

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Calcitriol

Batch No.: DR20131023	Piece: 2.52kg
Manufacture Date: 2013.10.23	Expiry Date: 2015.10
Specification : USP36	

TESTS:

Items	Specification	Results
Appearance	White or almost white crystals	Conforms
Identification	IR:--Concordant with RS	IR:--Concordant with RS
	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay	Conforms
Related substance	----	----
Pre-Calcitriol (HPLC)	≤1.0%	0.05%
Trans-Calcitriol (HPLC)	≤0.20%	0.08%
Triazoline adduct of pre-calcitriol	≤0.1%	N,D
1 β -calcitriol	≤0.1%	N,D
Methylene calcitriol	≤0.25%	N,D
Any other individual unidentified impurity	≤0.1%	Conforms
Total impurities	≤1.0%	0.17%
Total impurities	97.0%~103.0%	100.7%

Conclusion: The results conform with the USP36

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