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Innovating for  
affordable healthcare

**Shilpa Medicare Limited**

(Unit-2: 100% Export Oriented Unit)

Plot No: 33, 33A & 40-47, Raichur Industrial Growth Centre,  
Chicksugur-584 134, Raichur District, Karnataka State, India.

CIN No. L85110KA1987PLC008739

### CERTIFICATE OF ANALYSIS

|                         |                          |                          |                   |
|-------------------------|--------------------------|--------------------------|-------------------|
| <b>Material Name</b>    | : TRANEXAMIC ACID Ph.Eur | <b>Drug License No.</b>  | : KTK/25/564/2009 |
| <b>Batch No.</b>        | : TXAD210160             | <b>Batch Quantity</b>    | : 526.700 KG      |
| <b>Source Batch No.</b> | : TXA8210032             | <b>Dispatch Quantity</b> | : 25.000 KG       |
| <b>Mfg. Date</b>        | : MAR-2021               | <b>A.R.No.</b>           | : 40000052197     |
| <b>Retest Date</b>      | : FEB-2026               |                          |                   |

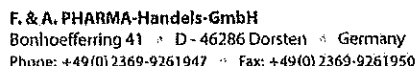
| S.No.  | Tests                                                   | Results                  | Specifications                                                                                                       |
|--------|---------------------------------------------------------|--------------------------|----------------------------------------------------------------------------------------------------------------------|
| 1      | Appearance <Ph.Eur 1.4>                                 | White crystalline powder | White or almost white, crystalline powder.                                                                           |
| 2      | Solubility <Ph.Eur 1.4>                                 | Complies                 | Freely soluble in water and in glacial acetic acid, practically insoluble in acetone and ethanol (96%)               |
| 3      | Identification by infrared absorption <Ph.Eur 2.2.24>   | Complies                 | The infrared absorption spectrum of the substance being examined should be concordant with the spectrum of standard. |
| 4      | pH <Ph.Eur 2.2.3>                                       | 7.60                     | Between 7.0 to 8.0                                                                                                   |
| 5      | Loss on drying (At 105°C for 2 hrs) <Ph.Eur 2.2.32>     | 0.23%w/w                 | Not more than 0.5% w/w                                                                                               |
| 6      | Sulphated ash <Ph.Eur 2.4.14>                           | 0.05%w/w                 | Not more than 0.1% w/w                                                                                               |
| 7      | Halides expressed as chlorides <Ph.Eur 2.4.4>           | Less than 140 ppm        | Not more than 140 ppm                                                                                                |
| 8      | Related substances (By HPLC) <Ph.Eur 2.2.29>            |                          |                                                                                                                      |
| 8.1    | Impurity-B                                              | Below RT                 | Not more than 0.15%                                                                                                  |
| 8.2    | Impurity-C                                              | Below RT                 | Not more than 0.05%                                                                                                  |
| 8.3    | Impurity-D                                              | Below RT                 | Not more than 0.05%                                                                                                  |
| 8.4    | Impurity-E                                              | Below RT                 | Not more than 0.05%                                                                                                  |
| 8.5    | Impurity-F                                              | Below RT                 | Not more than 0.05%                                                                                                  |
| 8.6    | Unspecified impurities                                  | Below RT                 | Not more than 0.05%                                                                                                  |
| 8.7    | Total impurities                                        | Below RT                 | Not more than 0.2%                                                                                                   |
| 9      | Assay by potentiometry (on dried basis) <Ph.Eur 2.2.20> | 100.6%w/w                | Between 99.0% to 101.0% w/w                                                                                          |
| 10     | Microbial limit tests                                   |                          |                                                                                                                      |
| 10.1   | Microbial enumeration tests <Ph.Eur 2.6.12>             |                          |                                                                                                                      |
| 10.1.1 | Total Aerobic Microbial Count                           | 10cfu/g                  | Not more than 1000 cfu/g                                                                                             |
| 10.1.2 | Total combined Yeast and Mould Count                    | Less than 10cfu/g        | Not more than 100 cfu/g                                                                                              |

|                                                 |                                                   |
|-------------------------------------------------|---------------------------------------------------|
| Checked by :<br>Purnaprajna Kulkarni 12.04.2021 | Approved by :<br>Chinua Bheemaraju V.V 12.04.2021 |
|-------------------------------------------------|---------------------------------------------------|

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|                         |                          |                          |                   |
|-------------------------|--------------------------|--------------------------|-------------------|
| <b>Material Name</b>    | : TRANEXAMIC ACID Ph.Eur |                          |                   |
| <b>Batch No.</b>        | : TXAD210160             | <b>Drug License No.</b>  | : KTK/25/564/2009 |
| <b>Source Batch No.</b> | : TXA8210032             | <b>Batch Quantity</b>    | : 526.700 KG      |
| <b>Mfg. Date</b>        | : MAR-2021               | <b>Dispatch Quantity</b> | : 25.000 KG       |
| <b>Retest Date</b>      | : FEB-2026               | <b>A.R.No.</b>           | : 40000052197     |

| S.No.  | Tests                                             | Results               | Specifications            |
|--------|---------------------------------------------------|-----------------------|---------------------------|
| 10.2   | Test for specified microorganisms <Ph.Eur 2.6.13> |                       |                           |
| 10.2.1 | Enterobacteria                                    | Absent                | Should be absent          |
| 10.2.2 | Escherichia coli                                  | Absent                | Should be absent          |
| 10.2.3 | Salmonella species                                | Absent                | Should be absent          |
| 10.2.4 | Pseudomonas aeruginosa                            | Absent                | Should be absent          |
| 10.2.5 | Staphylococcus aureus                             | Absent                | Should be absent          |
| 10.2.6 | Clostridia                                        | Absent                | Should be absent          |
| 10.2.7 | Candida albicans                                  | Absent                | Should be absent          |
| 11     | Bacterial endotoxin test<br><Ph.Eur 2.6.14>       | Less than 0.125 EU/mg | Not more than 0.125 EU/mg |

**Storage Condition :** Preserve in tight containers and store at controlled room temperature (20°C to 25°C).

**Remarks :** The material complies with the above specifications. RT: Reporting Threshold (0.03%); CEP No.: R0-CEP  
2018-048-Rev 00

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Checked by :

Purnaprajna Kulkarni 12.04.2021

Approved by:

Chinna Bhoomaraju V.V 12.04.2021

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