

Shaanxi greenyo biotech co., ltd

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CERTIFICATE OF ANALYSIS

Product	Retinoic acid/Tretinoin		
Batch No.	201110	Packing	25kg/Drum
Quantity	100kg	Mgf. Date	Nov.10,2020
Analysis Reference	USP40	Expire Date	Nov.09,2022
Items & Results			
Item	Spec.		Result
Appearance	A yellow or light-orange, Crystalline powder		Yellow crystalline powder
Identification	The IR adsorption spectrum should correspond with reference spectrum		conform
	Should exhibits maximum absorption at 352mm		conform
Loss on drying	$\leq 0.5\%$		0.07%
Residue on ignition	$\leq 0.1\%$		0.03%
Heavy metals	$\leq 0.002\%$		$< 0.002\%$
Related substances (Reporting threshold 0.05%)	Isotretinoin	$\leq 5.0\%$	$< 0.04\%$
	Impurity G	$\leq 0.2\%$	$< 0.05\%$
	Single unknown impurity	$\leq 0.10\%$	$RRT \approx 0.91 < 0.05\%$
	Total impurities (Except Isotretinoin)	$\leq 0.5\%$	0.01%
Residual solvents	Acetaldehyde	$\leq 15\text{ppm}$	$< 15\text{ppm}$
	Ethyl acetate	$\leq 5000\text{ppm}$	865ppm
Microbiolo gical limit tests	Bacteria	$\leq 100\text{CFU/g}$	$< 20\text{CFU/g}$
	Molds and yeasts	$\leq 100\text{CFU/g}$	$< 20\text{CFU/g}$
	Staphylococcus aureus and P.aeruginosa	Absent	Absent
Assay		98.0%~102.0%(dried substance)	99.6%
Conclusion		Conform to USP40	
Analyst		Supervisor of QC	