

## Certificate of Analysis

**Product name:** Hydrocortisone  
**Batch number:** 19E28-B05-194509  
**Base unit:** 25g  
**Expiration date:** 28.02.2023  
**Quality:** Ph.Eur.  
**Manufacturing date:** 24.09.2019  
**Inspection report no.:** INS-19-02676  
**IIN:** 100547-112-91

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, crystalline powder	conform		
Particle size	99% < 25µm / 90% < 10µm	conform		
Identification A	acc. to Ph. Eur.	conform		
Identification B	acc. to Ph. Eur.	conform		
Specific optical rotation	+162 - +168	+162,94		
Related substances	impurity C: max. 0,5%	0,06	%	
	impurity D: max. 0,5%	<0,05		
	impurity E: max. 0,5%	0,0		
	impurity I: max. 0,5%	0,0		
	impurity G: max. 0,4%	0,10		
	impurity F: max. 0,3%	<0,05		
	impurity A: max. 0,2%	<0,05		
	impurity B: max. 0,2%	0,0		
	impurity H: max. 0,15%	0,0		
	impurity N: max. 0,15%	<0,05		
	unspecified impurities: max. 0,10%	<0,05		
	total: 2,0%	0,16		
Loss on drying	max. 1,0%	0,14	%	
Assay Hydrocortisone	97,0 – 103,0%	101,13	%	
Metallic residues	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		
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: 07.10.2019

Conclusion: Approved