

ELEMENTAL IMPURITIES STATEMENT**ACEPROMAZINE MALEATE**

No metal catalysts or metal reagents are intentionally used in the formation of the drug substance, water or excipients used in the manufacture of Acepromazine Maleate.

The polyethylene liners used in the container closure systems of the product meet both EU and FDA food grade requirements and are suitable for the storage of pharmaceutical powders and tablets.

As there are several purification steps and phase separations in the Acepromazine Maleate process it is not expected there would be potential for carryover of elemental impurities from the raw materials where no heavy metal catalysts are used.



Sharon Redmond
QA Technician

Date: 23 Feb 2018

This statement is valid for 36 months from date of signature.

