

Sildenafil citrate

| | | |
|--|--|---|
| CODE ARTICLE: 8556 | BATCH: 0128692 | Active pharmaceutical ingredient |
| TEST DATE: 17/06/2024 | TEST: QC-00265408 | |
| EXPIRY DATE: 30/09/2028 | FABRICATION DATE: 01/10/2023 | MR: 667,00 |
| CAS: [171599-83-0] | FORMULA: C22H30N6O4S.C6H8O7 | |
| SYNONYMS / BOTANICAL NAME: 5-[2-Ethoxy-5-[(4-methylpiperazin-1-yl)sulfonyl]phenyl]-1-methyl-3-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one dihydrogen 2-hydroxypropane-1,2,3-tricarboxylate. | | |
| STORAGE: Store in tightly closed containers in a cool, dry place. | | |

| TEST | RESULTS | Units | MIN | MAX | METHOD |
|---|------------------------------|-------|-----|--------------------|------------------------|
| APPEARANCE | PASS | | | CRYSTALLINE POWDER | PH.EUR.* |
| COLOUR | PASS | | | WHITE | PH.EUR.* |
| SOLUBILITY | | | | | |
| SOLUBLE | SLIGHTLY SOLUBLE IN WATER | | | | PH.EUR.* |
| SOLUBLE | SLIGHTLY SOLUBLE IN METHANOL | | | | PH.EUR.* |
| INSOLUBLE | IN HEXAN | | | | PH.EUR. |
| IDENTIFICATION | | | | | |
| IR IDENTIFICATION | PASS | | | | PH.EUR.* |
| IMPURITY E | <0,1 % | | | <=0,1 | PH.EUR.* |
| RELATED SUBSTANCES (HPLC) | | | | | |
| TOTAL IMPURITIES | 0,1 % | | | <=0,5 | PH.EUR.* |
| UNSPECIFIED IMPURITIES | 0,05 % | | | <=0,10 | PH.EUR.* |
| IMPURITY A | <LQ=0,05 % | | | <=0,15 | PH.EUR.* |
| IMPURITY D | <LQ=0,05 % | | | <=0,15 | PH.EUR.* |
| WATER | 0,6 % | | 0,0 | 2,5 | PH.EUR.* |
| SULPHATED ASHES | 0,02 % | | 0,0 | 0,1 | PH.EUR.* |
| ASSAY (ANHYDROUS BASIS) | 98,1 % | | 98 | 102 | PH.EUR.* |
| SOLVENT RESIDUE | | | | | |
| METHANOL | N.D. ppm | | | 1500 | Manufacture's Standard |
| METHYLENE CHLORIDE | N.D. ppm | | | 400 | Manufacture's Standard |
| TOLUENE | N.D. ppm | | | 500 | Manufacture's Standard |
| ETHYL ACETATE | N.D. ppm | | | 3000 | Manufacture's Standard |
| N,N-DIMETHYL FORMAMIDE | N.D. ppm | | | 500 | Manufacture's Standard |
| ACETONE | N.D. ppm | | | 3000 | Manufacture's Standard |
| SAMPLING | COLLECT | | | | Manufacture's Standard |
| CORRECT BATCH | YES | | | | Manufacture's Standard |
| SPECIFICATION | PH.EUR 11 | | | | Manufacture's Standard |
| Risk Assessment Evaluation for Nitrosamines | PASS | | | | |
| Elemental Impurities ICHQ3D | PASS | | | | |
| NON-sterile | | | | | |



The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

Silvia Sancho-Tello Ripoll
Technical Director.

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.