



AbbVie Biotechnology GmbH
Knollstrasse
67061 Ludwigshafen
Germany

Certificate of Analysis

Customer: Chile

SAP Material Number: 20005285

Product Name: HUMIRA 40mg/0.4ml PEN X2
COL/ECU/CHL

Batch Number: 1133313

Expiration Date: 03/2022

List/Drug Code: 000554

LC/SC: B18 / N/A

Manufacture Date: 04/2020

Test/Characteristic	Specification	Result
Appearance Pre-filled syringes with aqueous solution	See Characteristic	Complies
Appearance, Clarity and opalescence Not more opalescent than reference suspension IV	See Characteristic	<= II
Appearance, Color Not more intensely colored than reference solution B7	See Characteristic	<= B8
Identity, Cation exchange HPLC The peak pattern complies with that of the characterized reference standard	See Characteristic	Complies
Purity, First acidic region	<=6 %	3 %
Purity, Second acidic region	<=14 %	11 %
Purity, Sum of lysine variants	>=80 %	84 %
Purity, Peak between lysine 1 and 2	<=3 %	1 %
Purity, Size exclusion HPLC	>=99 %	100 %
Purity, Sterility No evidence of microbial growth is found	See Characteristic	Complies
Purity, Endotoxins: filled syringes	<=20 EU/ml	<20 EU/ml
Potency, In vitro TNF neutralization	80-125 %	102 %
Potency, Lower fiducial limit	>=64 %	101 %
Potency, Upper fiducial limit	<=156 %	104 %
Quantity, Protein content (UV 280nm)	90-110 mg/mL	100 mg/mL
General Tests, pH value	4.9-5.5	5.2
General Tests, Osmolality	260-320 mOsm/kg	293 mOsm/kg
Pharm. Tests, Visible particles The solution is practically free from visible particles	See Characteristic	Complies
Pharm. Tests, Particles >= 10 micrometer	<=6000 Part./d.u.	73 Part./d.u.
Pharm. Tests, Particles >= 25 micrometer	<=600 Part./d.u.	0 Part./d.u.
Pharm. Tests, Extractable volume The volume measured for each container is not less than the nominal volume	See Characteristic	Complies
Drug substance used Adalimumab concentrate batch		1000334795
Bulkware used Humira bulk product		16118LX80
Appearance, Identity pre-filled syringe	See Characteristic	Complies



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Test/Characteristic

A pre-filled syringe containing liquid that is essentially free from visible particles is visible in the windows.

Appearance, Identity autoinjector

Assembled autoinjector is plum and gray with 2 caps (cap 1 = gray, cap 2 = plum) with numbers printed in white and syringe housing body with 2 viewing windows.

Appearance, Identity indicator band

The yellow indicator band is not visible in the windows.

Functional test, Cap 1 removal

Cap 1 including the needle shield must be removed completely, without premature lockout shroud deployment.

Cap 2 removal, Firing mechanism

Firing mechanism does not activate prior to pushing firing button when cap 2 is pulled off.

Functional test, Delivery time

Functional test, Delivered volume

Yellow indicator function

After ejection, the yellow indicator band must be visible in the viewing windows.

Functionality of the lockout shroud

After drug product ejection and removal of the device, the lockout shroud extends and locks over the needle.

Specification

See Characteristic

See Characteristic

See Characteristic

See Characteristic

≤ 10 s

≥ 0.4 ml

See Characteristic

See Characteristic

Result

Complies

Complies

Complies

Complies

4 s

0.4 ml

Complies

Complies

Name of product: HUMIRA 40mg/0.4ml PEN X2 COL/ECU/CHL

Marketing Authorization Number: B-2666

Active Ingredient Strength: ADALIMUMAB 40 MG

Product Dosage Form: AUTOINJECTOR

Package Size: OP2

Name of Authorisation Holder

Address Site: Vetter Pharma-Fertigung GmbH & Co.KG, Schützenstr. 87, 99-101, 88212 Ravensburg, Germany

Manufacturing licence No.: DE_BW_01_MIA_2019_0119/DE_BW_01_Vetter-Schützenstrasse

GMP Certificate No.: DE_BW_01_GMP_2019_0125

Site Address Packaging

Address Site: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany

Manufacturing licence No.: DE_RP_01_MIA_2020_0035/54.3/GMP/ABBVIE/HE/20200720

GMP Certificate No.: DE_RP_01_GMP_2020_0036

Qualified Person Release

Address Site: AbbVie Biotechnology GmbH, Knollstrasse, 67061 Ludwigshafen, Germany

Manufacturing licence No.: DE_RP_01_MIA_2016_0059



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Manufacture Date: 04/2020

GMP Certificate No.: DE_RP_01_GMP_2019_0046

Bulk Product Manufacturer

Address Site: Vetter Pharma-Fertigung GmbH & Co.KG, Schützenstr. 87, 99-101, 88212 Ravensburg, Germany

Manufacturing licence No.: DE_BW_01_MIA_2019_0119/DE_BW_01_Vetter-Schützenstrasse

GMP Certificate No.: DE_BW_01_GMP_2019_0125

Quality Control Bulk Product Manufacturer

Address Site: Vetter Pharma-Fertigung GmbH & Co.KG, Schützenstr. 87, 99-101, 88212 Ravensburg, Germany

Manufacturing licence No.: DE_BW_01_MIA_2019_0119/DE_BW_01_Vetter-Schützenstrasse

GMP Certificate No.: DE_BW_01_GMP_2019_0125

Authorisation Holder and Site Address of Final Quality Control

Address Site: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany

Manufacturing licence No.: DE_RP_01_MIA_2020_0035/54.3/GMP/ABBVIE/HE/20200720

GMP Certificate No.: DE_RP_01_GMP_2020_0036

Specification version used: FMS.R.001115.04 / Vers. 2.0 and FMS.R.000554.01 / Vers. 1.0

Storage condition: +2°C to +8°C, protect from light

Certification statement:

I hereby certify that all manufacturing steps 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 Authorization of the destination country.

This lot has been certified according to Article 51 Directive 2001/83/EC.

Faksimile

(Ratke, Dr., Rolf)
Qualified Person

Released By: Rolf Ratke

Release Date: 17-AUG-2020