



Bayer Oy Pansiontie 47 FI-20210 Turku Finland		Certificate of Analysis		Page: 1 of 3 Date: 2021-10-22
Material: 86996790		MIRENA 1X1 EVO EG		
Batch: TU0376P Date of manufacture: 2021-05-26 Expiry date: 2024-05-31		Country: Egypt		
From material: 83033836 Batch: TU034D1 Inspection lot: 040002415967		MIRENA EVO STERILIZED EXT.		Insp. instruction: P.5.2.01 - 5 Specification: P.5.1.01 - 5
Inspection	Acceptance criterion	UoM	Result	
Appearance	must comply		complies	
Formulation	Intrauterine system		Intrauterine system	
Surface property	free from visible impurities		free from visible impurities	
Colour of hormone sleeve	white to nearly white		nearly white	
Identity (TLC)	must comply		complies	
Sum of all impurities (TLC)	max. 2.0	%	0.7	
Ethylene oxide	max. 5	ppm	1	
Ethylene chlorohydrin	max. 10	ppm	1	
Breaking force	min. 12	N	27 25 27 24 24 26 26 26 25 28	
Breaking force, 10 s.u. no.o.single val.	min.9 s.u. with min.12 N		complies	
Breaking force, 10 s.u. no.o.single val.	10 s.u. with min.9 N		complies	
Breaking force, 20 s.u. no.o.single val.	min.19 s.u. with min.12 N		---	



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Inspection	Acceptance criterion	UoM	Result	
Assay of system	47 - 58	mg	52 53 53 53 54 54 53 53 54 53	
Uniformity of content, 10 s.u.	min.9 s.u. in 47-58 mg		complies	
Uniformity of content, 10 s.u.	10 s.u. in 45-60 mg		complies	
Uniformity of content, 20 s.u.	min.19 s.u. in 47-58 mg		---	
Uniformity of content, 20 s.u.	20 s.u. in 45-60 mg		---	
Release rate during 24 h, 6 s.u.	15 - 30	µg	21 21 21 21 21 21	
Sterility	sterile		sterile	

I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full conformation with the GMP requirements of the local Regulatory Authority and with the local Marketing Authorization specifications of the destination countries (s) / product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in conformation with GMP. This document is signed by Qualified Person.



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Comment:	N/A	

Batch release electronically signed:

Heini Lahti (GLXMH)

Date/time:

2021-10-21 07:41:52 p.m. EET (UTC + 2 hours)

Inspection lot:

040002444604