

Certificate of Analysis

Product Name: Infliximab

Material Number: 320071

Lot Number: PG1C20210102

Expiry Date: 01-Mar-2024

Specification Version: YBS00582021

Test Description	Specification	Test Result
Peptide Map	Chromatogram should be consistent with reference standard.	Complies
IEX-UPLC	The sample chromatogram should be consistent with reference standard and the relative retention time should be 0.90-1.10 of reference standard.	Complies The relative retention time is 0.99 of reference standard.
cIEF	Electrophoretogram should be consistent with reference standard, the difference of isoelectric point should be within ± 0.1 .	Complies The difference of isoelectric point is 0.0.
Oligosacchrides	Man5 $\leq 10.0\%$	Man5:1.2%
SEC-UPLC	The difference of retention time should be within ± 0.2 min. Based on area normalization method, the percent of major peak area should be NLT 98.0% and the percent of polymer peak area should be NML 2.0%.	Complies main peak 99.6%; HMWS 0.4%

CE-SDS (Reduced)	≥96.0% Main Peak (heavy +light) ≤4.0% NGHC	97.3%; Main Peak (heavy +light) 1.7%; NGHC
CE-SDS (Non-reduced)	The electrophoretogram should be consistent with the reference standard and the percent of major peak area should be NLT 92.0%.	Complies 97.5% Main Peak
IEX-UPLC	acidic peak ≤35.0% main peak ≥ 45.0% alkaline peak ≤25.0% main peak+ alkaline peak ≥ 65.0%	acidic peak 27.3% main peak 54.4% alkaline peak 18.4% main peak+ alkaline peak 72.7%
Host-cell- DNA residue	≤1pg/mg	<0.2pg/mg
HCP	≤100ppm(0.01%)	25.997ppm
Protein A residue	≤50ppm(0.005%)	5.221ppm
Bioassay	80%~120%	102%
Binding Activity	80%~120%	84%
Protein content	20~40mg/ml	29mg/ml
Bacterial Endotoxin (LAL)	<0.16EU/mg	<0.16EU/mg
pH	6.9~7.5	7.1
Osmolality	320~420mOsmol/kg	360mOsmol/kg
Polysorbate 80 content	0.05 ~ 0.15mg/ml	0.08mg/ml



迈博药业
Mabpharm Limited

泰州迈博太科药业有限公司

Taizhou Mabtech Pharmaceutical Co., Ltd.

Microbial limit	$\leq 1\text{cfu}/10\text{ml}$ Total aerobic microbial count;	$< 1\text{cfu}/10\text{ml}$ Total aerobic microbial count;
	$\leq 1\text{cfu}/10\text{ml}$ Mold and Yeast count	$< 1\text{cfu}/10\text{ml}$ Mold and Yeast count

Prepared by/Date:

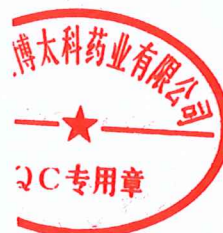


Reviewed by/Date:



Approved by/Date:

邵清 2021.12.27



Certificate of Analysis

Product Name: Infliximab

Material Number: 320071

Lot Number: PG1C20210203

Expiry Date: 13-Mar-2024

Specification Version: YBS00582021

Test Description	Specification	Test Result
Peptide Map	Chromatogram should be consistent with reference standard.	Complies
IEX-UPLC	The sample chromatogram should be consistent with reference standard and the relative retention time should be 0.90-1.10 of reference standard.	Complies The relative retention time is 1.00 of reference standard.
cIEF	Electrophoretogram should be consistent with reference standard, the difference of isoelectric point should be within ± 0.1 .	Complies The difference of isoelectric point is 0.0.
Oligosacchrides	Man5 $\leq 10.0\%$	Man5:1.2%
SEC-UPLC	The difference of retention time should be within $\pm 0.2\text{min}$. Based on area normalization method, the percent of major peak area should be NLT 98.0% and the percent of polymer peak area should be NML 2.0%.	Complies main peak 99.5%; HMWS 0.5%

CE-SDS (Reduced)	≥96.0% Main Peak (heavy +light) ≤4.0% NGHC	97.0%; Main Peak (heavy +light) 1.8%; NGHC
CE-SDS (Non-reduced)	The electrophoretogram should be consistent with the reference standard and the percent of major peak area should be NLT 92.0%.	Complies 97.5% Main Peak
IEX-UPLC	acidic peak ≤35.0% main peak ≥ 45.0% alkaline peak ≤25.0% main peak+ alkaline peak ≥ 65.0%	acidic peak 26.8% main peak 50.9% alkaline peak 22.3% main peak+ alkaline peak 73.2%
Host-cell- DNA residue	≤1pg/mg	<0.2pg/mg
HCP	≤100ppm(0.01%)	29.824ppm
Protein A residue	≤50ppm(0.005%)	5.511ppm
Bioassay	80%~120%	91%
Binding Activity	80%~120%	89%
Protein content	20~40mg/ml	28mg/ml
Bacterial Endotoxin (LAL)	<0.16EU/mg	<0.16EU/mg
pH	6.9~7.5	7.2
Osmolality	320~420mOsmol/kg	357mOsmol/kg
Polysorbate 80 content	0.05 ~ 0.15mg/ml	0.08mg/ml



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Microbial limit	$\leq 1\text{cfu}/10\text{ml}$ Total aerobic microbial count;	$< 1\text{cfu}/10\text{ml}$ Total aerobic microbial count;
	$\leq 1\text{cfu}/10\text{ml}$ Mold and Yeast count	$< 1\text{cfu}/10\text{ml}$ Mold and Yeast count

Prepared by/Date:

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QC专用章

Reviewed by/Date:

岳爱玲 2021.12.27
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Approved by/Date:

邵海 2021.12.27



Certificate of Analysis

Product Name: Infliximab

Material Number: 320071

Lot Number: PG1C20210204

Expiry Date: 19-Mar-2024

Specification Version: YBS00582021

Test Description	Specification	Test Result
Peptide Map	Chromatogram should be consistent with reference standard.	Complies
IEX-UPLC	The sample chromatogram should be consistent with reference standard and the relative retention time should be 0.90-1.10 of reference standard.	Complies The relative retention time is 1.00 of reference standard.
cIEF	Electrophoretogram should be consistent with reference standard, the difference of isoelectric point should be within ± 0.1 .	Complies The difference of isoelectric point is 0.0.
Oligosacchrides	Man5 $\leq 10.0\%$	Man5:1.2%
SEC-UPLC	The difference of retention time should be within $\pm 0.2\text{min}$. Based on area normalization method, the percent of major peak area should be NLT 98.0% and the percent of polymer peak area should be NML 2.0%.	Complies main peak 99.6%; HMWS 0.4%

CE-SDS (Reduced)	≥96.0% Main Peak (heavy +light) ≤4.0% NGHC	96.9%; Main Peak (heavy +light) 1.8%; NGHC
CE-SDS (Non-reduced)	The electrophoretogram should be consistent with the reference standard and the percent of major peak area should be NLT 92.0%.	Complies 97.8% Main Peak
IEX-UPLC	acidic peak ≤35.0% main peak ≥ 45.0% alkaline peak ≤25.0% main peak+ alkaline peak ≥ 65.0%	acidic peak 26.6% main peak 52.1% alkaline peak 21.4% main peak+ alkaline peak 73.4%
Host-cell- DNA residue	≤1pg/mg	<0.2pg/mg
HCP	≤100ppm(0.01%)	18.401ppm
Protein A residue	≤50ppm(0.005%)	4.426ppm
Bioassay	80%~120%	94%
Binding Activity	80%~120%	87%
Protein content	20~40mg/ml	28mg/ml
Bacterial Endotoxin (LAL)	<0.16EU/mg	<0.16EU/mg
pH	6.9~7.5	7.2
Osmolality	320~420mOsmol/kg	365mOsmol/kg
Polysorbate 80 content	0.05 ~ 0.15mg/ml	0.07mg/ml



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Prepared by/Date:

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QC专用章

Reviewed by/Date:

王爱环 2021.12.27
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Approved by/Date:

郭清X 2021.12.27



