

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/17/2017-10/27/2017* FEI NUMBER 3004599113
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Joseph E Grasela, Owner / President

FIRM NAME University Rx Specialists Inc	STREET ADDRESS 1875 3rd Ave
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92101-2604	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:  
OBSERVATION 1**

Non-depyrogenated equipment was used in sterile drug production.

Specifically,

your firm does not depyrogenate the (b) (4) that come into direct product contact during mixing of drug components in the ISO 8 Ante-Room 2. On 10/19/2017, we observed your technician using these (b) (4) in the production of the following products:

Drug product	Quantity	Lot #	BUD
Bi-Mix(Phentolamine/Papaverine) 2mg-30mg/MI Inj	(b) (4)	762803	1/26/2018
Bi-Mix(Phentolamine/Papaverine) 2mg-30mg/MI Inj	(b) (4)	762818	1/26/2018
Bi-Mix(Phentolamine/Papaverine) 2mg-30mg/MI Inj	(b) (4)	762823	1/26/2018
Bi-Mix(Phentolamine/Papaverine) 2mg-30mg/MI Inj	(b) (4)	762806	1/26/2018

**\*DATES OF INSPECTION**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator Theresa Kirkham, Generic Drug User Fee Amendments (GDUFA) Santiago Gallardo Johnson, Investigator	<p align="center">Rumany C Penn Investigator Signed By: 2001149000 Date Signed: 10-27-2017 12:25:24</p> <p align="center">X</p>	DATE ISSUED 10/27/2017
---------------------------------	---	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/17/2017-10/27/2017*
	FEI NUMBER 3004599113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Joseph E Grasela, Owner / President

FIRM NAME University Rx Specialists Inc	STREET ADDRESS 1875 3rd Ave
--	--------------------------------

CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92101-2604	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
--	---

10/17/2017(Tue), 10/18/2017(Wed), 10/19/2017(Thu), 10/20/2017(Fri), 10/23/2017(Mon),  
10/24/2017(Tue), 10/25/2017(Wed), 10/26/2017(Thu), 10/27/2017(Fri)

X Theresa Kirkham  
Generic Drug User Fee Amendments (GDUFA)  
Signed By: Theresa Kirkham -S  
Date Signed: 10/27/2017 12:29:01

X Santiago  
Gallardo  
Johnson -S  
Digitally signed by Santiago  
Gallardo Johnson -S  
DN: cn=Santiago Gallardo Johnson,  
ou=FDA, ou=CDER, ou=CDER,  
c=US, email=Santiago.GallardoJohnson@FDA.HHS.gov,  
serial=1027, date=2017.10.27 12:27:08 -0700

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator Theresa Kirkham, Generic Drug User Fee Amendments (GDUFA) Santiago Gallardo Johnson, Investigator	<p align="center">Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 10/27/2017 12:25:24</p> <p align="center">X</p>	DATE ISSUED 10/27/2017