

	Certificat de Libération <i>Release certificate</i>		1/1
	DOCUMENT N°: FOR0051		Version 08
	Date d'application : 25/01/2017 Doc de Référence : SOP0009		

PRODUIT/PRODUCT : Progestérone 200 mg EFFIK soft capsule

Présentation <i>Designation</i>	Pays <i>Country</i>	N° d'AMM <i>Authorisation Nbr</i>	Code EFFIK <i>EFFIK Id</i>	
PROGEVA 200 B30	Chili	F-23830/18	91000726	☒
PROGEVA 200 B4 sample	Chili	F-23830/18	91000727	☐

Numéro de lot/batch number :

PRODUIT FINI/FINISH PRODUCT : 18K21

PRODUIT VRAC/BULK PRODUCT : QB139527/1

DATE DE FABRICATION/MANUFACTURING DATE: 11/2018

DATE DE PEREMPTION/EXPIRY DATE : 11/2020

QUANTITE LIBEREE/RELEASED QUANTITY:

9 992 BOITES/box of de 30 unités/units

☒ **Aucune deviation Majeure/Critique / No Major/Critical deviation**

☐ **Déviati(n)s Critique(s)/Majeure(s)* étudiée(s) et clôturée(s) / Critical/Major deviation reviewed and closed. *Ref:.....**

DECISION : LIBERE / RELEASED



REFUSE/ REFUSED



Le Pharmacien Responsable des laboratoires EFFIK certifie que ce lot a été fabriqué, conditionné et contrôlé conformément aux spécifications du dossier d'AMM et aux exigences de la Législation pharmaceutique notamment les Bonnes Pratiques de Fabrication Européennes en vigueur et son annexe 16.

Qualified Person for laboratory EFFIK, certifies that the batch has been manufactured, packaged and controlled in accordance with marketing authorization and compliance with European Good Manufacturing Practices, annex 16 of cGMP and pharmaceutical legislation.

Date : 21/03/2019

Nom : Axelle DEJOUX
Pharmacien Responsable

Nom : Céline GNAKAMENE
ou Pharmacien Responsable Intérimaire

**Certificate of Analysis for Finished Product****Progesterone 200mg – Soft capsules**

Presentation :	PROGEVA 200 mg	Reference :	91000726
	Chili		
Batch number :	18K21	Subcontractor 1 :	CAPSUGEL
Bulk number :	QB139527/1	Subcontractor 2 :	DIEPHEZ
Manufacturing date :	11/2018	Subcontractor 3 :	EUROFINS
Expiry date :	11/2020	Monograph :	Intern

Test parameter	Specification	Result
Appearance	Whitish, ovoid soft Capsules containing a thick whitish suspension	Complies
Average mass - capsule	725.0 mg $\pm$ 5% (689.0 to 761.0 mg)	720,8
Average mass - contents	500.0 mg $\pm$ 5% (475.0 to 525.0 mg)	495,3
Uniformity of mass	The individual weight of no more than 2 capsules deviates from the average weight by more than $\pm$ 7.5%. None deviates more than $\pm$ 15% of the average weight.	Complies
Disintegration time	$\leq$ 30 minutes	12 min 14 s
Loss on drying (shell)	$\leq$ 8.0 %	4,6
Progesterone identification (TLC)	Positive (identical to reference)	Positive
Progesterone identification (HPLC)	Positive (identical to reference)	Positive
Progesterone assay (HPLC)	200 mg (190.0 – 210.0 mg) / Soft Capsule (95 – 105%)	201,5

Related Substances (HPLC)		
Impurity B	$\leq$ 0.5%	Not detected
Impurity C	$\leq$ 0.5%	Not detected
Any other unknown impurity	$\leq$ 0.2%	$\leq$ 0,1
Total impurities	$\leq$ 1.0%	0,1

Microbial contamination		
TAMC	$\leq 10^2$ CFU/g	<10
TYMC	≤ 10 CFU/g	<10
E. coli	Absence/g	Absence
P. aeruginosa	Absence/g	Absence
S. aureus	Absence/g	Absence
C. albicans	Absence/g	Absence

PACKAGING CONTROL			
Box of 30 capsules	☒	Conform : ☒	Non Conform : ☐
Box of 4 capsules	☐	Conform : ☐	Non Conform : ☐

Date :	Conform : ☒	Non conform : ☐
	Accepted : ☒	Refused : ☐

Name : Visa :