

# 503A Compliance Assessment

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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



<b>LOG OF SCRIPTS</b> COMBINED PRESCRIPTIONS Schedule: ALL 1 line report Printed 3/16/2016 Page 1 <b>Prescriptions filled between 12/10/2015 and 3/16/2016</b>	<div style="border: 1px solid black; width: 150px; height: 20px; margin: 0 auto;"></div> Las Vegas, NV 89102 Ph. (702)220-6073  NCPDP #2907080     BM8598899
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Sorted by: Fill date

Rx number	Date disp.	Date written	Patient	Qty and Drug	Doctor	Pharmacist Initials Re/Rm	Total	Tax	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	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%
00135079	12/10/2015	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	11/20/2015		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

 Professional Pharmacy  
List of RXs with PHI

Rx number	Date disp.	Patient	Qty	Drug	Doctor	
0199741	10/14/2015		6	TRI-MIX PAPA/PHENTO/ALPROS 30MG-1MG-20MCG/ML INJECTABLE		
0194747	10/14/2015		6	TRI-MIX PAPA/PHENTO/ALPROS 30MG-1MG-20MCG/ML INJECTABLE		
0201708	10/14/2015		8	METHYLCOBALAMIN (PF) 0.05 ML (SHORT) 25 MG/ML INJECTABLE		
0194248	10/14/2015		10	METHYLCOBALAMIN (PF) 0.3ML 25 MG/ML INJECTABLE		AMES
C0198892	10/14/2015		10	DHEA/TESTOSTERONE (SYR) 20MG/0.4MG PER GM CREAM		
0198893	10/14/2015		10	BI-ESTROGEN (80:20) (SYRINGE) 2.0MG/GM CREAM		
C0200146	10/14/2015		10	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		
0197188	10/14/2015		12	METHYLCOBALAMIN (PF) 0.3ML (SHORT) 25 MG/ML INJECTABLE		AMES
0201357	10/14/2015		12	HYDROXOCOBALAMIN (PF) (SYRINGES PREFILLED 0.2ML) (SHORT) 10MG/ML INJECTABLE		
0201662	10/14/2015		12	METHYLCOBALAMIN (PF) 0.06 ML (SHORT) 25 MG/ML INJECTABLE		AMES
0190878	10/14/2015		12	HYALURONIC ACID SOD 5MG SUPPOSITORY		
C0195859	10/14/2015		15	ESTRIOL/TESTOSTERONE VAGINAL 2MG/2MG PER GM CREAM		
0197115	10/14/2015		15	PROGESTERONE 50 MG/ 2CC GEL		
0199080	10/14/2015		15	METHYLCOBALAMIN (PF) 0.03 ML (SHORT) 25 MG/ML INJECTABLE		
0201704	10/14/2015		15	NIPPLE FORMULA 1% 0.05% 2% OINTMENT		
C0201705	10/14/2015		15	TRAMADOL (VET) 25 MG/ML SUSPENSION		
0201884	10/14/2015		20	BI-ESTROGEN (50/50) (SYRINGE) 0.4 MG / ML CREAM		
0190884	10/14/2015		22	BASIC ACID VAGINAL 600MG SUPPOSITORY		

# Prescription Log

COMPOUND DISPENSING LOG							
DATE	COMPOUND NAME & STRENGTH	RX#	PATIENT NAME	QTY DISP	DOCTOR NAME	LOT# DISPENSED	PRICE
12/31/15	Depacote 20mg/ml	1774782	[Redacted]	21	[Redacted]	123115B	00
	Phenytoin 100 mg/ml	1774783	[Redacted]	21	[Redacted]	123115B	00
	Valproic acid 500	1774785	[Redacted]	20	[Redacted]	123115B	SC
	Phenytoin 300	1774787	[Redacted]	30	[Redacted]	123115B	2.02
	Phenytoin 300	1774840	[Redacted]	108	[Redacted]	123115B	11.5
	Phenytoin 300	1774637	[Redacted]	30	[Redacted]	123115B	70
	Phenytoin 300	1775051	[Redacted]	15	[Redacted]	100815K	82.50
	Phenytoin 300	1774917	[Redacted]	12	[Redacted]	100815K	0
	Phenytoin 300	1774214	[Redacted]	5	[Redacted]	100815K	0
	Phenytoin 300	1774784	[Redacted]	5	[Redacted]	123115H	SC
	Phenytoin 300	1774784	[Redacted]	5	[Redacted]	123115H	SC
	Phenytoin 250	1774850	[Redacted]	30	[Redacted]	123115H	0
	Phenytoin 150	1775051	[Redacted]	0	[Redacted]	042315E	60
	Phenytoin 400mg/ml	1774784	[Redacted]	90	[Redacted]	102815F	75
	Phenytoin 1mg/ml	1774784	[Redacted]	200	[Redacted]	123115T	0
	Phenytoin 0.05/500	1774784	[Redacted]	100	[Redacted]	123115K	75
	Phenytoin 500	1776550	[Redacted]	60	[Redacted]	123115J	10
	Phenytoin 50		[Redacted]	30	[Redacted]	031315B	

# Individual Prescriptions

**[Redacted] Pharmacy Services** PLEASE ALLOW 48-72 HOURS TO PROCESS ALL ORDERS  
 [Redacted] Ste 108 [Redacted] **Purchase Order**

SOLD TO: [Redacted] Surgery Center 01 SHIPTO: [Redacted] Surgery Center 01

EMAIL: [Redacted] (SARA) [Redacted] (VICKI)

PURCHASE ORDER NO.		DATE ORDERED		DATE SHIPPED		FOR OFFICE USE ONLY	
PACKAGE Size	UNIT Size	QUANTITY Ordered	DESCRIPTION			Lot Number	Prescription Number
Example - 100	1mL	1.00	Fentanyl 50mcg/mL PF Syringes				
100	2 mL	1	Glycopyrrolate 0.2mg/mL 2mL Syringe				



# Individual Prescriptions

[Redacted] INC.  
[Redacted]

April 10, 2017  
David C. [Redacted] M.D.  
[Redacted]

**See attached patient information.**

**Please include 3 vials for emergency use.**

Mitomycin 0.5mg/ml; 1 ml vial. Use as directed for patients listed above.

*David C. [Redacted]*  
David C. [Redacted] M.D.

# Individual Prescriptions



Date: 4/13/16

Name:  Birth Date: 11/10/67

Address:  \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone # \_\_\_\_\_ Cell # \_\_\_\_\_

Best way to contact during the day: \_\_\_\_\_ e-mail: \_\_\_\_\_

DRUG:	Biest (8:2) _____	Progesterone _____	Testosterone _____
	Biest (5:5) _____	Thyroid Armour _____	
	Estriol (E3) _____	Nature-Throid _____	
	Estradiol (E2) _____	DHEA _____	Naltrexone _____

DOSAGE FORM:	Troche _____	Sublingual Drops _____	Vaginal Cream _____
	Cream _____	Suppositories _____	Capsules _____

How Many:	1/4	1/2	1	2
1/4 ml (6 drops)	1/2 ml (12 drops)	1 click (1/4 gm)		

When:	QAM	QHS	QD	BID	TID
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Qty: 2000 Refills: 0

Other Medication: Calcium Gluconate 1% (10mg/ml) NS inject

Sig: For eye exposure to hydrofluoric acid  
irrigate eyes

Qty: \_\_\_\_\_ Refills: \_\_\_\_\_ Agent: \_\_\_\_\_

Dr:  MD Pharmacist: \_\_\_\_\_

# Batch Record

Logged Formula Worksheet (standard)

3/10/2016 9:49:29 AM

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**MAGNESIUM GLYCINATE (37.5 MG ELEMENTAL) 250 MG CAPSULE LOXO**

Tall Man:

Flavor:  
Description:

Quantity made: 200 EACH

Batch yield: 200.000  
Qty remaining: 200.000

Schedule: L UFP

Active

Formula ID: 31532

Route of admin: ORAL

Date made: 3/10/2016  
Lot number: 03102016@17  
Beyond use date: September 6, 2016

9:43 AM

180 days after compounding date

Pharmacist: [Redacted]  
Technician: [Redacted]  
NDC1: 51927286100  
Packaging: AMBER CONTAINER  
Equipment:

**Pricing calculations from the log**  
Estimated price \$185.20 as of 3/4/2014  
  
Time to make: 0

Labeling: ROOM TEMPERATURE

**Stability information:**

Ingredients	Sch.	Quantity used	QS (Balance)
1 MAGNESIUM GLYCINATE (15% ELEMENTAL MAGNESI L Lot #: 123679/C Mfg: MEDISCA Chemical Code: U Volume: Potency: Purity: Balance: Tare: Result: 0.000 g Percent off: 0.00% Result: 33.700 g		50 GM Exp. date: 3/31/2017 QS amount:	<input type="checkbox"/> 50.007 g Whlsr: MEDISCA AWP: \$33.25 Bar code checked: <input checked="" type="checkbox"/> Each EACH contains 0.25 GM or 25% NDC: 38779248909 ChemInVd: 10258
3 LOXORAL POWDER Lot #: 6762509 Mfg: PCCA Chemical Code: U Volume: Potency: Purity: Balance: Tare: Result: 0.000 g Percent off: 0% Result: 33.700 g	L	33.7 GM Exp. date: 11/10/2017 QS amount:	<input type="checkbox"/> 33.700 g Whlsr: PCCA AWP: \$145.25 Bar code checked: <input checked="" type="checkbox"/> Each EACH contains 0.169 GM or 16.9% NDC: 51927477400 ChemInVd: 11161
4 CAPSULES, #1 CLEAR CAP/CLEAR BODY GELATIN Lot #: 151104001 Mfg: FREEDOM Chemical Code: U Volume: Potency: Purity: Balance:	-	200 EA Exp. date: 9/28/2020 QS amount:	<input type="checkbox"/> 200 EA Whlsr: LETCO AWP: \$20.00 Bar code checked: <input checked="" type="checkbox"/> Each EACH contains 1 EA or 100% NDC: 61991403305 ChemInVd: 11066

(Added all GM & GMS: 83.70 All ML: 0.00)

Log Instructions & Notes

$83.70 \div 2 = 41.85$



# Batch Record

**Formula Worksheet** (standard)   
 12/11/2009 8:49:55 AM  
 Page 1

**CHORIONIC GONADOTROPIN, PREMIX 10,000IU/ML(2ML) SOLUTION**  
CHORIONIC GONADOTROPIN, PREMIX

Flavor:  Schedule: L INJECTION Active   
 Class: ANTI-AGING Formula ID: 77362

Quantity made: 150 VIAL  
 Date made: \_\_\_/\_\_\_/\_\_\_  
 Lot number: \_\_\_\_\_ Dispensing pack size: \_\_\_\_\_  
 Beyond use date: \_\_\_/\_\_\_/\_\_\_ Time: \_\_\_:\_\_\_ Days to exp. 210 NDC1: \_\_\_\_\_  
 Pharmacist: \_\_\_\_\_ Initials: \_\_\_\_\_  
 Technician: \_\_\_\_\_ Initials: \_\_\_\_\_  
 Description: \_\_\_\_\_  
 Equipment: \_\_\_\_\_

Packaging: \_\_\_\_\_  
 Labeling: \_\_\_\_\_

Ingredients & Notes	Schedule	Quantity used	QS (Actual)	Opt.
1 CHORIONIC GONADOTROPHIN (HUMAN) POWDER 0 Mfg: _____ Lot #: _____ Checked: <input type="checkbox"/> Name or Initials: _____ (Each VIAL contains 1E4 UNIT or 1E6%) Ing. note: _____	L	1500000 UNIT	<input type="checkbox"/>	<input type="checkbox"/> Whlsr: _____
2 MANNITOL USP POWDER POWDER 0 Mfg: _____ Lot #: _____ Checked: <input type="checkbox"/> Name or Initials: _____ (Each VIAL contains 0.08 GM or 8%) Ing. note: _____		12 GM	<input type="checkbox"/>	<input type="checkbox"/> Whlsr: _____
3 WATER FOR INJECTION 1000ML'S LIQUID 0 Mfg: _____ Lot #: _____ Checked: <input type="checkbox"/> Name or Initials: _____ (Each VIAL contains 2 ML or 200%) Ing. note: _____	L	300 ML	<input checked="" type="checkbox"/>	<input type="checkbox"/> Whlsr: _____

09/30/2009 (Added all GM & GMS: 12.00) Time to make: \_\_\_\_\_

Devices	Quantity	Opt

# Questions?