

Ref. Chargenregister: 6671

Chargenfreigabe	
Produkt:	Isofluran CP
Charge:	B06A16A
Packungsgröße:	250 ml
Stückzahl:	7779
Land:	Deutschland
Verfalldatum:	12/2020
Herstelldatum:	01/2016

<input checked="" type="checkbox"/>	„Certificate of Conformance“ vorhanden
-------------------------------------	--

<input checked="" type="checkbox"/>	Es traten keine Abweichungen auf.	
<input type="checkbox"/>	Die folgenden Abweichungen traten auf:	Status:

CAPA-Prozess eingeleitet?	Nein <input checked="" type="checkbox"/>	Ja <input type="checkbox"/>	Referenz: _____
---------------------------	---	--------------------------------	-----------------

Datum / Unterschrift:

Name, Sachkundige Person	04. MAI 2016 
--------------------------	---

CERTIFICATE OF CONFORMITY

Name / Strength of Product: Isoflurane 250ml
Dosage Form: Inhalation Vapour, Liquid
Product MA Number: Zul.-Nr. 400806.00.00
Importing Country: Germany
Quantity Released: 7781 *7779 8*
Pack Size: 6x250ml
Manufacturer Batch Number: B06A16A
Morpeth Batch Number: B06A16A
Date of Manufacture: JAN2016
Expiry Date: DEC2020
Site of Manufacturer: Digwal Village, Kohir Mandal, Medak Dist 502321
Andhra Pradesh, India
Manufacturer MA Number: CODE: AP/DRUGS/220/96
Comments: N/A

See attached Certificate of Analysis for the above mentioned batch.

I hereby certify that the above information is authentic and accurate. This batch of product, including intermediates and raw materials, has been manufactured, packaged and QC analysed at the above-mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records are reviewed and found to be in compliance with GMP.

This batch has been released for the intended market.

Signature: *[Signature]* Date: *22/01/2016*

Quality Manager & QP under directive 2001/83/EC

4
04. MAY 2016
[Signature]

Piramal Healthcare,
Whatton Road,
Morpeth,
NE61 3YA
Tel: +44 (0) 1670 562400

Date Printed: 21Apr2016

Page 1 of 2

QS geprüft

03 05 16 LMS

Isoflurane 250 ml CP Germany
Product Lot Number: B06A16A
Bulk Product Code: 440532075
Supplier Lot Number: B06A16A

<u>TEST IDENTIFICATION</u>	<u>SPECIFICATION</u>	<u>RESULT</u>	<u>UNIT</u>
Identity by IR	The spectrum obtained with the substance being examined is concordant with that of the IR reference spectrum of Isoflurane Ph. Eur. / Working standard reference spectrum.	Conforms	
ACIDITY or ALKALINITY	NMT 0.1 ml of 0.01M Sodium Hydroxide or NMT 0.6 ml of 0.01M Hydrochloric Acid	Conforms	
RELATED SUBSTANCES (%v/v)			
a) Acetone	NMT 0.01% v/v	<0.0005	%
b) 1-Chloro-2,2,2-Trifluoroethylchloro-difluoromethyl ether (CECMF)	NMT 0.01% w/v	<0.001	%
c) 2,2,2-Trifluoroethyldifluoromethylether (FEFME)	NMT 0.007% v/v	<0.0004	%
d) 2,2,2-Trifluoroethylchlorodifluoromethylether (CMF)	NMT 0.003% v/v	<0.0004	%
e) 2,2,2-Trifluoro-1,1-dichloroethyldifluoromethyl ether (DCEF)	NMT 0.003% v/v	0.0007	%
f) Other Individual Impurity	NMT 0.003% v/v	<0.0004	%
g) Total Impurities	NMT 0.03% v/v	0.0007	%
CHLORIDES	NMT 10 ppm	Conforms	
FLUORIDES	NMT 10 ppm	Conforms	
NON-VOLATILE MATTER	NMT 0.02% w/v	0.00	%
WATER CONTENT	NMT 0.10% w/w	0.06	%
ASSAY (By GC)	Not less than 99.9% v/v	100.0	%
REFRACTIVE INDEX	1.2990 - 1.3005 at 20°C	1.2995	

Piramal Healthcare
Whalton Road,
Morpeth,
NE61 3YA
Tel +44 (0) 1670 562400

Date Printed 21Apr2016

Page 2 of 2

JS geprüft
17.05.16 LMS

Isoflurane 250 ml CP Germany

Product Lot Number: B06A16A
Bulk Product Code: 440532075
Supplier Lot Number: B06A16A

-
- *Appearance – Clear colourless mobile heavy liquid Boiling point about 48°C
 - *Odour – Characteristic odour
 - *Solubility – Practically insoluble in Purified Water miscible with Ethanol and Trichloroethylene
- * Characters results taken from the Manufacturers Certificate of Analysis

Signed *Lindon Sten* Date *22 Apr 2016*
Name *LINDON STEN*

Quality Manager EU QP under directive 2001/83/EC

Released by David Roberts

Date of Manufacture JAN 2016 Expiration Date DEC 2020

Bill
04. MAI 2018