

Certificate of Analysis

Product Name	Clobetasol Propionate	Manufacture Date	Oct.22, 2020
Batch Number	KN201022	Analysis Date	Oct.24, 2020
Batch Quantity	105kg	Expiration Date	Oct.21, 2023

Test	Specifications		Result
Assay(HPLC,basis on drying)	97.0~102.0%		99.4%
Appearance	White or almost white crystalline powder		almost white crystalline powder
Solubility	Practically insoluble in water,slightly soluble in benzene and diethyl ether ,sparingly soluble ethanol, soluble in acetone and in dimethyl sulfoxide, in chloroform, in methanol and in dioxane		Complies
Identification (IR)	Complies with the Standard		Complies
Melting point	about 196℃		194.0~195.0℃
Loss on drying	Max.2.0%		0.07%
Residue on ignition	max. 0.1%		0.06%
Heavy Metals	max.20ppm		Complies
Related Substances (HPLC)	-Singel impurity	N.m.t 1.0%	0.39%
	-Sum impurity	N.m.t 2.5%	0.46%
Organic volatile impurities			
As	<3ppm		Complies
THF	Not more than 720ppm		Complies
Methanol	Not more than 3000ppm		Complies
DMF	Not more than 880ppm		Complies
Pyridine	Not more than 200ppm		Complies
Dichloromethane	Not more than 600ppm		Complies
Ethanol	Not more than 5000ppm		Complies
Acetone	Not more than 5000ppm		Complies
Conclusion:The test product complies with the requirements of USP41.			

Packing description	1kg/1tin/1box
Storage	Preserve in tight, light-resistant containers.
Shelf life	3 years when properly sored