

Certificate of Analysis

Product name: Prednisolonum
Batch number: 19E28-B14-192090
Base unit: 5g
Expiration date: 22.03.2022
Quality: Ph.Eur.
Manufacturing date: 14.08.2019
Inspection report no.: INS-19-02737
IIN: 100940-112-91

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, crystalline, hygroscopic powder	conform		
Identification A	acc. to Ph. Eur.	conform		
Identification B	acc. to Ph. Eur.	conform		
Particle size	99% < 25 µm / 90% < 10 µm	conform		
Specific optical rotation	+113 - +119	+116,77		
Related substances	Impurity A: max. 1,0% Impurity B: max. 0,3% Impurity C: max. 0,3% Impurity F: max. 0,5% Impurity J: max. 0,3% Unspecified impurities: max. 0,10% Total impurities: max. 1,5%	0,34 0,06 0,05 <0,05 0,08 0,05 0,05	%	
Loss on drying	max. 1,0%	0,15	%	
Assay	96,5 – 102,0%	99,46	%	
Elemental impurities	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory: Fagron Poland

Release:
 Dorota Sutkowska
 Qualified Person



Fagron sp. z o.o.
Dorota Sutkowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 29.08.2019

Conclusion: Approved