

CERTIFICATE OF ANALYSIS

Product:	Hedylon 25mg	Batch No.:	1906296
Dosage form	tablets	PV-Nr.:	
Manufac. Date:	11.06.2019	Expiry Date:	05.2021

Parameter	Specification	Result
Appearance	White round tablets with "25" engraved on one side and a cross on the other side	conforms
Diameter	11.0 ± 0.20 mm	11.1 mm
Thickness	5.00 ± 0.30 mm	5.00 mm
Average mass	500 mg/tablet ± 3 % (485 – 515 mg/tablet)	502 mg/tablet
Uniformity of dosage units	Acceptance value ≤ 15.0	3.2
Hardness	NLT 4.0 kp	5.8 kp
Disintegration time	≤ 15 minutes	<1 min
Dissolution	after 15 minutes ≥ 80 %	93.3 %
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 %	98.1 %
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 cfu/g	< 10 cfu/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