TIANJIN JINJIN PHARMACEUTICAL CON LTD. CERTIFICATE OF ANALYSIS No.8 of Jingfu Road, Industrial Zone of Zhangjiawo Town, Xiging District, Tianjin, China

Tel:+86	22 87982602	Fax: 186 22 87982950 Analytical No.:
2022-002	下一元沙	Analytical No.:
Hydrocorti	sone m	12:00

Product Name:	my occo	City	
Batch No.:	TA0393	Manuf. Date:	2021.12.21
Quantity:	40Kg	Retest Date:	2024.12.20
Package:	drum or carton	Report Date:	2022.01.11
Items	Requirements		Results
Appearance (Ph.Eur.)	a white or almost white, crys	talline powder	White crystalline powder
Solubility (Ph.Eur.) (annual)	Practically insoluble in water soluble in acetone and in etha cent), slightly in methylene c	anol (96 per	Complies
Identification			(Y) '
 A. Infrared absorption (Ph.E) 			Complies
B. HPLC (Ph.Eur.)	meets the requirement		Complies
A. Infrared Spectroscopy (US	SP) meets the requirement		Complies
B. UV Spectroscopy (USP)	meets the requirement		Complies
Specific optical rotation			
(Ph.Eur.)	+162° to +168° (dried substa	ince)	+165.4°
(USP)	+150° to +156°		+153.7°
Loss on drying			
(Ph.Eur.)	maximum 1.0%		0.04%
(USP)	NMT 1.0%		0.03%
Residue on ignition (USP)	NMT 0.5%		0.00%
Related substances (Ph.Eur.)		7	
impurity D RRT 0.2	not more than 0.5%	×	ND
impurity H RRT 0.3	not more than 0.15%		ND .
impurity I PPT 0.5	not more than 0.5%		ND

	impurity I	RRT 0.5	not more than 0.5%	ND
	impurity G	RRT 0.8	not more than 0.4%	0.08%
	impurity E	RRT 0.86	not more than 0.5%	ND
		RRT 0.96	not more than 0.2%	0.05%
		RRT 1.1	not more than 0.2%	ND
		RRT 1.4	not more than 0.3%	ND
		RRT 1.5	not more than 0.5%	0.05%
		RRT 1.7	not more than 0.15%	ND
Any unspecified impurity		ed impurity	not more than 0.10%	ND
	Sum of impurities		not more than 2.0%	0.18%
Or	ganic impuritie			
	Individual imp		NMT 0.5%	0.11%
			NT (T 2 00/	0.270/

Organic impurities (USP)		
Individual impurities	NMT 0.5%	0.11%
Total impurities	NMT 2.0%	0.37%
Assay		
UV Absorption (Ph.Eur.)	97.0% to 103.0% (dried substance)	100.6%
HPLC (USP)	97.0% - 102.0% on the dried basis	99.8%
Residual solvent(In-house)		
Methanol	not more than 3000ppm	71ppm
Ethanal	not more than 2000nnm	not datast

not detect out Ethanol not more than 2000ppm Acetone not more than 5000ppm not detect out DMF not more than 880ppm not detect out not detect out Methylene chloride not more than 600ppm Particle size(In-house) 90% not more than 15 microns Complies

CONCLUSION: THE PRODUCT CONFORMS TO Ph.Eur.9/USP 41

Responsible Person:

Report No .:

24.01.13

Checker: 基版伟 Date:

201,13

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