

Batch Certificate Certificate of Analysis / Conformance

MERCK SHARP & DOHME B.V.
WAARDERWEG 39, 2031 BN HAARLEM
THE NETHERLAND S

Batch Number S006968
Primary Pack Batch Number 0000911645
Material 1991809
Product Number 4045
Material Description GARDASIL 0.5ML
10X1DOSE VIAL WHO
Manufacturing Date 11-JUL-2018
Expiry Date 11-07-2021

Disposition: Accepted	
I. van der Heijden	05-APR-2019 10:30:29 EST
<i>Electronic Signature</i>	

Approved under the authority of Executive Director QO / Qualified Person
Dominique Mudde, M.Biotech - Merck Sharp & Dohme BV, Haarlem, The Netherlands

Characteristic	Specification	Result	Pass/Fail
Characteristics	White due to alum suspension, cloudy liquid Conforms to specifications	Conforms	PASS
Aluminum (mg/mL)	0.35 - 0.62 mg/mL	0.43 mg/ml	PASS
Bacterial Endotoxins (EU/mL)	Maximum 10 EU/mL	< 5 eu/ml	PASS
Identity (IVRP)	Presence of the type-specific Virus Like Particles (VLPs) confirmed	Conforms	PASS
In Vitro Relative Potency: Type 6 (U/mL)	Minimum 26 units/mL	36 U/mL	PASS
In Vitro Relative Potency: Type 11 (U/mL)	Minimum 55 units/mL	87 U/mL	PASS
In Vitro Relative Potency: Type 16 (U/mL)	Minimum 53 units/mL	94 U/mL	PASS
In Vitro Relative Potency: Type 18 (U/mL)	Minimum 23 units/mL	42 U/mL	PASS
In Vitro Relative Potency: Total IVRP (U/mL)	Maximum 500 units/mL	258 U/mL	PASS
pH	5.7 - 6.7	6.2	PASS
Sterility	No observed microbial growth	Conforms	PASS
Volume of Fill (mL)	Minimum 0.5 mL	0.6 ml	PASS
Time Out of Refrigeration in Mfg	Max. 3060 minutes	2076 min	PASS
Time Out of Refrigeration in Packaging	Max. 1800 minutes	780 min	PASS
Time Out of Refrigeration in Transport	Max. 120 minutes	120 min	PASS
Time Out of Refrigeration Total	Max. 4980 minutes	2976 min	PASS
Bulk Manufacturing Site		Merck Sharp & Dohme Corp. West Point. US	PASS

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 Dominique Mudde, M.Biotech - Merck Sharp & Dohme BV, Haarlem, The Netherlands

Characteristic	Specification	Result	Pass/Fail
Primary Packaging Site		Merck Sharp & Dohme Corp. West Point. US	PASS

I hereby certify that the above information is authentic and accurate. This batch of product, including intermediates and active substance(s), has been manufactured, including packaging/labeling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications and requirements in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with cGMP. Reported results are obtained directly after manufacturing. This batch has been released in accordance with EC Directive 2001/83/EC. This Certificate of Analysis shows the release specifications.

Packaging Site	Mfg. Auth. Num.	Cert/Eud Num
Packaging Site	MSD B.V. Netherlands, HAARLEM, NL 108958 F	NL/H 17/2002429
Primary Packaging Sites	Merck Sharp & Dohme Corp., West Point PA, US 11365	NL/H 14/1001468
Release Site	MSD B.V. Netherlands, HAARLEM, NL 108958 F	NL/H 17/2002429

Target Country	Moldova
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MERCK SHARP & DOHME CORP.

A SUBSIDIARY OF MERCK & CO., INC., WEST POINT, PENNSYLVANIA 19486

TO WHOM IT MAY CONCERN:

Human Papillomavirus (HPV) Vaccine

GARDASIL®

Product/Material Number 4045 / 2003414

<u>Fill Number</u>	<u>Unlabeled Finish</u>	<u>Date of Manufacture</u>	<u>Total Vials Manufactured</u>
0000855419	0000911645	11 July 2018	802,929

<u>Bulk Number</u>		
Type 6	0000827807	0000841351
Type 11	0000827809	
Type 16	0000817923	
Type 18	0000635369	

Monovalent Bulk Manufacturing	Building 60A (West Point)
Formulation	Building 38
Filling Process	Building 38

I hereby certify that the above batch was manufactured and tested in conformance with Good Manufacturing Practices as outlined in the US Code of Federal Regulations and the standards of the Eudralex Good Manufacturing Practices. Based on the documentation review, this batch meets the quality assurance release requirements at Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., and there are no outstanding quality issues associated with this batch.



Daniel Nugent
Release Coordinator
West Point Quality Operations

12 December 2018
Date

MERCK SHARP & DOHME CORP.

A Subsidiary of Merck & Co., Inc., West Point, Pennsylvania 19486

**Human Papillomavirus (HPV) Vaccine
FINAL CONTAINER PROTOCOL
ADDENDUM**

Human Papillomavirus (HPV) Vaccine

Lot Number : 0000855419 / 0000911645

Manufacturing Date: 11-July-2018

TEST	SPECIFICATION	RESULT
Form:	Liquid	Conforms
Color :	White due to alum suspension	Conforms
Appearance :	Cloudy	Conforms

Signature



Date

12 December 2018