



C87-2

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**D.K. Pharmachem Pvt. Ltd.**  
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**CERTIFICATE OF ANALYSIS OF WORKING STANDARD**

<b>Product Name : Calcitriol BP</b>			
Batch No	: 16CCT009	WS No.	: WRS-013
Date of Preparation	: 29/12/2016	Valid up to	: NOV-2018

SR. No.	TESTS	SPECIFICATIONS	RESULTS
1	Description	White or almost white crystals.	White crystals
2	Solubility	Practically insoluble in water, freely soluble in ethanol (96 %), soluble in fatty oils.	Practically insoluble in water, freely soluble in ethanol (96%), soluble in fatty oils.
3	Identification A) IR B) HPLC	A) IR – Concordant with RS B) The principal peak in the chromatogram obtained with the test solution is similar in retention time in the chromatogram obtained with reference solution (a).	A) IR – Concordant with RS B) Complies
4	Related Substances Impurity A Impurity B Impurity C Unspecified Impurity Sum of the Related Substances	Not more than 0.5 % Not more than 0.5 % Not more than 0.5 % Not more than 0.1 % Not greater than 1.0 %	Not Detected Not Detected Not Detected 0.05% 0.08%
5	Assay (by HPLC)	97.0 % - 103.0 %	98.57%

Remarks: The Batch complies with respect to the BP Specification.

Storage: Under nitrogen, in an air tight container, protected from light, at a temperature of 2°C to 8°C

	Checked By	Approved By
<i>(P)</i> 29/12/2016	<i>Quasar</i> 29/12/2016	<i>Varsha</i> 29/12/2016
Mr. Kishor Mahajan	Mr. Nandkishor Nabar	Mrs. Varsha Ambre
QC- Officer	AGM- Quality Control	Manager- Quality Assurance

Facilities: F 32, W - 7 & 4 / 5 / 6, MIDC, Badlapur, Thane - 421 503, Maharashtra, INDIA. Tel : 91 251 2690 111, Fax : 91 251 2690 366  
E mail : dkc@dkpharmachem.com, Web : www.dkpharmachem.com, CIN NO.: 11 - 53428 of 1989

Marketing : 606 / 607, Gateway Plaza, Hiranandani Gardens, Powai, Mumbai - 400 076, INDIA. Tel : 91 22 4245 3211, 3212  
E mail : marketing@dkpharmachem.com, Fax: 91 22 4215 3114

