DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and 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 WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

a) Your firm has no written procedures outlining the responsibilities of the Quality Unit, including release or rejection of finished drug products.

b) Written procedures are not review and approved and have not been assigned effective dates.

c) Your firm placed an incorrect Beyond Use Date (BUD) on the label for Lot #25070112 of Estradiol Cypionate 2mg/1mL Injection. The product was made on 07/07/2025 and the BUD placed on the label was 01/31/2025.

d) Media fills performed by your firm with each of the technicians that work in the ISO (b)(4) area do not closely simulate actual production conditions or cover worst case or most challenging conditions. Please refer to **OBSERVATION 2** for details.

e) Your firm's sterilization cycles used to render sterile drug products sterile via (b)(4), (b) (4) and/or (b)(4) have not been validated. Please refer to **OBSERVATION 2** for details.

f) Your firm has not validated the cleaning, sterilization and/or (b) (4) process for the stoppers, vials and ointment tubes used by your firm to package sterile drug

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

products. Please refer to **OBSERVATION 7** for details.

g) Your firm is not performing environmental or personnel monitoring in the classified areas (ISO (b)(4)/ISO (b)(4)/ISO (b)(4)) (b) (4) that sterile drugs products are produced. Your firm is not performing environmental monitoring during media fills. Please refer to **OBSERVATION 4** for details.

h) Your firm failed to replace a leaking HEPA filter when first advised of issue and then failed to perform an investigation and product impact assessment. Please refer to **OBSERVATION 6** for details.

i) Your firm does not conduct routine testing for sterility as applicable, endotoxin as applicable, or potency (assay) for all drug products produced by your firm (sterile and non-sterile). Please refer to **OBSERVATIONS 8 & 13** for details.

j) Your firm does not have an established stability testing program to justify the Beyond Use Dates (BUD) placed on your drug products (sterile and non-sterile). Please refer to **OBSERVATION 9** for details.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic and sterilization process.

Specifically,

a) Media fills performed by your firm with each of the technicians that work in the ISO (b)(4) area do not closely simulate actual production conditions or cover worst case or most

challenging conditions. The media fill your firm performs has the technician filling media into (b) (4) vials and media into (b) (4) control vials. The vials are received with a kit already stoppered and the media is introduced to the vial using a syringe via the septum. In routine production, your firm fills various size vials (30cc, 50cc and 100cc vials), dropper bottles (5mL, 10mL and 15mL), syringes and ointment tubes. All vials, stoppers and tubes used by your firm are sterilized/ (b) (4) by your firm. Vials are filled and then stoppered (b) (4) by the technician. The technician places the tip and cap on the dropper bottles (b) (4). Tubes are crimped by the technician after filling. Syringes are received sterile/ (b) (4) and then filled by the technician.

In addition, documentation of the media fills performed are incomplete in that they do not include how the media was prepared, the order in which the vials are filled with media and the volume filled in each, and documentation of all consumables used such as syringes, filters, and the water used to reconstitute the media. Your firm is using store brand (b) (4) water to reconstitute the media.

b) Your firm's sterilization cycles used to render drug products sterile via (b)(4), (b) (4) (b) (4) and/or (b)(4), have not been validated. Your firm prepares various drug products from bulk non-sterile active pharmaceutical ingredients (API) and excipients that are to be sterilized via (b)(4), (b) (4) and/or (b)(4). There are some drug products where the final product has components that are placed in (b) (4) (b) (4) and added to other (b)(4) sterilized components.

Examples of finished drug products that are (b) (4) include:

- Corticotropin (ACTH) LA Gel 40U/1mL Injection
- Reserpine (Aqueous) 2.5mg/1mL IM Injection

- Xylazine 10mg/1mL Injection

Examples of finished drug products that are (b) (4) include:

- Praziquantel 100mg/1mL Injection
- Estradiol Cypionate 2mg/1mL IM Injection (one component is also placed (b) (4) (b) (4) before (b) (4) of final product)
- Cyclosporine 0.2% Sterile Ophthalmic Solution is (b) (4) in bulk and then filled into a sterile dropper bottle.

Examples of finished drug products where a component of the final drug product is (b) (4) or put (b) (4) include:

- Chloramphenicol 1% Sterile Ophthalmic Ointment
- Edetate Disodium (EDTA) 1% Ophthalmic Ointment
- Gentamicin 0.4% (4mg/1mL) Ophthalmic Ointment
- Itraconazole 1% in 10% DMSO Sterile Ophthalmic Ointment – In addition your firm used a (b) (4) for lot #25050100 of made on 05/07/2025. The batch record states an "(b)(4) (b)(4) (b)(4)" is to be used.

c) Smoke studies performed in the ISO (b) (4) Laminar Flow Hoods (LFH) are not representative of all activities performed. For example, on 09/12/2025 I watched the filling of lot #25090389 of Tacrolimus 0.02% Ophthalmic Solution. There were (b) (4) of stoppers and (b) (4) caps propped up against the face of the HEPA filter and side of the LFH, (b) (4) vials, beaker of (b) (4) on a hot plate, tray of sterile dropper bottles with tips and caps, crimper, and some packaged syringes. In the smoke study video dated 09/04/2025, there is only the hot plate and a spray bottle inside the LFH.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge	
FIRM NAME Petscript Inc.	STREET ADDRESS 3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not.

Specifically,

a) Your firm has no written procedure for how to perform (b) (4) testing, including specifications for pass/fail of the test. Your firm is not documenting performing (b) (4) testing of (b)(4) used to make sterile drug products.

b) Stoppers and (b) (4) caps are removed from an (b) (4) and placed directly onto the surface of the LFH when filling. The technician then places the stopper onto the vial using their gloved hand. When filling sterile drug products into dropper bottles the tips and caps are also manually placed onto the dropper bottle by the technician using their gloved hand.

c) On 09/12/2025 I watched the filling of lot #25090389 of Tacrolimus 0.02% Ophthalmic Solution. There were (b) (4) of stoppers and (b) (4) caps propped up against the face of the HEPA filter inside the ISO (b) (4) Laminar Flow Hood.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

a) Your firm is not performing environmental or personnel monitoring in the classified areas (ISO (b)(4)/ISO (b)(4)) (b) (4) that sterile drugs products are produced. Viable surface sampling and viable active air sampling is performed (b) (4) every (b)(4) when your rooms and hoods are certified.

In addition, your firm does not perform non-viable particulate monitoring in the ISO (b)(4) Laminar Flow Hood during production/filling of sterile drug products.

Your firm is not monitoring each operator working in the ISO (b)(4) Laminar Flow Hood each day drug products are prepared. Your firm is currently sampling (b) (4) (b) (4) when a media fill is performed.

b) Your firm is not performing environmental monitoring during media fills.

OBSERVATION 5

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically, gowning for personnel working in the ISO (b)(4)/ISO (b)(4) classified areas consists of the following: scrubs worn from home, a disposable sterile field gown that ties in the back, a single non-sterile hair net, non-sterile face mask, and non-sterile shoe covers. A single pair of sterile gloves are donned after the technician has donned the other gowning materials. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing sterile drug products.

Gowning in the ISO (b)(4) prep area consists of scrubs worn from home, shoe covers and gloves. There is no requirement for a hair net or any other protective clothing while preparing/mixing

drug products and container/closures that will then be either (b) (4) and/or placed (b) (4) for sterilization.

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, during the certification of the cleanrooms on 09/05/2024 and 03/07/2025, one of the HEPA filters in (b) (4) Room (b) (4) (ISO (b) (4)) needed attention due to leaks detected. The report does not note the size of the leaks. The HEPA filter was not replaced until after the 03/07/2025 certification, which was not documented. Your firm did not re-certify the room after the replacement of the HEPA filter until 09/04/2025. Your firm did not perform an investigation into the leaking HEPA filter or perform a product impact assessment.

Your firm does not maintain a log of all lots made in each of the (b) (4) cleanrooms however, from 09/05/2024-03/07/2025, your firm made approximately (b)(4) lots of sterile drug products.

OBSERVATION 7

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

a) Your firm has not validated the sterilization and/or (b) (4) process for the stoppers and vials used by your firm to package sterile drug products. Your firm does

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge	
FIRM NAME Petscript Inc.	STREET ADDRESS 3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

not clean the stoppers before (b) (4) them or clean the vials before wrapping in (b) (4) and putting in (b) (4)

b) Your firm has not validated the re-sterilization of stoppers. According to your technician who works in the cleanroom producing/filling sterile drug products, unused rubber stoppers that have already been (b) (4), can be placed back into inventory and processed again. Your firm has no system for tracking the rubber stoppers that may have been subjected to the sterilization process more than once.

c) Your firm initially sterilizes stoppers and (b) (4) caps in an (b) (4) Each (b) (4) of use, the technician will remove a certain quantity of stoppers and caps to be used for each lot prepared on a given (b) (4). At the end of the (b) (4), the unused stoppers and caps are then placed into a new (b) (4) for storage. At the beginning of each (b) (4) a new batch of stoppers and caps are (b) (4) for use. Your firm has not validated this process to ensure that all stoppers and caps remain sterile throughout the timeframe used post initial sterilization.

OBSERVATION 8

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm is not testing any of your drug products labeled as sterile for sterility and/or endotoxin prior to release/distribution.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 9

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug products. Your firm has no written and approved stability protocols and no final written and approved reports. In addition, your firm has not performed container closure integrity testing.

Your firm has no documentation of a stability study having been performed to justify the Beyond Use Dates (BUD) placed on your sterile and non-sterile drug products. Examples include:

i. Lot #24050745 of Xylazine 10mg/1mL Injection had a BUD of 200 days
ii. Lot #25080172 of Estradiol Cypionate 2mg/1mL IM Injection had a BUD of 205 days
iii. Lot #25070632 of Reserpine (Aqueous) 2.5mg/1mL IM Injection had a BUD of 187 days
iv. Lot #25060197 of Praziquantel 100mg/1mL Injection had a BUD of 209 days
v. Lot #25070372 of Gentamicin 0.4% (4mg/1mL) Ophthalmic Ointment had a BUD of 199 days
vi. Edetate Disodium (EDTA) 1% Ophthalmic Ointment had a BUD of 195 days. Lot #2508213 had a BUD of 204 days.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge	
FIRM NAME Petscript Inc.	STREET ADDRESS 3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

vii. Lot #25040770 of Ponazuril 150mg/1mL Oral Paste had a BUD of 215 days

viii. Lot #25070449 of Febendazole 200mg/1mL Oral Suspension had a BUD of 199 days

ix. Lot #25050407 of Pimobendan 10mg Quadrisect Tablets had a BUD of 374 days

OBSERVATION 10

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm has not validated the cleaning process for equipment, beakers, utensils and other items used to make both sterile and non-sterile drug products. Most equipment, beakers and utensils used for sterile and non-sterile drug products are first cleaned with store brand liquid dish soap and sponges or scrub brushes. The glass, utensils and some other items used for non-sterile drug products are then placed into a dishwasher using (b)(4) brand dishwashing detergent. Your firm has no documentation to show that the use of these soaps and detergents are appropriate and suitable for use in cleaning equipment used in the preparation of pharmaceutical products.

Dies and punches used to make tablets are cleaned with (b) (4) Your firm has not evaluated the effectiveness of (b) (4) as a cleaner for all active pharmaceutical ingredients used to make tablets such as enrofloxacin, trilostane, gabapentin, and metronidazole benzoate.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm's batch records do not include documentation and/or complete documentation of each significant step in the production of drug products. For example,

a) Your firm used a (b) (4) for lot #25050100 of Itraconazole 1% in 10% DMSO Sterile Ophthalmic Ointment made on 05/07/2025. The batch record states an "(b)(4) (b)(4)" is to be used.

b) Your firm does not record the lot number of the packaging materials such as vials, stoppers, (b) (4) caps, dropper bottles, syringes, and bottles used to package finished dosage drug products (sterile and non-sterile).

c) Your firm does not record in the batch record the lot number, brand and size of sterilizing filter used for any sterile drug product.

d) Your firm fills sterile and non-sterile drug products into containers labeled as stock which you will then later use to fill finished product containers and label for shipment to a customer. Your firm does not document the filling of product from stock products, including the date performed, the packaging container used, the label placed on the product and the quantity. In addition, if flavoring or other ingredients are added to the product at the time of filling from the stock solution, your firm does not document this activity, including the lot number of the ingredient used.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge	
FIRM NAME Petscript Inc.	STREET ADDRESS 3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 12

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, drug product containers, closures, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a) Your firm is incubating media fill vials at a temperature above (b) (4) °C. The temperature documented in the Incubator (b) (4) Monitoring Log for media fill vials incubated from 01/29/2025-02/26/2025 ranged from 35.3°C-40°C. The temperature documented in the Incubator (b) (4) Monitoring Log for media fill vials incubated from 04/29/2025-05/14/2025 ranged from 34°C-44.4°C. The temperature documented in the Incubator (b) (4) Monitoring Log for media fill vials incubated from 08/01-14/2025 ranged from 33.4°C-36°C.

b) Your firm is incubating (b)(4) used for personnel monitoring for (b) (4) at the same temperatures listed above for the media fills. Your firm has no documentation to show that an incubation period of this duration and at this temperature is appropriate and does not adversely affect the agar.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 13

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 does not conduct routine testing for potency (assay) for all drug products produced by your firm (sterile and non-sterile),

OBSERVATION 14

Written procedures are lacking which describe in sufficient detail the receipt, identification, sampling, testing, approval and rejection of components.

Specifically, your firm is using a grocery-store brand (b) (4) water to make sterile and non-sterile drug products. Your firm does not perform testing (analytical or microbiological) to show the water at least/at minimum meets the specifications for (b) (4) Water, USP. The quality of the water is not appropriate for pharmaceutical use. Non-sterile drug products made with the (b) (4) water include the gelatin base used to make chewable treats such as lot #25080231 of Pimobendan 1.25mg Chewable Treat and lot #25060237 of Fluoxetine 10mg Chewable Treat. Sterile drug products made with (b) (4) water include the Sodium Carboxymethylcellulose 2.5% Gel used to make Corticotropin (ACTH) 40U/1mL IM Injection.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025* FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 15

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm is preparing various sterile and non-sterile drug products from bulk drug substances. Your firm does not perform any testing, including an identity test, on the incoming bulk drug substances or excipients used to make these products.

OBSERVATION 16

Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm is not bracketing the range of use when calibrating the analytical balances used to weigh raw materials and/or perform in process weight checks during the preparation of sterile and non-sterile drug products. Calibration by an outside vendor consists of (b) (4). In addition, your firm has no documentation to show that the standard weight set used to perform (b) (4) verification of the balances has been calibrated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	9/8/2025-9/18/2025*
	FEI NUMBER 3010282564

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lloyd Wade Sparks, RPh, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Petscript Inc.	3020 Lamar Ave
CITY, STATE, ZIP CODE, COUNTRY Paris, TX 75460-5014	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

*DATES OF INSPECTION

9/08/2025(Mon), 9/09/2025(Tue), 9/10/2025(Wed), 9/11/2025(Thu), 9/12/2025(Fri), 9/15/2025(Mon), 9/17/2025(Wed), 9/18/2025(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Margaret M Annes, CSO Katherine M Breed, Veterinary Medical Officer	X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 09-18-2025 10:39:11	9/18/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."