



<b>Article</b>	<b>2272</b>	<b>Hydrocortisonacetat, mikronisiert, API</b>
<b>Synonym</b>		<b>Hydrocortisoni acetat (mikrobielle Herkunft)</b>
<b>Synonym</b>		<b>Hydrocortisone acetate, micronized, API</b>
<b>Batch</b>	<b>170862</b>	
<b>Specification</b>	<b>PH.EUR. 8.7</b>	
<b>Expiry date</b>	<b>02.2020</b>	

Test	Specification	Result
Characters	In accordance	Complies
-Appearance	In accordance	Complies
-Solubility	In accordance	Complies
Identification	In accordance	Complies
-IR spectrophotometry	In accordance	Complies
-B	In accordance	Complies
-Raman spectrophotometry	In accordance	Not carried out
Tests	In accordance	Complies
-Specific optical rotation	+158 - +167	+165
-Related substances	In accordance	Complies
- Impurity C	Max 0,6 %	Max 0,05 %
- Impurity A	Max 0,5 %	Max 0,05 %
- Impurity B	Max 0,3 %	0,09 %
- Impurity D	Max 0,3 %	Max 0,05 %
- Impurity E	Max 0,3 %	0,09 %
- Impurity G	Max 0,15 %	Max 0,05 %
- Unspec. impurity	Je max 0,10 %	Je max 0,05 %
- Sum of all imp.	Max 1,5 %	0,30 %
-Loss on drying	Max 0,5 %	0,05 %
Assay	97,0 - 102,0 %	99,33 %
Correction factor weighing (f, NRF)	*****	1,007
Complies specification	*****	Yes



## Certificate of analysis

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Test	Specification	Result
GMP-conform		
Release date	12.04.2017	Head of Quality Control
Manufacturer	Henan Lihua Pharmaceutical CO. LTD.	
Manufacturer Batch	K06M20170207M	
Manufacturer City	455 000 Anyang, Henan Province Anyang	
Manufacturer street	Middle of Huanghe Street, Hi-tech Industry Development Z.	
Manufacturer Country	China	

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