RAWPHARMA BIZ PVT LTD 1101-CITY CENTRE-2 SCIENCE CITY ROAD, SOLA AHMEDABAD, 380060 GUJARAT, INDIA

Product Name: Vitamin D₃

| TEST | SPECIFICATION | RESULTS | |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--|
| Description | | | |
| Description | White or almost white crystals, odourless or almost odourless. | White crystals, odourless. | |
| Identification | | | |
| INFRARED ABSORPTION | Infra-red absorption spectrum of test sample shall be in concordant with the reference spectrum of Cholecalciferol standard. | Complies | |
| Solubility | | | |
| Solubility | Freely soluble in ethanol (95 per cent), in acetone, in chloroform and in ether; practically insoluble in water. It is soluble in fixed oils. | Complies | |
| Specific optical Rotation | | | |
| Specific Optical Rotation | 105 to 112 ° | 107° | |
| U.V. Absorptiometric Determination | | | |
| Light absorption at 265nm of 0.001% Solution in ethanol | 0.46 to 0.50 | 0.48 | |
| 7-DEHYDROCHOLESTEROL | | | |

| TEST | SPECIFICATION | RESULTS | |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|
| 7-DEHYDROCHOLESTEROL | In the chromatogram obtained with the test solution any violet spot with an Rf value slightly lower than that of the principal spot (due to 7- Dehydrocholesterol and appearing slowly) shall not be more intense that the spot in the chromatogram obtained with reference solution (a). | Complies | |
| Assay | | | |
| HPLC | 97.0 to 103.0 % | 99.6 % | |
| Residual solvents | | | |
| Methanol | Maximum 1000 ppm | <6.00 ppm | |
| Ethanol | Maximum 1000 ppm | <10.00 ppm | |
| Pyridine | Maximum 100 ppm | <4.00 ppm | |
| Methyl Formate | Maximum 1000 ppm | 126.49 ppm | |
| Petroleum Ether | Maximum 290 ppm | <2.00 ppm | |
| Acetone | Maximum 1000 ppm | <10.00 ppm | |
| Benzene | Maximum 2 ppm | <0.2 ppm | |

OPINION: The above product is declared as standard quality.

Checked by: Kiran Mistry Analyzed By: Gaurang Patel