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

ENQUIRY REF. No.	KAPL/QAD/020/2553
DATE	06-03-2025
DUE DATE	13-03-2025 (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	QSPHPL411	15CMX4.6MM, 5MIC, PHENYL GROUP BOUNDED TO POROUS	NOS	2

Please ensure that your offer reaches us on or before Due Date by courier OR Speed post or By hand in sealed cover only to below office address:

M/s. Karnataka Antibiotics and Pharmaceuticals Limited Plot No.37, Arka The Business Centre, NTTF Main Road, Peenya Industrial Area 2nd Phase, Bengaluru-560058 ph. No.080-23571590

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:

1).IF YOU ARE NOT PARTICIPATING IN THE TENDER PLEASE SEND A REGRET LETTER .

2).VENDER HAS TO QUOTE AS PER OUR TENDER IN YOUR COMPANY LETTER HEAD.

3).QUOTATION MUST BE SUBMITTED IN TWO SEALED COVERS (TECHNICAL & COMMERCIAL /PRICE BID) SEPARATELY AND IN ONE ENVELOP OR ELSE YOUR PROPOSAL WILL NOT BE CONSIDERED.

IF YOU NEED ANY CLARIFICATION, PLEASE CONTACT US.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB: 9945317873

compound A, pantoprazole related compound D and F*, each of, is not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent), the area of any peak corresponding to pantoprazole related compound B is not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent).

Paracetamol and Tramadol Tablets N

Paracetamol and Tramadol Hydrochloride Tablets

Paracetamol and Tramadol Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of paracetamol, $C_8H_9NO_2$ and tramadol hydrochloride, $C_{16}H_{25}NO_2,HCl$.

Usual strength. Paracetamol 325 mg and Tramadol Hydrochloride 37.5 mg.

Identification

In the Assay, the principal peaks in the chromatogram obtained with test solution (b) and (c) correspond to the principal peaks in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*,
Speed and time. 50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, dilute if necessary, with the dissolution medium.

Reference solution. A solution containing 0.036 per cent w/v of *paracetamol IPRS* and 0.004 per cent w/v of *tramadol hydrochloride IPRS* in the dissolution medium.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- column temperature: 30°,
- mobile phase: a mixture of 80 volumes of a buffer solution prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 2.5 with *orthophosphoric acid* and 20 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 272 nm,
- injection volume: 25 µl.

The relative retention time with reference to tramadol for paracetamol is about 0.5.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to paracetamol and tramadol is not less than 5.0, the relative standard deviation for replicate injections for both the peaks is not more than 2.0 per cent.

Inject the reference solution and the test solution. Run the chromatogram twice the retention time of the tramadol.

Calculate the content of $C_8H_9NO_2$ and $C_{16}H_{25}NO_2,HCl$ in the medium.

Q. Not less than 80 per cent of the stated amount of $C_8H_9NO_2$ and $C_{16}H_{25}NO_2,HCl$.

4-Aminophenol. Not more than 0.15 per cent.

Determine by liquid chromatography (2.4.14).

NOTE — Prepare the solutions immediately before use and protect from light.

Solvent mixture. 90 volumes of a buffer solution prepared by dissolving 4.0 g of *sodium citrate dihydrate* and 1.5 g of *anhydrous citric acid* in 1000 ml of *water* and 10 volumes of *acetonitrile*.

Test solution (a). Disperse a quantity of powdered tablets containing 1 g of Paracetamol in the solvent mixture and dilute to 100.0 ml with the solvent mixture.

Test solution (b). Dilute 10.0 ml of test solution (a) to 20.0 ml with the solvent mixture.

Reference solution (a). A 0.0025 per cent w/v solution of *4-aminophenol IPRS* in the solvent mixture.

Reference solution (b). Dilute 25.0 ml of test solution (a) and 15.0 ml of reference solution (a) to 50.0 ml with the solvent mixture

Reference solution (c). Dilute 5.0 ml of reference solution (a) to 50.0 ml with the solvent mixture

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octylsilane consists of both reversed-phase (an alkyl chain longer than C8) and weak cation-exchange (carboxyl groups) functional groups bonded to porous or nonporous silica (5 µm),

Glucose 0.115 g

- mobile phase: A 0.01M phosphate buffer prepared by dissolving 0.6 g of *potassium dihydrogen orthophosphate* and 0.82 g of *disodium hydrogen orthophosphate anhydrous* in 1000 ml of *water*, adjusted to pH 7.0,
  B. *water*,
  C. *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 300 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Mobile phase C (per cent v/v)
0	90	5	5
5	90	5	5
7	10	10	80
7.1	90	5	5
10	90	5	5

NOTE — The retention time for 4-aminophenol is about 4.2 to 5.3.

Inject reference solution (b) and (c). The test is not valid unless the resolution between the peaks due to 4-aminophenol and nearest peak is not less than 1.0, the tailing factor is not more than 1.5 for 4-aminophenol peak and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (b) and the signal-to-noise ratio is not less than 20 in the chromatogram obtained with reference solution (c).

Inject reference solution (b) and test solution (b).

Calculate the percentage of 4-aminophenol (C_6H_7NO) relative to paracetamol, using following expression:

$$4\text{-Aminophenol} = \left[\frac{r_u}{(r_s - r_u)}\right] \times \left[\frac{W_s}{W_u}\right] \times 100$$

where, r_u = peak response of 4-aminophenol from test solution (b),

r_s = peak response of 4-aminophenol from reference solution (b),

W_s = amount of 4-aminophenol IPRS added to reference solution (b) (mg),

W_u = amount of paracetamol in test solution (b) (mg).

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 10 volumes of *methanol* and 90 volumes of *water*.

Test solution. Disperse a quantity of the powdered tablets containing 37.5 mg of *tramadol hydrochloride* in 30 ml of the solvent mixture, with the aid of ultrasound for 30 minutes with intermittent shaking and dilute to 50.0 ml with the solvent mixture. Centrifuge the solution and use the supernatant liquid, filter.

Reference solution. A solution containing 0.0075 per cent w/v, each of, *tramadol hydrochloride IPRS* and *tramadol related compound A IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with phenyl group bonded to porous silica (5 µm),
- column temperature: 50°,
- mobile phase: a mixture of 92 volumes of *water*, 8 volumes of *tetrahydrofuran*, 0.1 volume of *triethylamine* and 0.1 volume of *trifluoroacetic acid*, adjusted to pH 2.3,
- flow rate: 1 ml per minute,
- spectrophotometer set at 216 nm,
- injection volume: 30 µl.

Name	Relative retention time
Paracetamol	0.38
O-desmethyl-tramadol[1]	0.6
Tramadol related compound A[2]	0.8
Tramadol	1.0

[1]3-{(1*RS*,2*RS*)-2-[(Dimethylamino)methyl]-1-hydroxycyclohexyl}phenol,
[2]*RS*,*SR*-1-(3-Methoxyphenyl)-2-(dimethylaminomethyl) cyclohexanol hydrochloride.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to tramadol related compound A and tramadol hydrochloride is not less than 2.0 and the relative standard deviation for replicate injections is not more than 6.0 per cent for tramadol peak.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to o-desmethyl-tramadol and tramadol related compound A, each of, is not more than twice the area of the principal peak in the chromatogram obtained with the reference solution (0.2 per cent), the area of any other secondary peak is not more than twice the area of the principal peak in the chromatogram obtained with the reference solution (0.2 per cent) and the sum of areas of all the secondary peaks is not more than 8 times the area of the principal peak in the chromatogram obtained with the reference solution (0.8 per cent). Ignore the peaks due to paracetamol and 4-aminophenol.

Uniformity of content. Complies with the test stated under Tablets.

Determine by liquid chromatography (2.4.14), as described under Assay with the following modification.

Test solution. Disperse one tablet in 30 ml of the solvent mixture, with the aid of ultrasound for 30 minutes with intermittent shaking and dilute to 50.0 ml with the solvent mixture, centrifuge. Dilute 1.0 ml of the supernatant liquid to 10.0 ml with the solvent mixture.

Inject the reference solution and the test solution. Run the chromatogram 4 times the retention time of the paracetamol peak.

Calculate the content of the $C_{16}H_{25}NO_2,HCl$ in the tablet.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. 10 volumes of *methanol* and 90 volumes of *water*.

Test solution (a). Weigh and powder 20 tablets. Disperse a quantity of the powder containing 325 mg of Paracetamol in 30 ml of the solvent mixture, with the aid of ultrasound for 30 minutes with intermittent shaking and dilute to 50.0 ml with the solvent mixture. Centrifuge and use the supernatant liquid.

Test solution (b). Dilute 1.0 ml of test solution (a) to 100.0 ml with the solvent mixture.

Test solution (c). Dilute 5.0 ml of test solution (a) to 50.0 ml with the solvent mixture.

Reference solution. A solution containing 0.0065 per cent w/v of *paracetamol IPRS* and 0.0075 per cent w/v of *tramadol hydrochloride IPRS* in the solvent mixture.

Use the chromatographic system as described under Related substances with the following modification.

- spectrophotometer set at 216 nm (for tramadol hydrochloride) and 249 nm (for paracetamol),
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to paracetamol and tramadol hydrochloride is not less than 10.0, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent for both the peaks.

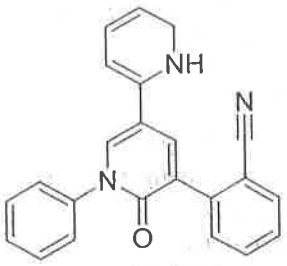
Inject the reference solution, test solution (b) (for paracetamol) and test solution (c) (for tramadol hydrochloride). Run the chromatogram 4 times the retention time of the paracetamol peak.

Calculate the content of $C_8H_9NO_2$ and $C_{16}H_{25}NO_2,HCl$ in the tablets.

Storage. Store protected from moisture, at a temperature not exceeding 30°.

Perampanel

N



, $^3/_4$ H_2O

$C_{23}H_{15}N_3O$, $^3/_4H_2O$ Mol. Wt. 362.9

Perampanel is 2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzonitrile hydrate (4:3).

Perampanel contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{23}H_{15}N_3O$, calculated on the anhydrous basis.

Category. Antiepileptic.

Description. A white to yellowish white powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *perampanel IPRS* or with the reference spectrum of perampanel.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (b).

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 40 volumes of *acetonitrile* and 60 volumes of *water*.

Test solution. Dissolve 100 mg of the substance under examination in the mobile phase B and dilute to 50.0 ml with the mobile phase B. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

Reference solution (a). A 0.2 per cent w/v solution of *perampanel IPRS* in mobile phase B.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the solvent mixture.

Reference solution (c). Dilute 1.0 ml of reference solution (b) to 100.0 ml with the solvent mixture.

Reference solution (d). A 0.01 per cent w/v solution of *perampanel impurity F IPRS (methyl 2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzoate)* in mobile phase B. Transfer 1.0 ml of the solution to a 50-ml volumetric

termine by liquid chromatography (2.4.14), as described under Assay with the following modification.

Test solution. Disperse one tablet in 30 ml of the solvent mixture, with the aid of ultrasound for 30 minutes with intermittent shaking and dilute to 50.0 ml with the solvent mixture, centrifuge. Dilute 1.0 ml of the supernatant liquid to 10.0 ml with the solvent mixture.

Inject the reference solution and the test solution. Run the chromatogram 4 times the retention time of the paracetamol peak.

Calculate the content of the $C_{16}H_{25}NO_2,HCl$ in the tablet.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. 10 volumes of *methanol* and 90 volumes of *water*.

Test solution (a). Weigh and powder 20 tablets. Disperse a quantity of the powder containing 325 mg of Paracetamol in 30 ml of the solvent mixture, with the aid of ultrasound for 30 minutes with intermittent shaking and dilute to 50.0 ml with the solvent mixture. Centrifuge and use the supernatant liquid.

Test solution (b). Dilute 1.0 ml of test solution (a) to 100.0 ml with the solvent mixture.

Test solution (c). Dilute 5.0 ml of test solution (a) to 50.0 ml with the solvent mixture.

Reference solution. A solution containing 0.0065 per cent w/v of *paracetamol IPRS* and 0.0075 per cent w/v of *tramadol hydrochloride IPRS* in the solvent mixture.

Use the chromatographic system as described under Related substances with the following modification.

- spectrophotometer set at 216 nm (for tramadol hydrochloride) and 249 nm (for paracetamol),
- injection volume: 20 µl.

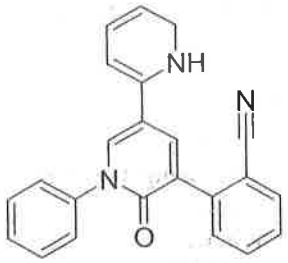
Inject the reference solution. The test is not valid unless the resolution between the peaks due to paracetamol and tramadol hydrochloride is not less than 10.0, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent for both the peaks.

Inject the reference solution, test solution (b) (for paracetamol) and test solution (c) (for tramadol hydrochloride). Run the chromatogram 4 times the retention time of the paracetamol peak.

Calculate the content of $C_8H_9NO_2$ and $C_{16}H_{25}NO_2,HCl$ in the tablets.

Storage. Store protected from moisture, at a temperature not exceeding 30°.

Perampanel



, $^3/_4$ H_2O

$C_{23}H_{15}N_3O$, $^3/_4H_2O$ Mol. Wt. 362.9

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Category. Antiepileptic.

Description. A white to yellowish white powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *perampanel IPRS* or with the reference spectrum of perampanel.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (b).

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 40 volumes of *acetonitrile* and 60 volumes of *water*.

Test solution. Dissolve 100 mg of the substance under examination in the mobile phase B and dilute to 50.0 ml with the mobile phase B. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

Reference solution (a). A 0.2 per cent w/v solution of *perampanel IPRS* in mobile phase B.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the solvent mixture.

Reference solution (c). Dilute 1.0 ml of reference solution (b) to 100.0 ml with the solvent mixture.

Reference solution (d). A 0.01 per cent w/v solution of *perampanel impurity F IPRS (methyl 2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl)benzoate)* in mobile phase B. Transfer 1.0 ml of the solution to a 50-ml volumetric

QUALITY CONTROL DEPARTMENT		KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED
		(A Government of India Enterprise)

User Requirement specifications

Material Description : HPLC COLUMN 15 cm x 4.6mm, 5u, Phenyl group bonded to porous silica

URS Number: QC/URS/025/0325

1. Description and Quantity:

Material Description	15cm x 4.6mm, 5u ,packed with phenyl group bonded to porous silica
Item code	QSPHPL411
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Name	15cm x 4.6mm, 5u ,packed with phenyl group bonded to porous silica
2	Matrix active group	Phenyl group bobnded to porous silica
3	Particle size	5u
4	Length (mm)	150
5	Internal Diameter (I.D.)	4.6 mm
6	Particle type	Base-Deactivated Silica
7	Particle Shape	Spherical
8	External Construction Materials	Stainless Steel
9	Endcapped	Yes
10	USP Classification	L11
11	Separation Mode	Reverse phase
12	P^H Range	2-8
13	Maximum Pressure	6000 psi (410 Bar)
14	Pore Size	100 °A