



Sichuan Yuxin Pharmaceutical Co.,Ltd

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Certificate of Analysis

Product Name	Vitamin D2 /Ergocalciferol		
Batch Number	150503	Potency	40,000,000IU/ g
Analysis Date	21 st ,May,2015	Report Date	22 nd ,May,2015
Analysis Based on	IP/USP		
Product Manufactured by	Sichuan Yuxin Pharmaceutical Co., Ltd .	Product Provided by	Sichuan Yuxin Pharmaceutical Co., Ltd .
Product Quantity	50kgs		
Manufactured Date	20 th ,May,2015	Expiry Date	19 th ,May,2017

Items	Standard	Analyzed Results
Description	Should be a white needle-shape crystal or white crystal powder ; give out no smell , no taste ; be easy to lose activity in air or light .	White crystal powder without any smell or taste .
Identification	1. Dissolve about 0.5mg of vitamin D2 into 5ml chloroform, add 0.3ml acetic anhydride and 0.1ml sulfuric acid, shake and mix vigorously. The mixture is initially produced bright red color , and then rapidly changes violet and finally blue to green .	Positive reaction
	2. The infrared absorption spectroscopy should be in according with spectrum of comparison	The infrared absorption spectrum of the sample is in according with the standard
Examination	Dissolve 10mg of vitamin D2 into 2ml of 90% ethanol, add 2ml solution of digitalis saponin and incubate for 18 hours. No precipitation or cloud should be observed.	Passed
Melting Range	Between 115°C and 119°C	115.7°C
Specific Rotation	Between +103 ° and +106 °	+105.5 °
Solubility	Freely soluble in alcohol	Complies
Reducing Substances	<20ppm	Complies
Ergosterol(By TLC)	The principal spot in the chromatogram obtained with the test solution is initially orange-yellow and then becomes brown.In the chromatogram of the test solution,any slowly appearing violet spot(corresponding to ergosterol)immediately below the principal spot is not more intense than the spot in the chromatogram obtained with reference solution(b)(0.2%).There is no spot in the	Complies



	chromatogram of the test solution that does not correspond to one of the spots in the chromatograms of reference solutions(a)and (b).	
Organic Volatility Impurities	Corresponding using method IV(467)	Complies
Assay	Between 97 % and 103 %	98.0%
Store Condition	Store in airtight container ,under nitrogen,protected from light,At a temperature between 2°C-8°C	
Conclusion	The sample is in accordance with IP/USP	

Manager of QC: 何明

Examiner: 胡阿忠

Analyst: 王承

