

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Ascend Laboratories, LLC would like to inform you of a product recall involving Aripiprazole Tablets USP, 10mg. An out-of-specification (OOS) result was observed during long-term stability study ($25 \pm 2^{\circ}\text{C}$ / $60 \pm 5\%$ RH) at the 6-month interval for Aripiprazole Tablets USP 10 mg, Batch No. 24144162. The assay result was reported as 105.5%, exceeding the upper specification limit of 105.0% (acceptable limit: 95.0%-105.0%).

Aripiprazole is a second-generation antipsychotic drug. It works by balancing serotonin and dopamine, two neurotransmitters responsible for transmitting signals between nerve cells, in the brain. Serotonin and dopamine are responsible for regulating thoughts and mood. Aripiprazole is commonly prescribed to treat schizophrenia, bipolar disorder, depression, Tourette's Syndrome and autism induced irritability. This medication is only prescribed to adults and children 6 years of age and older. The slight elevation in assay value above the acceptable limit indicates a marginally higher dose than labeled. However, this is not expected to significantly impact the product's quality or pose a threat to patient safety.

Our firm began shipping this product on June 1, 2025.

PRODUCT: Aripiprazole Tablets USP, 10mg

LOT NUMBER: 67877-432-03

LOT NUMBER: 24144162

EXPIRATION DATE: 9/30/27