



S.C. PASTEUR – FILIALA FILIPESTI S.R.L.
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APROVED,
Quality Control Manager
Bancila Dorina

CERTIFICATE OF ANALYSIS

FP No. 393 / 26.02.2018

Product name: PROGESTIN - tablets
Manufacturer: S.C. PASTEUR FILIALA FILIPESTI SRL
Batch no: 024801
Manufacturing date: 02.2018
Expiry date: 01.2020

Parameters	UM	Limits	Results
Appearance	-	Uncoated tablets, with uniform appearance, disc-shape, flat surface or lenticular, homogenous and compact structure, intact edges, white colour, odorless, bitter taste	Complies
Average weight	mg/tablet	90 – 110 (100±10%)	100
Disintegration	Min.	Max 15	1
Friability	%	Max 1	0.1
Identification , Inactive Components	-	Positive Test	Complies
Identification , Active Substance	-	Positiv Test	Complies
Assay, Active Substance	mg/tablets	4.75 – 5.25 (5.00±5%)	4.94
Microbiological quality			
TAMC	CFU/g	Max.10 ³	<1
TYMC	CFU/g	Max.10 ²	<1
<i>Escherichia coli</i>	CFU/g	Absent	Absent
Packing	Tablets/bottle Tablets/blister Blister/box	20, 30, 50, 100 10 2, 10	10 2

Conclusions: The analysed product complies with the quality specifications no. QS-CA-FP-178

TESTED BY,
Quality Analyst: Turcu Adriana

VERIFIED,
Head Laboratory: Brotac Ioneia



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DECLARATION OF CONFORMITY

No. 402 date 26.06.2017

We, hereby, "PASTEUR – FILIPESTI SUBSIDIARY, Ltd.", located in Romania, Filipestii de Padure, 944, Principala Street, Prahova department, registered in Trade Register at number J29 / 501 / 06.07.1999, VAT No. RO11928947 / 08.08.2002, we assure, guarantee and declare on own liability, according to Art. 4 from Government Decision no. 1022 / 2002 as:

PRODUCT: PROGESTIN– tablets, 2 blisters x 10 tablets

BATCH: 024801

EXPIRY DATE: 01.2020

to which this declarations relates, is not health, safety and life-threatening, does no have negative impact on the environment, when used as directed in the original packaging and is in accordance whith the quality specification No. **QS – QA – FP – 178**

Marketing conditions of use are in accordance with the approved technical dossier Institute for Control of Biological Products and Veterinary Medicines within NATIONAL SANITARY VETERINARY AND FOOD AND SAFETY AGENCY.

QUALIFIED PERSON,
Chem Andreea Moldovan

