

**ZYTIGA® (abiraterone acetate)
ZYTIGA - Open Bottle Stability**

CLINICAL DATA

Open Bottle Stability

Film-Coated 500 mg Tablets

An in-use stability study of ZYTIGA 500 mg oral film-coated tablets in 60 count high-density polyethylene (HDPE) bottles was performed to simulate the daily use of the medication by the patient. The product remained stable when stored in HDPE bottles during 24 months at 25°C/60% relative humidity (RH) and 30°C/75% RH.¹

Uncoated 250 mg Tablets

A 30-day study of ZYTIGA tablets stored in open, HDPE bottles for 30 days at 30°C/65% RH and 25°C/60% RH was conducted. The product met study specifications for 30 days. This study was not conducted to assess open bottle stability for longer periods of time.²

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 22 October 2024.

REFERENCES

1. Data on File. In-Use Stability Report. Janssen Research & Development, LLC. TV-TEC-146269; 2017.
2. Data on File. Open Bottle Stability Study. Janssen Research & Development, LLC; 2013.