

CERTIFICATE OF ANALYSIS

Product:	Hedylon 5mg	Batch No.:	1906294
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	4.4
Hardness	NLT 2.0 kp	3.6 kp
Disintegration time	≤ 15.0 minutes	<2 min
Dissolution	after 15 min ≥ 80 %	101.7 %
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 %	98.3%
Purity		
Each single impurity	≤ 1.0 %	0.5 %
Total impurities	≤ 3.0 %	0.7 %
Microbial purity cat. 3A*		
TAMC	max. 10 ³ cfu/g	< 10 cfu/g < 10 fu/g absent/g
TYMC	max. 10 ² fu/g	
Escherichia coli	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