

**UCB Farchim S.A.**Zone Industrielle de Planchy
Chemin de Croix-Blanche 10
1630 Bulle - Switzerland**Invoice n. 90000081**

Document date: 18 January 2018

Ship-to address :

GLAXOSMITHKLINE EXPORT LIMITED JEBEL ALI
BRANCH PHARMACEUTICALS
P.O. Box 17136
. DUBAI
EMIR.ARAB.UNIS

Bill-to address :

GLAXOSMITHKLINE TRADING SERVICES LTD
980 GREAT WEST ROAD
BRENTFORD
Middlesex
TW8 9GS
GRANDE BRETAGNE

Sold-to address :

GLAXOSMITHKLINE TRADING SERVICES LTD
980 GREAT WEST ROAD
BRENTFORD
Middlesex
TW8 9GS
GRANDE BRETAGNE

VAT registration no:

Payer: 20000391
Your reference: OI000001075478001
Our reference: 92889095
Order date: 21 Sep 2017
Terms of delivery: FCA MOEHLIN
Mode of transport: Boat - Collected

Currency: EUR

Invoice Details				
Material Code	Description	Batch Value	Quantity	Amount
CIA03691	XYZAL 5MG 30TAB RB GSK MEA	226406	33,480 EA	
	Gross Value	623.30 EUR / 1000 EA		20,868.08
	Taric code: 30049000			
CIA03691	XYZAL 5MG 30TAB RB GSK MEA	228834	16,560 EA	
	Gross Value	623.30 EUR / 1000 EA		10,321.85
	Taric code: 30049000			
Total Gross Value				31,189.93
Total item discount amount				0.00
Total Net Value				31,189.93
		VAT%	VAT base	VAT
Output Tax		0,000%	31,189.93 EUR	0.00
Output Tax		0,000%	36,702.44 CHF	0.00

To be paid (VAT incl.)**31,189.93**

THIRTY-ONE THOUSAND ONE HUNDRED EIGHTY-NINE EURO NINETY-THREE

Payment conditions:

Payment within 60 days due net

Latest due date:

19 Mar 2018

Payment method:

Shipping remarks:

Order n°.: 1547659

Delivery n°.: 81976292

VAT no: CHE-103.818.575 TVA

Phone: +41588223306

Fax:

Chemin de Croix-Blanche 10
1630 Bulle - Switzerland

E-mail: Isabelle.Gremaud@ucb.com

Bank: Bank Mendes Gans NV
Amsterdam, The Netherlands
BIC: BKMGNL2A
IBAN: NL02 BKMG 0261 1565 27

**UCB Farchim S.A.**Zone Industrielle de Planchy
Chemin de Croix-Blanche 10
1630 Bulle - Switzerland**Invoice n. 90000081**
Document date: 18 January 2018

Material Code	Description	Batch Value	Quantity Price Unit	Amount Discount
Gross weight: 1,041.791 KG	Volume: 5,354.280 CD3			
Net weight: 154.625 KG				

We hereby certify that this invoice is true and correct in all respects.

VAT no: CHE-103.818.575 TVA

Phone: +41588223306

Fax:

Chemin de Croix-Blanche 10
1630 Bulle - Switzerland

E-mail: Isabelle.Gremaud@ucb.com

Bank: Bank Mendes Gans NV
Amsterdam, The Netherlands
BIC: BKMGNL2A
IBAN: NL02 BKMG 0261 1565 27

UCB Farchim S.A.

Zone Industrielle de Planchy
Chemin de Croix-Blanche 10
1630 Bulle - Switzerland

Packing List / Delivery Note
81976292

Ship-to address

GLAXOSMITHKLINE EXPORT LIMITED JEBEL ALI
BRANCH PHARMACEUTICALS
P.O. Box 17136
. DUBAI
EMIR.ARAB.UNIS

Sold-to address:

GLAXOSMITHKLINE TRADING SERVICES LTD
980 GREAT WEST ROAD
BRENTFORD
Middlesex
TW8 9GS
UNITED KINGDOM

Shipping point address

Galliker Transport AG
Bäumlimattstrasse 7
4313 MÖHLIN
SWITZERLAND

Req. delivery date: 22 Jan 2018
Customer number: 20004007
Customer purch.Order: OI000001075478001
Order number/date: 1547659 / 21 Sep 2017
Customer VAT: GB239820839

Terms of delivery: FCA MOEHLIN
Means of transport: Boat - Collected
Packages: Pallet: 9

Loading weight:	861.791 KG	Gross HU:	1,041.791 KG	Total volume:
Net weight material:	154.625 KG	Gross material:	861.788 KG	

E-GDP Information:

The product should be stored and transported according to its "Registered Storage Conditions".

The Storage Conditions on the shipping label reflect the "Warehouse temperature conditions" at which the products are stored at UCB. The warehouse temperature conditions will always be within the limits of the Registered Storage conditions.

For distribution activities, it is also acceptable to transport the product at the "Transport Conditions". Please note that those "Transport Conditions" may be broader than the "Registered Storage Conditions" only if they are supported by a set of scientific data approved by the quality unit."

Shipping details

SSCC (HU Identification) Material	Description Batch	Dimension Description Warehouse temperature conditions Other Storage Conditions Registered Storage Conditions	Loading weight Net weight Expiration date	Gross weight Qty material
180325296909501334 CIA03691	Pallet 228834	80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified Store below 30°C	99.199 17.799KG 31 Aug 2022	119.199 KG 5,760 EA
180325296909502553 CIA03691	Pallet 228834	80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 31 Aug 2022	119.199 KG 5,760 EA

UCB Farchim S.A.

Zone Industrielle de Planchy
Chemin de Croix-Blanche 10
1630 Bulle - Switzerland

Packing List / Delivery Note
81976292

SSCC (HU Identification) Material	Description Batch	Dimension Description Warehouse temperature conditions Other Storage Conditions Registered Storage Conditions	Loading weight Net weight Expiration date	Gross weight Qty material
180325296909503178 CIA03691	Pallet 228834	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	86.799 15.574KG 31 Aug 2022	106.799 KG 5,040 EA
180325296909503697 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 30 Jun 2022	119.199 KG 5,760 EA
180325296909505257 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 30 Jun 2022	119.199 KG 5,760 EA
180325296909505585 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 30 Jun 2022	119.199 KG 5,760 EA
180325296909505820 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 30 Jun 2022	119.199 KG 5,760 EA
180325296909505950 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified	99.199 17.799KG 30 Jun 2022	119.199 KG 5,760 EA
180325296909506070 CIA03691	Pallet 226406	Store below 30°C 80 x 120 x 110 CM XYZAL 5MG 30TAB RB GSK MEA 15-25 °C (59-77°F) Not specified Store below 30°C	80.599 14.461KG 30 Jun 2022	100.599 KG 4,680 EA

CERTIFICATE OF QUALITY

UCB FARCHIM SA	
Released by 	
Responsible Person	09 January 2018
Z.L. de Planchy Chemin de Croix Blanche 10 1630 Bulle	
Date :	12.01.2018

XYZAL (CIA03691)

5 mg

30 Tablets

complies with the required specifications as shown hereafter:

CERTIFICATE OF ANALYSIS

N° 201701448

UCB SPECIFICATIONS PARAMETERS

SPECIFICATIONS

BATCH: 226406 RESULTS

Appearance

White to off-white, oval film-coated tablet with a Y logo on one side.

Complies

Water content

Max. 6.0% at release

4.9%

Average mass

103 mg ± 7.5%

102 mg

Uniformity of mass

Percentage deviation : 7.5%
of average mass

-3.9% + 2.1%

Identification

- ucb 28556

-Titanium dioxide (E171)^(a)

Positive

Positive

Positive

N.A.

Assay:

-Levocetirizine

4.75 mg to 5.25 mg/tablet

4.87 mg/tablet

Impurities

Achiral related substance:

p-chlorobenzhydrylpiperazine

Max. 0.3%

<0.10%

p-chlorobenzhydrol

Max. 0.2%

<0.10%

p-chlorobenzophenone

Max. 0.2%

<0.10%

Any unspecified related substance

Max. 0.2%

Not Quantifiable

Total related substance

Max. 0.8%

Not Quantifiable

Chiral related substance:

ucb 28557

Max. 2.0%

0.6%

Dissolution

Q= 75% after 30 minutes
acceptance criteria USP
(limited to stage 2)

96% 94%

93% 96%

97% 96%

Microbiological quality^(b)

Conform to Ph Eur.(5.1.4)

N.A.

^(a)If tested

^(b)Test performed on one out of every ten batches

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Manufacturing date: 06/07/2017

Expiry date : 30/06/2022

Storage conditions : Store below 30°C

Country: Middle East

Dr. Paolo Pizzorni
Pharmacist, Qualified Person



UCB FARCHIM SA
Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411
CH-1630 Bulle
Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220228
Product Code : CIA30073

Complies with the required specifications as shown hereafter:

Test	Specification	Result
Description		
Appearance	White to off-white powder.	Complies
Solubility	Freely soluble in water, very slightly soluble in chloroform and acetone	Complies
Identifications		
IR spectrum	Complies to the reference substance	Complies
UV spectrum	Complies to the reference substance (The UV spectrum may be omitted if the IR spectrum, the chlorides and the chiral chromatography are carried out.)	Not performed routinely
Chlorides (EU)	Positive	Positive
Chlorides (US)	Positive	Positive
Chiral chromatography (EU/US)	The identification of Levocetirizine 2HCL is demonstrated if retention time does not differ from more than 3.0 % compared with the retention time of the system suitability	Complies
Chiral chromatography (JP)	The identification of Levocetirizine 2HCL is demonstrated if retention time does not differ from more than 3.0 % compared with the retention time of the system suitability	Complies
Appearance of 5% solution	Clear (opalescence lower than T1) and not more intensely colored than YB7	Complies
Water content	Not more than 1.0%	0.1 %
Sulphated ash	Not more than 0.2%	0.1 %
Heavy metals (US)	Not more than 10 ppm	Complies
Heavy metals (EU)	Not more than 10 ppm	Complies
Assay by titration (on anhydrous substance)	99.0% to 100.5%	99.8 %
Assay by HPLC (EU/US) (on anhydrous substance)	98.0% to 102.0%	100.0 %
Assay by HPLC (JP) (on anhydrous substance)	98.0% to 102.0%	99.8 %
Achiral related substances (EU/US)		
(2-(4-((2-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)-acetic acid	Not more than 0.2%	<0.10 %



UCB FARCHIM SA

Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411
CH-1630 Bulle
Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220228
Product Code : CIA30073

Complies with the required specifications as shown hereafter:

Test	Specification	Result
2-(p-chlorobenzhydryl-piperazine)- 2-ethoxyacetamide	Not more than 0.2%	<0.10 %
p-chlorobenzhydrylpiperazine	Not more than 0.2%	<0.10 %
UCB 30462	Not more than 0.2%	<0.10 %
Any unspecified impurity	Not more than 0.1%	Not Quantifiable %
Total of unspecified impurities	Not more than 0.2%	Not Quantifiable %
Total of impurities	Not more than 0.3%	Not Quantifiable %
Achiral related substances (JP)		
(2-(4-((2-chlorophenyl) phenylmethyl)-1-piperazinyl) ethoxy)-acetic acid	Not more than 0.2%	<0.10 %
2-(p-chlorobenzhydryl-piperazine)- 2-ethoxyacetamide	Not more than 0.2%	<0.10 %
p-chlorobenzhydrylpiperazine	Not more than 0.2%	<0.10 %
UCB 30462	Not more than 0.2%	<0.10 %
Any unspecified impurity	Not more than 0.1%	Not Quantifiable %
Total of unspecified impurities	Not more than 0.2%	Not Quantifiable %
Total of impurities	Not more than 0.3%	Not Quantifiable %
Chiral related substance (EU/US)	Not more than 2.0%	0.62 %
UCB 28557		
Chiral related substance (JP)	Not more than 2.0%	0.61 %
UCB 28557		
Residual solvents		
Acetone	Not more than 300 ppm	12 ppm
Toluene	Not more than 10 ppm	<2 ppm
Diisopropylether	Not more than 10 ppm	<2 ppm
Mesityloxyde	Not more than 20 ppm	2 ppm
pH	1.2 to 1.8	1.4
LOD	Not more than 1.0 %	Not performed routinely



UCB FARCHIM SA

Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411

CH-1630 Bulle

Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220228
Product Code : CIA30073

Certification Statement:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including quality control, in full compliance with the GMP requirements of the local Regulatory Authority. The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Manufacturing Date : 20-May-2017

Retest Date : 19-May-2022

This is an electronic signature

Issued By : Carole Merieux
Responsible Person Deputy

Release Date : 12-Jun-2017

Responsible Person : Florian Gurtler

UCB FARCHIM SA Tel: +41 26 919 02 00

08 January 2018

CERTIFICATE OF QUALITY

XYZAL (CIA03691)

5 mg

30 Tablets

complies with the required specifications as shown hereafter:

CERTIFICATE OF ANALYSIS

N° 201701402

UCB SPECIFICATIONS PARAMETERS

SPECIFICATIONS

BATCH: 228834
RESULTS

Appearance

White to off-white, oval film-coated tablet with a Y logo on one side.

Complies

Water content

Max. 6.0% at release

4.4%

Average mass

103 mg \pm 7.5%

102 mg

Uniformity of mass

Percentage deviation : 7.5%
of average mass

-2.0% + 1.6%

Identification

- ucb 28556

Positive

Positive

-Titanium dioxide (E171)^(a)

Positive

N.A.

Assay:

-Levocetirizine

4.75 mg to 5.25 mg/tablet

4.85 mg/tablet

Impurities

Achiral related substance:

p-chlorobenzhydrylpiperazine

Max. 0.3%

<0.10%

p-chlorobenzhydrol

Max. 0.2%

<0.10%

p-chlorobenzophenone

Max. 0.2%

<0.10%

Any unspecified related substance

Max. 0.2%

Not Quantifiable

Total related substance

Max. 0.8%

Not Quantifiable

Chiral related substance:

ucb 28557

Max. 2.0%

0.7%

Dissolution

Q= 75% after 30 minutes
acceptance criteria USP
(limited to stage 2)

94% 97%

100% 95%

98% 96%

Microbiological quality^(b)

Conform to Ph Eur.(5.1.4)

N.A.

^(a)If tested

^(b)Test performed on one out of every ten batches

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Manufacturing date: 11/09/2017

Expiry date : 31/08/2022

Storage conditions : Store below 30°C

Country: Middle East

Dr. Paolo Pizzorni
Pharmacist, Qualified Person



UCB FARCHIM SA
Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411
CH-1630 Bulle
Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220232
Product Code : CIA30073

Complies with the required specifications as shown hereafter:

Test	Specification	Result
Description		
Appearance	White to off-white powder.	Complies
Solubility	Freely soluble in water, very slightly soluble in chloroform and acetone	Complies
Identifications		
IR spectrum	Complies to the reference substance	Complies
UV spectrum	Complies to the reference substance (The UV spectrum may be omitted if the IR spectrum, the chlorides and the chiral chromatography are carried out.)	Not performed routinely
Chlorides (EU)	Positive	Positive
Chlorides (US)	Positive	Positive
Chiral chromatography (EU/US)	The identification of Levocetirizine 2HCL is demonstrated if retention time does not differ from more than 3.0 % compared with the retention time of the system suitability	Complies
Chiral chromatography (JP)	The identification of Levocetirizine 2HCL is demonstrated if retention time does not differ from more than 3.0 % compared with the retention time of the system suitability	Complies
Appearance of 5% solution	Clear (opalescence lower than T1) and not more intensely colored than YB7	Complies
Water content	Not more than 1.0%	0.0 %
Sulphated ash	Not more than 0.2%	0.0 %
Heavy metals (US)	Not more than 10 ppm	Complies
Heavy metals (EU)	Not more than 10 ppm	Complies
Assay by titration (on anhydrous substance)	99.0% to 100.5%	100.1 %
Assay by HPLC (EU/US) (on anhydrous substance)	98.0% to 102.0%	99.6 %
Assay by HPLC (JP) (on anhydrous substance)	98.0% to 102.0%	99.3 %
Achiral related substances (EU/US)		
(2-(4-((2-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)-acetic acid	Not more than 0.2%	<0.10 %



UCB FARCHIM SA
Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411
CH-1630 Bulle
Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220232
Product Code : CIA30073

Complies with the required specifications as shown hereafter:

Test	Specification	Result
2-(p-chlorobenzhydryl-piperazine)-2-ethoxyacetamide	Not more than 0.2%	<0.10 %
p-chlorobenzhydrylpiperazine	Not more than 0.2%	<0.10 %
UCB 30462	Not more than 0.2%	<0.10 %
Any unspecified impurity	Not more than 0.1%	Not Quantifiable %
Total of unspecified impurities	Not more than 0.2%	Not Quantifiable %
Total of impurities	Not more than 0.3%	Not Quantifiable %
Achiral related substances (JP)		
(2-(4-((2-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)-acetic acid	Not more than 0.2%	<0.10 %
2-(p-chlorobenzhydryl-piperazine)-2-ethoxyacetamide	Not more than 0.2%	<0.10 %
p-chlorobenzhydrylpiperazine	Not more than 0.2%	<0.10 %
UCB 30462	Not more than 0.2%	<0.10 %
Any unspecified impurity	Not more than 0.1%	Not Quantifiable %
Total of unspecified impurities	Not more than 0.2%	Not Quantifiable %
Total of impurities	Not more than 0.3%	Not Quantifiable %
Chiral related substance (EU/US)	Not more than 2.0%	0.74 %
UCB 28557		
Chiral related substance (JP)	Not more than 2.0%	0.73 %
UCB 28557		
Residual solvents		
Acetone	Not more than 300 ppm	11 ppm
Toluene	Not more than 10 ppm	<2 ppm
Diisopropylether	Not more than 10 ppm	<2 ppm
Mesityloxide	Not more than 20 ppm	<2 ppm
pH	1.2 to 1.8	1.4
LOD	Not more than 1.0 %	Not performed routinely



UCB FARCHIM SA

Z.I. de Planchy 10, Chemin de Croix Blanche P.O Box 411
CH-1630 Bulle
Switzerland

Certificate of Analysis

Levocetirizine 2 HCl

Batch Number : 220232
Product Code : CIA30073

Certification Statement:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including quality control, in full compliance with the GMP requirements of the local Regulatory Authority. The batch processing and analysis records were reviewed and found to be in compliance with GMP.

Manufacturing Date : 29-May-2017

Retest Date : 28-May-2022

This is an electronic signature

Issued By : Carole Merieux
Responsible Person Deputy

Release Date : 19-Jun-2017

Responsible Person : Florian Gurtler

UCB FARCHIM SA Tel: +41 26 919 02 00