

CERTIFICATE OF ANALYSIS

Product: Hedylon 5mg **Batch No.:** 1906312
Dosage form: tablets **PV-Nr.:**
Manufac. Date: 10.06.2019 **Expiry Date:** 05/2021

Parameter	Specification	Result
Appearance	White round tablets with "5" engraved on one side and a cross on the other side	conforms
Diameter	6.50 ± 0.20 mm	6.58 mm
Thickness	2.80 ± 0.30 mm	3.00 mm
Average mass	100 mg/tablet ± 4 % (96 – 104 mg/tablet)	100 mg/tablet
Uniformity of dosage units	Acceptance value ≤ 15.0	4.5
Hardness	NLT 2.0 kp	3.4 kp
Disintegration time	≤ 15.0 minutes	<2 min
Dissolution	after 15 min ≥ 80 %	92.0 %
Identity		
Prednisolon (HPLC)	Retention time of the principal peak in the chromatogram obtained with the test solution corresponds to that of the reference solution	conforms
Assay (%)		
Prednisolon (HPLC)	95.0 – 105.0 %	96.5 %
Purity		
Each single impurity	≤ 1.0 %	0.5 %
Total impurities	≤ 3.0 %	0.8 %
Microbial purity cat. 3A*		
TAMC	max. 10 ³ cfu/g	< 10 cfu/g
TYMC	max. 10 ² fu/g	< 10 fu/g
Escherichia coli	absent/g	absent/g

"The finished product has been tested in accordance with the testing instruction and is of the required quality"

Date: 2019-09-19

- Head of Quality Control -

Along with you



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BATCH CERTIFICATE FOR MEDICINAL PRODUCTS

CERTIFICADO DE LOTE PARA MEDICAMENTOS

CODE / CÓDIGO	PA7051/RO0000
NAME / NOMBRE	HEDYLON 5 mg 100 Tablets
DOSAGE FORM / FORMA FARMACEÚTICA	Comprimidos
BATCH NUMBER / NÚMERO DE LOTE	1906312
UNITS / UNIDADES	1.100 UN
MANUFACTURING DATE / FECHA FABRICACIÓN	06/2019
EXPIRY DATE / FECHA CADUCIDAD	05/2021
DESTINATION COUNTRY / PAÍS DE DESTINO	RUMANIA REF 19/207

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Por la presente, certifico que todas las etapas de fabricación de este lote de producto terminado se han realizado en total cumplimiento con los requisitos de las NCF de la UE y con los requisitos de la Autorización de Comercialización del país de destino.

ÀNGELS GARCÍA TOBAJAS

Deputy Qualified Person / Persona Cualificada Suplente
INDUSTRIAL VETERINARIA, S.A.

Esplugues de Llobregat (Barcelona), 24 de Octubre de 2019