कर्नाटका एन्टिबायोटिक्स एण्ड फार्मास्युटिकल्स लिमिटेड
(भारत सरकार का उद्यम)
KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED
(A Government of India Enterprise)

| | |
|---|---|
| ENQUIRY REF. No. | KAPL/QAD/020/0375 |
| DATE | 03/06/2025 |
| DUE DATE | 09/06/2025(13.00HRS) |

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVELOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it/ OR MAIL, with other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for below mentioned material/s

| SL. NO. | ITEM CODE | ITEM DESCRIPTION | UOM | QTY. |
|---|---|---|---|---|
| 01 | OFD070 | NUCLEOSIL C18 COLUMN 100A,5µM,4.6MMX25CM | NOS | 02 |

OTHER TERMS:

1. F.O.R TERMS : DOOR DELIVERY
2. GST % : PLEASE SPECIFY
3. PACKING & FORWARDING CHARGES : NOT APPLICABLE
4. CREDIT PERIOD : 30 DAYS
5. DELIVERY OFFERED :

NOTE: IN CASE YOU ARE NOT QUOTING PLEASE SEND THE REGRET LETTER.

Thanking you,

MAKE - MACHERY - NAGEL

3/6

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

3/6

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

MASTER COPY

# KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LIMITED, BENGALURU

## RESEARCH AND DEVELOPMENT

### User Requirement Specifications

Material Description: NUCLEOSIL C18 Column 100Å, 5 µm, 4.6 mm X 25 cm

URS Number: RD/URS/010/0425/V1

**1. Description and Quantity**

| | |
|---|---|
| Material Description | NUCLEOSIL C18 Column 100Å, 5 µm, 4.6 mm X 25 cm |
| Item Code | QFD070 |
| Quantity/Box | 1 |

**2. User Specifications**

| # | Requirement | Specification |
|---|---|---|
| 1. | Detailed Description | EC HPLC column EC 250/4.6 NUCLEOSIL 100-5 C18 length: 250 mm, ID: 4.6 mm pack of 1 |
| 2. | Make | Macherey-Nagel |
| 3. | Brand | Nucleosil |
| 4. | Part No. | MN-720014.46 |
| 5. | Matrix active group | C18 (RP-18, ODS, Octadecyl) |
| 6. | Particle size | 5 µm |
| 7. | Surface Area ($m^2$ /g) | 350.0 |
| 8. | Length | 25 cm |
| 9. | Internal Diameter (I.D.) | 4.6 mm |
| 10. | Pore Size | 100 Å |
| 11. | Particle Substrate | Silica |
| 12. | Particle Shape | Spherical, fully porous |
| 13. | External Construction Materials | Stainless Steel |
| 14. | Endcapped | YES |
| 15. | USP Classification | L1 |
| 16. | Separation Mode | Reversed Phase Chromatography (RP) |
| 17. | pH Range | 2-8 |
| 18. | Maximum Pressure | 400 bar pressure (5801 psi) |
| 19. | Age of Column | Must be no more than 24 months old at the time of delivery |

# Tramadol Injection

**Action and use**

μ-Opioid receptor ($OP_3$, MOR) agonist and noradrenaline reuptake inhibitor; analgesic.

## DEFINITION

Tramadol Injection contains Tramadol Hydrochloride.

*The Injection complies with the requirements stated under Parenteral Preparations and with the following requirements.*

**Content of tramadol hydrochloride, $C_{16}H_{25}NO_2$,HCl** 95.0 to 105.0% of the stated amount.

## IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

## TESTS

**Acidity or alkalinity**

pH of a solution containing 5% w/v of Tramadol Hydrochloride, 6.0 to 7.0, Appendix V L.

**Clarity and colour of solution**

The injection is *clear*, Appendix IV A, and *colourless*, Appendix IV B, Method I.

**Related substances**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute the injection with sufficient mobile phase to produce a solution containing 0.05% w/v of Tramadol Hydrochloride.

(2) Dilute 1 volume of solution (1) to 50 volumes with the mobile phase and further dilute 1 volume to 10 volumes with the mobile phase.

(3) 0.005% w/v each of *tramadol hydrochloride BPCRS* and *tramadol impurity A BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 μm) (Nucleosil 100-5 C18 is suitable).

(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.0 mL per minute.

(d) Use an ambient column temperature.

(e) Use a detection wavelength of 270 nm.

(f) Inject 20 μL of each solution.

(g) For solution (1) allow the chromatography to proceed for five times the retention time of the principal peak.

MOBILE PHASE

295 volumes of *acetonitrile* and 705 volumes of 0.2% w/v of *trifluoroacetic acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity A and tramadol is at least 3.0.

CALCULATION OF IMPURITIES

For each impurity, use the concentration of tramadol hydrochloride in solution (2).

For the reporting threshold, use the concentration of tramadol hydrochloride in solution (2).

Tramadol retention time: about 5 minutes.

Relative retention: impurity D, about 0.7; impurity A, about 0.9; impurity 1, about 1.2; impurity 2, about 1.9; impurity C, about 2.4; impurity B, about 2.7 and impurity 3, about 4.2.

LIMITS

- unspecified impurities: for each impurity, not more than 0.2%;
- total impurities: not more than 1.0%;
- reporting threshold: 0.1%.

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute the injection with sufficient mobile phase to produce a solution containing 0.05% w/v of Tramadol Hydrochloride.

(2) 0.05% w/v of *tramadol hydrochloride BPCRS* in the mobile phase.

(3) 0.005% w/v each of *tramadol hydrochloride BPCRS* and *tramadol impurity A BPCRS* in the mobile phase.

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

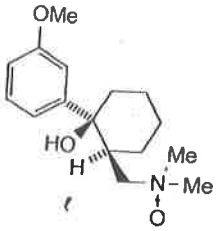
The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity A and tramadol is at least 3.0.

DETERMINATION OF CONTENT

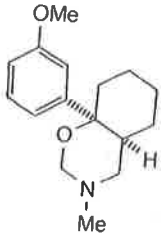
Calculate the content of $C_{16}H_{25}NO_2$,HCl in the injection from the chromatograms obtained and using the declared content of $C_{16}H_{25}NO_2$,HCl in *tramadol hydrochloride BPCRS*.

## IMPURITIES

The impurities limited by the requirements of this monograph include impurities A to D listed under Tramadol Hydrochloride and:




1. (1*RS*,2*RS*)-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol N-oxide




2. 8*a*-(3-methoxyphenyl)-3-methyloctahydro-2*H*-1,3-benzoxazine


# EC HPLC column EC 250/4.6 NUCLEOSIL 100-5 C18 length: 250 mm, ID: 4.6 mm pack of 1

**Part Number:** MN-720014.46
**Manufacturer:** Macherey-Nagel

## €475.00

Excl. 19% taxes, excl. Shipping costs

**Delivery Time:** on stock

1 Add to Cart Request a quote

MACHEREY-NAGEL

## Product Line

→ Nucleosil

| Product details | Support-Downloads |
|---|---|
| **Description** | EC HPLC column EC 250/4.6 NUCLEOSIL 100-5 C18 length: 250 mm, ID: 4.6 mm pack of 1 |
| **Quantity** | 1 Stk. |
| **Manufacturer** | Macherey-Nagel |
| **Brand** | Nucleosil |
| **Product Type** | HPLC Column |
| **Length** | 250 mm |
| **Internal Diameter** | 4.6 mm |
| **Particle Size** | 5 µm |
| **Chemistry** | C18 (RP-18, ODS, Octadecyl) |
| **Chemistry Producers Term** | C18 |
| **Pore Size** | 100 Å |
| **USP Class** | L1 |
| **Carbon Load** | 15.0 % |

| | |
|---|---|
| **Bet Surface Area [m2/g]** | 350.0 |
| **Endcapping** | endcapped |
| **Country of Origin** | Germany |
| **Column Type** | Analytical Column |
| **Hardware Material** | Stainless Steel |
| **Hardware Type** | Ready-to-use Column |
| **pH Minimum** | 2.0 |
| **pH Maximum** | 8.0 |
| **Temperature Maximum [°C]** | 60 |
| **Mode of Separation** | Reversed Phase Chromatography (RP) |
| **Technology** | HPLC |
| **Matrix** | Silica |
| **Particle Morphology** | spherical, fully porous |
| **Pressure Stability** | 400 bar |



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