

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2015-1548
Application: B.4.6 - Fulfill Data Requirements for Full Registration
Product: Arylex Active
Registration Number: 31302
Active ingredients (a.i.): Halauxifen
PMRA Document Number : 2573635

Purpose of Application

The purpose of this application was to address the data requirement for full registration of Arylex Active. The data requirement was GLP compliant 5 batch analytical data from commercial scale material.

Chemistry Assessment

The data requirement of registration for this product included the provision of commercial-scale batch data. Data to fulfill this requirement were provided, reviewed and found to be acceptable. As such, the chemistry requirements for Arylex Active have been fulfilled.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

PMRA has reviewed information provided in support of the addressing the data requirement for the registration of Arylex Active. Based on this review, the data requirement for the registration of Arylex Active has been satisfied and the product is acceptable for full registration.

References

- 2525985 2014, Batch Analysis Study for Halauxifen-methyl Technical, DACO: 2.13.3 CBI
- 2525986 2014, Batch Analysis Study for Halauxifen-methyl Technical, DACO: 2.13.3 CBI

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