

瑾岚医药技术开发有限公司

JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED Hangzhou ROYAL Import & Export Co.,Ltd.

Certificate of Analysis

Product name	Alfacalcidol		
Batch No.	18RY101501	CAS No.	41294-56-8
Mfg. Date	2018.10.15	Exp. Date	2021.10.14
Standard	EP8	Quantity	1KG

Tests	Specifications	Result		
Appearance	White to off white crystal	Conforms		
Identification	Infrared spectrum corresponds to that of the standard preparation	Conforms		
	UV max peak:262~266nm	263nm		
	The principal peal in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution	Conforms		
Solubility	Practically insoluble in water, freely soluble in alcohol(96%),soluble in fatty oils	Conforms		
Related compounds	Triazoline adduct of pre-alfaclidol ≤0.5%	Conforms		
	Trans- alfaclidol≤0.5%	Conforms		
	1β - alfaclidol≤0.5%	Conforms		
	Unknown single impurity≤0.1%	Conforms		
	Totally impurities≤1.0%	0.32%		
Assay	97.0%~102.0%	99%		
Purity	≤99.0%	99.68%		
Storage:In N2, air/light free, under 2~8oC.				
Conclusion : Conforms to EP8 standard				

Tested by: Alice

Checked by: Penny

Approved by: Michelle

Add: Room 606, Fuyi Center, #298 Quanfuqiao Road, Jianggan Area, Hangzhou, ChinaTel: 0086-571-85829052-801/802Fax: 0086-571-85829153Email:sales06@royalpharms.comHttp://www.royalpharms.com