

**TRACLEER® (bosentan)**  
**TRACLEER - Film-Coated Tablet Storage and Stability Information**

## **BACKGROUND/GUIDELINES**

### **Shelf Life**

The film-coated tablets have a shelf life of 5 years.<sup>1</sup>

### **Stability After Opening of Original Packaging**

For the film-coated tablets packed in white high-density polyethylene bottles, use within 30 days after the first opening.<sup>1</sup>

### **Stability of Cut TRACLEER Tablets**

The physical and chemical stability of half-cut TRACLEER 62.5 mg tablets were evaluated after 4 weeks of storage at room temperature in a high-density polyethylene plastic bottle. During this time, the bottle was opened and closed 5 times a week to simulate its standard use. Visual inspection and dissolution evaluation revealed no significant changes in the physical and chemical characteristics of the tablet under the conditions tested.<sup>2</sup>

### **Stability of Crushed TRACLEER Tablets**

A study investigating the stability of crushed TRACLEER 62.5 mg tablets found that the crushed tablets were stable for a period of 6 months when stored below 30°C, 65% relative humidity and protected from light. Furthermore, crushed TRACLEER 62.5 mg tablets diluted 1:1 with lactose were stable for a period of 2 months when stored under similar conditions.<sup>3</sup>

## **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 06 November 2024.

## **REFERENCES**

1. Data on File. Bosentan. CCDS Version 8. Janssen Research & Development, LLC. EDMS-ERI-205912245; 2019.
2. Data on File. Bosentan. In-Use Stability. Janssen Research & Development, LLC. Document No. 03-R-011-V01; 2003.
3. Data on File. Bosentan. Final Stability Report. Janssen Research & Development, LLC. SR10-10A; 2010.