

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration Los Angeles District Office 19701 Fairchild, (949) 608-2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/26/2018 - 04/03/2018
	FEI NUMBER 3005256616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Justin Y. Chen, Owner

FIRM NAME Chen Shwezin DBA Park Compounding Pharmacy	STREET ADDRESS 4333 Park Terrace Drive, #160
CITY, STATE AND ZIP CODE Westlake Village, CA 91361	TYPE OF ESTABLISHMENT INSPECTED producer of non-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 (I) (WE) OBSERVED:

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm conducted potency testing on three finished drug products during the previous eight months which were supposed to represent all distributed products and dosage forms. Product selection did not consider factors such as difficulty to produce or the relative amount of active ingredient. Examples of drug products distributed without adequate assurance they met their labeled strength claims include:

- Lidocaine + Tetracaine 23+7% cream, 60 mL, lot 02072018@12
- Diclofenac suppository, 100 mg, lot 01042018@13
- Trichloroacetic Acid 35% solution, 60 mL, lot 03142018@16
- Cantharidin Plus liquid, 100 mg/10 mL, lot 01192018@13
- Benzocaine + Lidocaine + Tetracaine 20+8+4% Lipoderm, 30 gm, lot 03132010@32

OBSERVATION 2

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, there were no written cleaning, sanitization, or maintenance procedures. I observed equipment designated clean was soiled. There was no documented evidence cleaning agents effectively removed drug products residues, and that cleaning agents were completely removed.

A) Capsule plates designated clean and ready for production use contained powder residue on the inner edges of the slots which directly contact open capsules during filling. There was visible, loose powder on the upper work surfaces and outer housing of three of (b) (4) capsule machines.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L. Hunt -S	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Nicholas L. Hunt, Investigator	DATE ISSUED 04/03/2018
	<small>Digitally signed by Nicholas L. Hunt -S DN: cn=US, o=US Government, ou=FDA, ou=People 63.2942.19.2026100.1.1=201712211, email=Nicholas.L.Hunt-S Date: 2018.04.03 10:50:47-0700</small>		

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration Los Angeles District Office 19701 Fairchild, (949) 608-2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/26/2018 - 04/03/2018
	FEI NUMBER 3005256616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Justin Y. Chen, Owner

FIRM NAME Chen Shwezin DBA Park Compounding Pharmacy	STREET ADDRESS 4333 Park Terrace Drive, #160
---	---

CITY, STATE AND ZIP CODE Westlake Village, CA 91361	TYPE OF ESTABLISHMENT INSPECTED producer of non-sterile drug products
--	--

B) I observed an apparent hair stuck to residue on one roller of an (b) (4) ointment mill which was designated clean and ready for production use.

C) 5 o (b) (4) spatulas used to transfer finished drug products into their final container-closure had several sections missing from the bottom edge which created a rough, uneven surface. Your firm could not explain where the missing pieces were located. I observed the spatulas available for use in the production area, and production personnel confirmed they use the spatulas regularly.

D) (b) (4) powder containment hoods used during topical and oral solid dosage drug production were damaged and not easily cleanable. The seams were sealed with black duct tape and clear packaging tape. There were several large cracks sealed with tape, and there was powder residue visible on the exposed adhesive. Both hoods were designated clean and ready for use.

E) I watched personnel wash encapsulation components and various utensils used to produce hazardous and non-hazardous drug products. They used (b) (4) water and (b) (4). There was no documentation the cleaning process and cleaning agent effectively removed all drug product residues. Personnel wiped encapsulation components with (b) (4) but did not sanitize any other utensils.

F) Your firm used (b) (4) in its residential dishwasher. The dishwasher cleaned glassware and plastic jars from the (b) (4) mixer which were used to produce hazardous and non-hazardous drug products. There was no documentation the cleaning process and cleaning agent effectively removed all drug product residues.

OBSERVATION 3

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written, and followed.

Specifically, the tool used to (b) (4) compress powder into capsules was cleaned, sanitized, and then stored on a soiled, wet cloth for approximately (b) (4) hours. The tool was upright on the protrusions which directly contact powder inside the capsules.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L. Hunt -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nicholas L. Hunt, Investigator	DATE ISSUED 04/03/2018
	<small>Digitally signed by Nicholas L. Hunt -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=200172221 1, cn=Nicholas L. Hunt -S Date: 2018.04.03 17:21:04 -0700'</small>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration Los Angeles District Office 19701 Fairchild, (949) 608-2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/26/2018 - 04/03/2018
	FEI NUMBER 3005256616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Justin Y. Chen, Owner

FIRM NAME Chen Shwezin DBA Park Compounding Pharmacy	STREET ADDRESS 4333 Park Terrace Drive, #160
---	---

CITY, STATE AND ZIP CODE Westlake Village, CA 91361	TYPE OF ESTABLISHMENT INSPECTED producer of non-sterile drug products
--	--

OBSERVATION 4
 Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, your firm did not perform microbiological or ionic testing to ensure water quality met applicable standards for non-sterile drug production. Production personnel used (b) (4) Water to produce water based suspensions. Water for drug production was supplied in (b) (4) and dispensed from a water cooler in the employee break room. I observed employees fill their personal water bottles using the same water cooler. (b) (4) was used to produce Trichloroacetic Acid 35% solution, 60 mL, lot 03142018@16.

OBSERVATION 5
 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans, and test procedures designed to assure drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm did not establish specifications for acceptable levels of microorganisms or conduct microbial enumeration tests for non-sterile drug products. Examples of drug products distributed without microbial enumeration information include:

- Lidocaine + Tetracaine 23+7% cream, 60 mL, lot 02072018@12
- Diclofenac suppository, 100 mg, lot 01042018@13
- Trichloroacetic Acid 35% solution, 60 mL, lot 03142018@16
- Cantharidin Plus liquid, 100 mg/10 mL, lot 01192018@13
- Benzocaine + Lidocaine + Tetracaine 20+8+4% Lipoderm, 30 gm, lot 03132010@32

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L. Hunt -S	EMPLOYEE(S) NAME AND TITLE (<i>Print or Type</i>) Nicholas L. Hunt, Investigator	DATE ISSUED 04/03/2018
	<small>Digitally signed by Nicholas L. Hunt -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001722211, cn=Nicholas L. Hunt -S Date: 2018.04.03 17:21:37 -07'00'</small>		