

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2014-4923
Application: Changes TGAI Chemistry-Specifications
Product: Famoxadone Technical
Registration Number: 27436
Active ingredients (a.i.): famoxadone
PMRA Document Number : 2552331

Purpose of Application

The purpose of this application was to amend the manufacturing process and update the product specification.

Chemistry Assessment

Common Name: famoxadone
CAS Chemical Name: 5-methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione
IUPAC Chemical Name: *rac*-(5*R*)-3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione

Famoxadone Technical has the following properties:

Property	Result
Colour and physical state	Pale cream powder
Nominal concentration	97.8%
Odour	Characteristic of burnt plastic and similar to vanilla
Specific gravity	1.310
Vapour pressure	6.4×10^{-7} Pa at 20°C
pH	6.56

Property	Result	
Solubility in water at 20°C	<u>pH</u>	<u>µg/L</u>
	unbuffered	52
	2	143
	3	191
	5	243
	7	111
	9	38
n-Octanol/water partition coefficient (K_{ow})	<u>pH</u>	<u>log K_{ow}</u>
	3.0	4.59
	5.0	4.80
	7.0	4.65
	9.0	5.55

The chemistry requirements for Famoxadone Technical have been fulfilled.

Health Assessments

The change in manufacturing process of Famoxadone Technical results in a product that is toxicologically equivalent to that of the original process. No toxicological data were reviewed or are required.

Food residues and occupational assessments were not required for this application.

Environmental and Value Assessments

It was determined that environmental and value assessments were not required for this application.

Conclusion

Following review of the application the amendment to the the manufacturing process and product specification were approved.

References

PMRA

Document

Number Reference

2468079 2014, DuPont - 40617: Batch Analysis Of Famoxadone (DPX-JE874) Technical - Confidential, Daco: 2.13.3 CBI

2468080 2014, DuPont - 40617: Batch Analysis of Famoxadone (DPX-JE874) Technical - Non- Confidential, DACO: 2.13.3

- 2468081 2014, DuPont - 40041: Technical Grade Famoxadone (DPX-JE874) Manufacturing Description and Formation of Impurities- Confidential, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
- 2468083 2014, Dupont - 40041: Technical Grade Famoxadone (DPX-JE874) Manufacturing Description and Formation of Impurities- Non Confidential, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 2468084 2014, Famoxadone (DPX-JE874) Identity, Composition, and Certified Limits - Non Confiedential, DACO: 2.12.1
- 2468085 2014, Famoxadone (DPX-JE874) Identity, Composition, and Certified Limits - Confidential, DACO: 2.12.1 CBI
- 2468086 2014, Description and Validation of the Analytical Method for Determination of Residual Solvent in Technical Grade Famoxadone (DPX-JE874)-Non Confidential, DACO: 2.13.1
- 2468087 2014, Description and Validation of the Analytical Method for Determination of Residual Solvent In Technical Grade Famoxadone (DPX-JE874) - Confidential, DACO: 2.13.1 CBI
- 2468088 2014, Batch Analysis of Famoxadone (DPX-JE874) Technical - Confidential, DACO: 2.13 CBI
- 2468090 2014, Batch Analysis of Famoxadone (DPX-JE874) Technical- Non-Confidential, DACO: 2.13, CBI
- 2490991 2012, Description and Validation of the Analytical Methods for Determination of Impurities in Technical Grade Famoxadone (DPX-JE874), DACO: 2.13.1 CBI
- 2490992 2012, Description and Validation of the Analytical Methods for Determination of Impurities in Technical Grade Famoxadone (DPX-JE874), DACO: 2.13.1
- 2490993 2012, Confirmation of Impurities Identification in Technical Grade Famoxadone (DPX-JE874) by Mass Spectroscopy and UV/Vis Detection, DACO: 2.13.1 CBI
- 2490994 2012, Confirmation of Impurities Identification in Technical Grade Famoxadone (DPX-JE874) by Mass Spectroscopy and UV/Vis Detection, DACO: 2.13.1 CBI
- 2490996 2011, Determination of Famoxadone (DPX-JE874) in Technical Grade Famoxadone, DACO: 2.13.1 CBI
- 2490997 2011, Validation of the Analytical Method for Determination of Famoxadone (DPX-JE874) in Technical Grade Famoxadone, DACO: 2.13.1 CBI
- 2490998 2011, Validation of the Analytical Method for Determination of Famoxadone (DPX-JE874) in Technical Grade Famoxadone, DACO: 2.13.1

- 2490999 2011, Determination of [CBI removed] in Famoxadone Technical Gas Chromatographic (GC) Trace Level Method, DACO: 2.13.1 CBI
- 2491000 2011, Determination Of [CBI removed] in Famoxadone Technical Gas Chromatographic (GC) Mass Spectrometry Trace Level Method, DACO: 2.13.1 CBI
- 2491001 2011, Determination of Famoxadone in Famoxadone Technical Reversed-Phase Liquid Chromatographic (RPLC) Assay Method, DACO: 2.13.1 CBI
- 2491002 2011, Determination of [CBI removed] in Famoxadone Technical Reversed-Phase Liquid Chromatographic (RPLC) Trace Level Method, DACO: 2.13.1 CBI
- 2491003 2011, Determination of [CBI removed] in Famoxadone Technical Reversed-Phase Liquid Chromatographic (RPLC)/Mass Spectrometry Trace Level Method, DACO: 2.13.1 CBI
- 2491004 2010, Technical And Formulated Pesticides and Other Substances Determination of Inorganic Anions And Cations Ion Chromatography (IC) Method, DACO: 2.13.1 CBI
- 2491005 2008, Determination of [CBI removed] Method, DACO: 2.13.1

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2016**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.