



S.C. PASTEUR – FILIALA FILIPESTI S.R.L.
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APROVED,

Quality Control Manager
Idomir Liliana

CERTIFICATE OF ANALYSIS

FP No. 2389 / 24.10.2017

Product name: **PROGESTIN - tablets**
Manufacturer: **S.C PASTEUR FILIALA FILIPESTI SRL**
Batch no: 015941
Manufacturing date: 10.2017
Expiry date: 09.2019

Parameters	UM	Limits	Results
Appearance	-	Uncoated tabletes, 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%)	102
Disintegration	Min.	Max. 15	1
Friability	%	Max.1	0.1
Identification , Inactive Components	-	Positive Test	Complies
Identification , Medroxyprogesterone Acetate	-	Positiv Test	Complies
Assay, Medroxyprogesterone Acetate	mg/tablets	4.75 – 5.25 (5.00±5%)	4,80
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 x 20, 30, 50, 100 tablets Box x 10 bl x 10 tablets Box x 2 bl x 10 tablets	2 blisters x 10 tablets

Conclusions: The analysed product complies with the quality specifications no. **QS-CA-FP-178** and can be released on market.

TESTED BY,
Quality Analyst: Ionescu Ana-Maria

VERIFIED,
Lab. Manager: Dinu Ionela



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DECLARATION OF CONFORMITY

No. 2562 date 24.10.2017

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 for veterinary use – 2 blisters x 10 tablets

BATCH: 015941

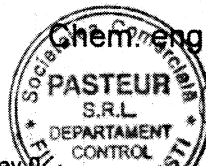
EXPIRY DATE: 09.2019

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. eng. Liviu Moraru



COD: PF-POP-038-01 ed.1/rev.0

VAT #: RO 11928947, IBAN: RO44 RNCB 0072 0496 9042 0001