MAYOLY CHC
CONSUMER HEALTHCARE

CERTIFICATE OF ANALYSIS / СЕРТИФІКАТ АНАЛІЗУ

PROBIOLOG TRANSIT PLUS 28 STICKS/ ПРОБІОЛОГ® ТРАНЗИТ ПЛЮС 28 СТІКА

Batch n°/ Номер серії : 2555
Manufacturing Date / Дата виробництва :03/09/2025
Best before end of / Придатний до :09/2027

Analysis/Аналіз	Specifications/Специфікації	Results/Результати
PERFORMANCE / ЕФЕКТИВНІСТЬ		
Visual control of powder / Візуальний контроль порошку	White / білого кольору	White/ білого кольору
Water activity / Водна активність	≤ 0.2 Aw ≤ 0.2 водної активності	0.166
PURITY / ЧИСТОТА		
Gluten/ Глютену	<20 ppm	<5 ppm
B.Lactis count/ Кількість біфідобактерій лактіс	≥ 3 $x10^9$ CFU/stick after production ≥ 3 $x10^9$ КУО /стіку після виробництва	1.03 $x10^{10}$ CFU/stick 1.03$x10^{10}$ КУО / стіку
Inulin and fructose polymers / Полімери інуліну та фруктози	5.1 – 6.9 g/stick 5.1- 6.9 г/стіку	5.6 g/stick 5.6 г/стіку
Enterobacteriaceae/ Ентеробактерії	$<10^2$ cfu/ /g $<10^2$ КУО/г	$<10^2$ $<10^2$
Salmonella/ Сальмонела	Absent/25g відсутні/25г	Absent/25g відсутні/25г
E. Coli/ Кишечна палочка	Absent/g відсутні/г	Absent/g відсутні/г
Total aerobic count/ Загальне число життєздатних аеробних мікроорганізмів	$\leq 10^4$ cfu/g $\leq 10^4$ КУО/г	$<10^3$ cfu/g $<10^3$ КУО/г
Total yeast moulds/	$\leq 10^2$ cfu/g	$<10^2$ cfu/g

Вх. № 2016 від 17.02.26 [signature]

Загальне число дріжджових та пліснявих грибів	*≤ 10^2 КУО/г*	*<10^2 КУО/г*

Remarks / Примітки :

☒ *Conforms / Відповідає* ☐ *Not conforms / Не відповідає* *Date / Дата : 18/12/2025*

Signature / Підпис :

Stéphanie Daoust
Quality and Regulatory affairs Manager

MAYOLY CONSUMER HEALTHCARE
6 avenue de l'Europe - B.P 51
78401 CHATOU Cedex
FRANCE

Based on CoA from manufacturer (batch 2555)

Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
(ALSO KNOWN AS PFIZER MANUFACTURING BELGIUM)
RIJKSWEG 12
2870 PUURS – SINT-AMANDS
(FORMERLY KNOWN AS PUURS)
(BELGIUM)
TEL: +32 (0)3890.92.11

Product Name: SOLU-MEDROL 1000MG 1X VIAL+ 15.6ML VIAL POWD AND SOLVENT (BENZYL ALCOHOL (9MG/ML), WFI) FOR SOL. FOR INJECTION (METHYLPREDNISOLONE SODIUM SUCCINATE)

Batch Number: MH1962

Material Number: F000099838

Date of Manufacture: 01-2025

Expiration Date:12-2029

Date COA Generated: 04-2025

Specification Name: P0698001002UA

TEST	METHOD	RESULT	UNIT	LIMITS
11-KMR 21-HS	TM1155A	<= 0.1	%	NMT 0.2 %
17-DESOXY-21-ALDEHYDE	TM1155A	<= 0.1	%	NMT 0.2 % TOR, NMT 0.5 % EOSL
17-KMR	TM1155A	<= 0.1	%	NMT 0.2 %TOR, NMT 0.3 % EOSL
CLARITY	PH EUR	MEETS TEST		NMT REFERENCE II
COLOR OF SOLUTION	PH EUR	MEETS TEST		NMT Y5 (METHOD II)
UNIFORMITY OF DOSAGE UNITS (UDU) BY CONTENT UNIFORMITY (CU)	TM1155A	MEETS TEST		MEETS PH EUR REQUIREMENTS
DESCRIPTION	VISUAL	MEETS TEST		WHITE TO OFF-WHITE CAKE
DIMER	TM1155A	<= 0.1	%	NMT 0.2 %
E MATTOX ALDEHYDE	TM1155A	<= 0.1	%	NMT 0.2 % TOR, NMT 0.3 % EOSL
BACTERIAL ENDOTOXINS	PH EUR	MEETS TEST		MEETS PH EUR REQUIREMENTS (NMT 0.17 EU/MG) AT RELEASE ONLY
METHYLPREDNISOLONE IDENTIFICATION - IR	USP	POSITIVE		POSITIVE
METHYLPREDNISOLONE IDENTIFICATION	TM1155A	POSITIVE		POSITIVE

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Specification Name: P0698001002UA

TEST	METHOD	RESULT	UNIT	LIMITS
LARGEST UNSPECIFIED DEGRADATION PRODUCTS	TM1155A	<= 0.1	%	NMT 0.2 %
LOSS ON DRYING	GP0143	0.4	%	NMT 2.0 %
METHYLPREDNISOLONE ASSAY	TM1155A	1.01	G/CONT	0.95 TO 1.05 G/VIAL (95 % TO 105 %)
MR	TM1155A	1.2	%	NMT 2.7 % TOR, NMT 4.6 % EOSL
MR 17-HS	TM1155A	0.9	%	NMT 1.9 %
PARTICLES >= 10 MCM	PH EUR	17	PART/CONT	MEETS PH EUR REQUIREMENTS
PARTICLES >= 25 MCM	PH EUR	0	PART/CONT	MEETS PH EUR REQUIREMENTS
PH	POTENTIOMETRIC	7.5		7.0 TO 8.0
SOLUBILITY	VISUAL	21	SEC	NMT 60 SECONDS
STERILITY	PH EUR	MEETS TEST		MEETS PH EUR REQUIREMENTS
TOTAL DEGRADATION PRODUCTS	TM1155A	2.2	%	NMT 4.7 % TOR, NMT 7.3 % EOSL
Z MATTOX ALDEHYDE	TM1155A	<= 0.1	%	NMT 0.2 % TOR, NMT 0.4 % EOSL

BATCH: LY0897

Product Name: SOLU-MEDROL 1000MG 1X VIAL+ 15.6ML VIAL POWD AND SOLVENT (BENZYL ALCOHOL (9MG/ML), WFI) FOR SOL. FOR INJECTION (METHYLPREDNISOLONE SODIUM SUCCINATE)

Batch Number: MH1962

Material Number: F000099838

Date of Manufacture: 01-2025

Expiration Date:12-2029

Date COA Generated: 04-2025

Specification Name: P0698001002UA

I HEREBY CERTIFY THAT THE FOREGOING INFORMATION IS TRUSTWORTHY AND ACCURATE. THIS PRODUCT BATCH WAS MANUFACTURED (INCLUDING ITS PACKING/LABELING) AND SUBJECTED TO QUALITY CONTROL AT THE AFOREMENTIONED SITE IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS ESTABLISHED BY THE LOCAL REGULATORY BODY, AS WELL AS IN ACCORDANCE WITH THE SPECIFICATIONS CONTAINED IN THE REGISTRATION FILE OR MARKETING AUTHORIZATION OF THE MANUFACTURING COUNTRY OR IMPORTING COUNTRY, IF THE PRODUCT HAS BEEN IMPORTED, OR IN THE FILE OF SPECIFICATIONS FOR THE STUDIED MEDICINAL PRODUCT. THE RECORDS OF MANUFACTURE, PACKING, AND TESTING HAVE BEEN REVIEWED AND GMP COMPLIANCE ESTABLISHED.

THE COMBINATION OF THE PUURS LOT NUMBER, ITEMNUMBER, SPECIFICATION NAME AND DATE THE COA IS GENERATED ARE CONSIDERED AS THE UNIQUE NUMBER OF CERTIFICATE OF ANALYSE.

BATCH SIZE: 2998

DILUENT USED - LOT NUMBER : MD8113

REGISTRATION NUMBER: UA/2047/01/03

UKRAINE - UA

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: Helena Van Ranst Lot Release Local Timestamp: 29-APR-2025 08:52:48 Server Timestamp: 29-APR-2025 08:52:41

	Certificate of Compliance Manufacturer's Declaration	
Pfizer	PFIZER MANUFACTURING BELGIUM NV (ALSO KNOWN AS PFIZER MANUFACTURING BELGIUM) RIJKSWEG 12 2870 PUURS – SINT-AMANDS (FORMERLY KNOWN AS PUURS) (BELGIUM) TEL: +32 (0)3890.92.11	

Product Name: SOLU-MEDROL 1000MG 1X VIAL+ 15.6ML VIAL POWD AND SOLVENT (BENZYL ALCOHOL (9MG/ML), WFI) FOR SOL. FOR INJECTION (METHYLPREDNISOLONE SODIUM SUCCINATE)

Batch Number: MH1962

Material Number: F000099838

Date of Manufacture: 01-2025

Expiration Date:12-2029

Date COA Generated: 04-2025

Specification Name: P0698001002UA

CERTIFICATE OF QUALITY

MANUFACTURING / QUALITY CONTROL SITE: See Declaration on Manufacturing Sites
LICENCE NUMBER: See Declaration on Manufacturing Sites
GMP CERT. OR REFERENCE NUMBER IN EudraGMP: See Declaration on Manufacturing Sites

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ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: Helena Van Ranst Lot Release Local Timestamp: 29-APR-2025 08:52:48 Server Timestamp: 29-APR-2025 08:52:41

Signature QP Delegate

Jenny Cresens Jenny Cresens
29 Apr 2025 08:23:055-0400

REASON: I approve this document.

186bf8e3-0701-412f-856c-86877ffd956b

Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
(ALSO KNOWN AS PFIZER MANUFACTURING BELGIUM)
RIJKSWEG 12
2870 PUURS – SINT-AMANDS
(FORMERLY KNOWN AS PUURS)
(BELGIUM)
TEL: +32 (0)3890.92.11

Puurs Batch Number: MD8113 Date Generated: 04-2025
Product Name: BACTERIOSTATIC WATER FOR INJECTION 15.6 ML VIAL (0.9% BENZYLALCOHOL)
Material Number: H000203336
Date of Manufacture: 01-2025
Expiration Date:12-2029 Specification Name: P0780029003I

TEST	RESULT	UNIT	LIMITS
BENZYLALCOHOL	9.4	MG/ML	8.1 TO 10.4 MG/ML
DESCRIPTION	MEETS TEST		MEETS TEST: CLEAR, COLORLESS LIQUID WITH A SLIGHT ODOR OF BENZYL ALCOHOL
ENDOTOXINS	MEETS TEST		NMT 0.5 EU/ML
EXTRACTABLE VOLUME	MEETS TEST		MEETS PH EUR REQUIREMENTS
IDENTIFICATION BENZYL ALCOHOL	POSITIVE		POSITIVE
PARTICLES >= 10 MCM	210	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
PARTICLES >= 25 MCM	2	PART/CONT	MEETS CURRENT PH EUR REQUIREMENTS
STERILITY	MEETS TEST		MEETS PH EUR REQUIREMENTS (MEMBRANE FILTRATION)

BATCH: N/A

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.
THIS BATCH OF PRODUCT HAS BEEN FABRICATED/MANUFACTURED, INCLUDING PACKAGING AND QUALITY CONTROL IN FULL COMPLIANCE WITH THE GMP REQUIREMENTS OF THE LOCAL REGULATORY AUTHORITY AND WITH THE SPECIFICATIONS IN THE MARKETING AUTHORISATION OF THE IMPORTING COUNTRY:

UKRAINE - UA

THE BATCH PROCESSING/PACKAGING AND ANALYSIS WERE REVIEWED AND FOUND TO BE IN COMPLIANCE WITH GMP.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Electronic Signature: ARNE POLLET Lot Release Local Timestamp: 26-FEB-2025 10:39:25 Server Timestamp: 26-FEB-2025 10:39:21

Signature QP Delegate Jenny Cresens Jenny Cresens
29 Apr 2025 08:23:058-0400
REASON: I approve this document.

186bf8e3-0701-412f-856c-86877ffd956b