

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product:	Contacera 15mg/ml	Man Date:	08 / 2014
Customer:	Zoetis	Expiry Date:	07 / 2017
Livery:	Hungary, UK	Pack Size:	100ml
Batch No.:	H30297/D	Quantity:	300
Bulk Batch No.:	H30297		

TESTS	SPECIFICATIONS	RESULT
Appearance	An off-white to yellowish coloured suspension.	Complies
Identification Meloxicam	The chromatography of the assay exhibits a major peak due to Meloxicam, the retention time of which corresponds to that exhibited in the chromatogram of the standard in the HPLC assay. Alternative UV method §: The absorption spectrum of the sample solution exhibits a maximum at about 340 nm.	Complies Non-routine Test
Active Assay	1.5% w/v Meloxicam ± 5% (1.425 - 1.575 %w/v)	1.491%w/v Complies
pH	4.3 ± 0.5	4.4 Complies
Identification Preservative	The chromatography of the assay exhibits a major peak due to Sodium Benzoate, the retention time of which corresponds to that exhibited in the chromatogram of the standard.	Complies
Preservative Assay	0.5% w/v Sodium Benzoate ± 10% (0.45 - 0.55 %w/v)	0.52%w/v Complies
Particle size analysis **	D(10): NMT 30 µm D(50): NMT 55 µm D(90): NMT 110 µm	Non-routine test Non-routine test Non-routine test
Viscosity §	5 - 15 P	Non-routine Test
Microbiological Quality*	Conforms to Ph. Eur., Monographs 2.6.12 and 2.6.13	Non-routine Test
Uniformity of Mass of Delivered dose	Conforms to Ph. Eur., Monograph 2.9.27	Complies

* This is a non-routine test, conducted on one in every 6 batches manufactured.

§ This is a non-routine test, conducted on one in every 10 batches manufactured.

** This is a non-routine test, conducted on one batch manufactured per year.

This product has been manufactured, analysed and packaged in accordance with the Marketing Authorisation No. EU/2/12/144/005 and with Directive 91/412/EEC. There was one deviation associated with the above batch, reference DEV-14-0166, which has been assessed and there is no adverse impact on product quality, safety or efficacy. There was one QC Out of Spec. associated with the above batch, reference QC -14-034, which has been assessed and there is no adverse impact on product quality, safety or efficacy.

The product is fit for use and may be released for sale.

Checked By: *Seamus O'Connell* Date: 29/07/2014
Quality Assurance (Signature)

Approved By: *Anne Kelly* Date: 29/07/2014
Qualified Person (Signature)

Anne Kelly
Qualified Person (Print Name)