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

ENQUIRY REF. No.	KAPL/QAD/020/0978
DATE	02/08/2024
DUE DATE	05/08/2024 (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	QSPHPL750	(25CMX4.6MM)END –CAPPED, ODS NUCLEOSIL100-5C18,	NOS	02

1. Please ensure that your offer reaches us on or before Due Date by courier OR S peed post Or you can also mail us to our email: purenp@kaplindia.com.
2. Please send your quotation mentioning item code.

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,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

British Pharmacopoeia | Quality standards

Entries in this edition will be effective from 01 July 2024

Tramadol Injection

General Notices

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).

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

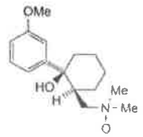
The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity A and tramadol is at least 3.0.

DETERMINATION OF CONTENT

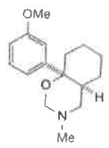
Calculate the content of $C_{16}H_{25}NO_2$,HCl in the injection from the chromatograms obtained and using the declared content of $C_{16}H_{25}NO_2$,HCl in *tramadol hydrochloride BPCRS*.

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