12/10/2015 and 3/16/2016

Las Vegas, NV 89102 Ph. (702)220-6073

NCPDP #2907080

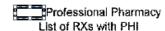
BM8598899

Sorted by: Fill date

Rx number	Date disp.	Date written	Patient	Qty and Drug	Doctor	Pharmacist Initials R		n Total	Тах	Cost	% profit
00135077	12/10/2015	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%,		MC	0	0 \$2,138.50	\$0.00	\$61.66	97.12%
00135078		11/20/2015		240 FBD FLURBIP, 20%, BACLOFEN 5%, DMS 2%, MEI		MC	0	0 \$2,310.49	\$0.00	\$34.70	98.50%
00135079	,	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%,		MC	0	0 \$2,138.50	\$0.00	\$ 61.66	97.12%
00135080	12/10/2015			240 FBD FLURBIP, 20%, BACLOFEN 5%, DMS 2%, MEI		MC	0	0 \$2,310.49	\$0.00	\$34.70	98.50%
00135081	12/10/2015	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%, *		MC	0	0 \$2,138.50	\$0.00	\$61,66	97.12%
00135082	12/10/2015	11/20/2015		240 FBD FLURBIP. 20%, BACLOFEN 5%, DMS 2%, MEI		MC	0	0 \$2,310.49	\$0.00	\$34.70	98.50%
00135083	12/10/2015	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%,		MC	0	0 \$2,138.50	\$0.00	\$61.66	97.12%
00135084	12/10/2015	11/20/2015		240 FBD FLURBIP. 20%, BACLOFEN 5%, DMS 2%, MEI		MC	0	0 \$2,310.49	\$0.00	\$34.70	98,50%
00135085	12/10/2015	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%,		MC	0	0 \$2,138.50	\$0.00	\$61.66	97.12%
00135086	12/10/2015	11/20/2015		240 FBD FLURBIP. 20%, BACLOFEN 5%, DMS 2%, MEI		MC	0	0 \$2,310.49	\$0.00	\$34.70	98.50%
00135087	12/10/2015	11/20/2015		240 GCB GABAPENTIN 10%, CYCLOBENZAPRINE 6%,		MC	0	0 \$2,138.50	\$0.00	\$61.66	97.12%



Prescription Log



Rx number	Date disp.	Patient Qt	Prug	Doctor	
0199741	10/14/2015		TRI-MIX PAPAV/PHENTO/ALPROS 30MG-1MG-20MCG/ML INJECTABLE		
0194747	10/14/2015		TRI-MIX PAPAV/PHENTO/ALPROS 30MG-1MG-20MCG/ML INJECTABLE		
0201706	10/14/2015		METHYLCOBALAMIN (PF) 0.05 ML (SHORT) 25 MG/ML INJECTABLE		
0194248	10/14/2015	10	METHYLCOBALAMIN (PF) 0.3ML 25 MG/ML INJECTABLE		AMES
C0198992	10/14/2015	14	DHEA/TESTOSTERONE (SYR) 20MG/0.4MG PER GM CREAM		
0198993	10/14/2015	10	BI-ESTROGEN (80:20) (SYRINGE) 2.0MG/GM CREAM		
C0200146	10/14/2015	16	BUPRENORPHINE VET 0.3 MG PER ML SUSPENSION		
0201709	10/14/2015	10	METHYLCOBALAMIN (PF) 0,4ML 25 MG/ML INJECTABLE		
0198439	10/14/2015	12	METHYLCOBALAMIN (PF) 0,3ML 25 MG/ML INJECTABLE		
0197186	10/14/2015		METHYLCOBALAMIN (PF) 0.3ML (SHORT) 25 MG/ML INJECTABLE		AMES
0201357	10/14/2015		HYDROXOCOBALAMIN (PF) (SYRINGES PREFILLED 0.2ML) (SHORT) 10MG/ML INJECTA	<u>.</u>	
0201662	10/14/2015	12	METHYLCOBALAMIN (PF) 0,08 ML (SHORT) 25 MG/ML INJECTABLE		AMES
0190678	10/14/2015	1:	HYALURONIC ACID SOD 5MG SUPPOSITORY	j	
C0195859	10/14/2015	1	ESTRIOL/TESTOSTERONE VAGINAL 2MG/2MG PER GM CREAM		
0197115	10/14/2015		PROGESTERONE 50 MG/ 2CC GEL		
0199080	10/14/2015	1!	METHYLCOBALAMIN (PF) 0.03 ML (SHORT) 25 MG/ML INJECTABLE		
0201704	10/14/2015	18	NIPPLE FORMULA 1% 0.05% 2% OINTMENT		
C0201705	10/14/2015	1:	TRAMADOL (VET) 25 MG/ML SUSPENSION	_	
0201684	10/14/2015	2	BI-ESTROGEN (50/50) (SYRINGE) 0.4 MG / ML CREAM		
0100904	AMANDASE	. 2	BODIC ACIO MACINAL SONAC SUIDBOSTORY		

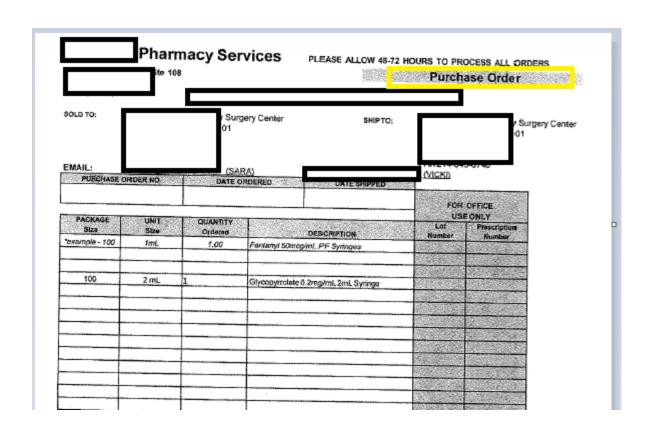


Prescription Log

	COMPOUND DISPENSING LOG									
Pathis	COMPOUND NAME & STRENGTH ORTACIONS TO JOYNA INTO THE COMPOUND NAME & STRENGTH ORTACIONS TO JOYNA INTO ORTACIONS TO JOYNA INTO ORTACIONA ORTACIO	1774788 1774788 1774788 1774887 1774887 1774887 1774887 1774880 1774880 1774880 1774880 1774880 1774880 17747884 17747884	PATIENT NAME STATIS CALVIA CAL	TY DISP		LOT# DISPENSED (29150) (29150) (29150) (29150) (29150) (29150) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151) (29151)	PRICE OF SUPPLY SOLD TO			

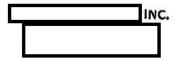


Individual Prescriptions





Individual Prescriptions



April 10, 2017 David C. M.D.

See attached patient information.

Please include 3 vials for emergency use.

Mitomycin 0. 5mg/mi; 1 ml vial. Use as directed for patients listed above.



Individual Prescriptions



	A COMI	OUNDING PE	ARMACY	1. THEOREM CO.	
Date: 4113/14	unun militario				
Name:	36532	1	Birth Da	11/10/47	
City:		Stat	ie:	Zip:	
Telephone #	layı	Cell e-mail:	4		
Biest (5:5) _ Estriol (E3)		Progesterone _ Thyroid Armou Nature-Throid DHEA	u	Testosterone	
Estradiol (E	4)	UnitA		INGILI CAUTIC	
DOSAGE FORM:	Troche	Sub	lingual Drops	Vaginal Cream	
	Cream	Sup	positories	Capsules	
How Many: 1/4 ml (6 drops)	1/4 1/ 1/2 ml (12 drops)	2 1 1 click (1/4 gm	ż		
When:	QAM QHS	QD BID	TID		
Qty: 2000	Refills: _				
Other Medication:			àlucon	ate 1% (100	
Sig:	for.	eize es	cposure	to hydrafly	eric acid
Qty:	Remis:	A8	ent:	-/	
Dr:	1	1D Ph	armacist:		



Batch Record

3/10/2016 9:49:29 AM Page 1 MAGNESIUM GLYCINATE (37	7.5 MG ELEMENTAL) 250 MG	CAPSULE LOXO			
Tall Man:					
Flavor: Description:			Schedule: L UI	FP Active	
Quantity made: 200 EAC	CH Batch yie Qty remainir	eld: 200.000	Route of admin: ORA		32
Date made: 3/10/2016 Lot number: 03102016 Beyond use date: September	6 6@17	Pricing of Estimated	calculations from the	e log	
Pharmacist: Technician: NDC1: 51927286 Packaging: AMBER (5100		Tim	e to make: 0	
Equipment: Labeling: ROOM TI	V			Y	
Stability information: Ingredients	Sch.	Quantity used	QS_(Balance)		
MAGNESIUM GLYCINATE (15' Lot #: 123679/C Chemical Code: U Purity: Balance: Tare: Result 0.000 a	% FLEMENTAL MAGNESI L Mfg: MEDISCA Volume: Potency:	50 GM Exp. date: 3/31/2017 QS amount:	50.007 g Whisr: MEDISCA	AWP: \$33.25	50
Description of the control of the co	1010 T g	Bar code NDC:	checked Each EACH contai 38779248909	ins 0.25 GM or 25% ChemInvID: 10258	1
LOXORAL POWDER Lot #: 6762509	Mfg: PCCA	33.7 GM Exp. date: 11/10/201	33.790 g Whisr: PCCA		
Chemical Code: U	Volume: Potency:	QS amount:		AWP: \$145.25	
Purity:	Volume: Potency:		/_	ins 0.169 GM or 16.9%	
Purity: Balance: Tare: Result: 0.000 g Percent off: 0%, Result: 33.700 g CAPSULES, #1/CLEAR CAP/Cl Lot #: 1511040001	LEAR BODY GELATIN - Mfg: FREEDOM	Bar code NDC: 9 200 EA Exp. date: 9/28/2020	checked A Each EACH contail	ns 0.169 GM or 16.9% ChemlnvID: 11161	
Purity: Balance: Tare: Result: 0.000 g Percent off: 0%, Result: 33.700 g CAPSULES, #1/CLEAR CAP/CI	LEAR BODY GELATIN -	Bar code NDC: 200 EA Exp. date: 9/28/2020 QS amount:	checked A Each EACH contail	ns 0.169 GM or 16.9% CheminviD: 11161	

Batch Record



12	ormula Worksheet (standard) 2/11/2009 8:49:55 AM age 1					
F	HORIONIC GONADOTROPIN, PREMIX 10,00 chorionic gonadotropin, premix lavor: Quantity made: 150 VIAL Date made:// Lot number://	Class:	ANTI-AGING Dispensing pack	size:	INJECTION Idule: L. Active Formula ID: 77362	
	Beyond use date://_Time:: Pharmacist: Technician: Description: Equipment: Packaging: Labeling:	Initials:		IDC1:		
ing	CHORIONIC GONADOTROPHIN (HUMAN) POWDER Mfg: Lot #: Checked: Name or Initials: (Each VIAL contains 1E4 UNIT or 1E6%) Ing. note:	Schedule 0 L	1500000 UNIT Exp. date:	QS (Actual	Nopt Whisr:	
2	MANNITOL USP POWDER POWDER 0 Mfg: Lot #: Checked:		12 GM Exp. date:		- Whisr:	
3	WATER FOR INJECTION 1000ML'S LIQUID 0 Mfg: Lot #; Checked: Name or Initials: (Each VIAL contains 2 ML or 200%) Ing. note:		300 ML Exp. date:	×	- Whisr:	
	09/30/2009	(Added all	GM & GMS: 12.00) Time to mak			
De:	vices		Quantity	Ont		



Questions?