

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

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| DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6751 Steger Dr. Cincinnati OH 45237 513-679-2700 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 4/29-30/14 and 5/9, 14, 22/14 |
| | FEI NUMBER 3002992930 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Jacqueline S. Bernard, President and Owner

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| FIRM NAME Wickliffe Pharmaceutical Inc. | STREET ADDRESS 4340 Georgetown Rd. |
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| CITY, STATE AND ZIP CODE Lexington KY 40511 | TYPE OF ESTABLISHMENT INSPECTED compounding pharmacy |
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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:

1. FDA laboratory analysis of lot 28-03-2014@44 (BUD 9/24/2014) of toltrazuril and pyrimethamine suspension labeled to contain 416 mg/ml toltrazuril and 17 mg/ml pyrimethamine and dispensed under Rx #294545 resulted in the following values:

- a. Sub 1 was 405 +/- 69 mg/ml pyrimethamine or 2380% of the declared potency.
- b. Sub 1 was 15.5 +/- 2.5 mg/ml toltrazuril or 3.74% of the declared potency.

2. FDA laboratory analysis of lot 25-03-2014@25 (BUD 9/21/2014) of toltrazuril and pyrimethamine oral paste labeled to contain 227 mg/ml toltrazuril and 340 mg/ml pyrimethamine and dispensed under Rx #311791 resulted in the following values:

- a. Sub A was 277 mg/ml pyrimethamine or 82% of the declared potency.
- b. Sub B was 283 mg/ml pyrimethamine or 83% of the declared potency.
- c. Sub A was 182 mg/ml toltrazuril or 80% of the declared potency.
- d. Sub B was 184 mg/ml toltrazuril or 81% of the declared potency.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE  | EMPLOYEE(S) NAME AND TITLE (Print or Type) Kathleen Dant Culver, Investigator/Drug Preapproval Manager | DATE ISSUED 5/22/14 |
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