

CTCBIO Inc.

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Certificate of Analysis

- Product : Please Orally Soluble Film 100mg
(Sildenafil Orally Soluble Film 100mg)
- Batch No. : 23003
- Certificate No. : QCP-231013-01
- Mfg. Date : Sep-06-2023
- Expiry Date : Sep-05-2027

Results of Analysis

TEST ITEMS	SPECIFICATIONS	RESULTS
1. Appearance	Blue or Light-blue, rectangular Orally soluble film	Conforms
2. Identification	a. Retention time of the sample corresponds to that of the standard b. When determined the IR spectra of the drug and Sildenafil STD as the ATR method under the IR Spectrophotometry, both spectra exhibit similar intensities of absorption at the same wavenumbers	Conforms
3. Loss on drying	Not more than 8.0 %	4.3 %
4. Disintegration	Not more than 5 min	1' 30"
5. Dissolution	Not less than 80% (Q) after 30 min	100 %
6. Content Uniformity	Not more than 15.0 %	1.3 %
7. Related Substances		
- Impurity A	Not more than 0.2 %	N.D
- Impurity B	Not more than 0.2 %	N.D
- Impurity C	Not more than 0.2 %	N.D
- Impurity D	Not more than 0.2 %	N.D

- Individual Impurity	Not more than 0.2 %	0.02 % (max.)
- Total Impurities	Not more than 2.0 %	0.06 %
8. Assay	95.0 ~ 105.0 %	99.6 %
9. Microbial Test	TAMC : NMT 1000 cfu/g TYMC : NMT 100 cfu/g Specific microorganism : Not Detected - Escherichia coli	Less than 90 cfu/g Less than 90 cfu/g N.D
10. Leak test	No test solution permeated	Conforms

Conform with specification, In House

We hereby certify that the above are correct

Date of Analysis : Oct-24-2023

Date of Issue : Oct-24-2023

Approved by



CTCBIO Quality Control Department