

|                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br>PT. MERSIFARMA TM<br>SUKABUMI-INDONESIA                                                                                                                                                                                                                                                                                                                          | <b>FORMULIR LATAR BELAKANG<br/> PERMINTAAN BARANG<br/> HABIS PAKAI</b><br><b>DEPARTEMEN: R&amp;D</b>                                                                                                                                                                                                                                                                                                           | Diisi oleh Pemohon<br><br>No. : <u>150</u> /LBPBHP/ <u>IX</u> /20 <u>26</u>                                                                                                                                                                                                                                                                                                                                                                             |
| Nama Barang Habis Pakai:<br><br>Norepinephrine Bitartrate USP Injectable Grade ex Harman Finocem Limited (IBA00307)<br><i>Berlaku untuk satu jenis barang</i>                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                | Rencana Waktu Penggunaan:<br>6 Januari 2027<br>Lead time Purchasing:<br>80 Hari Kerja                                                                                                                                                                                                                                                                                                                                                                   |
| Masa Waktu Pakai <u>s/d Expired Date</u> Masa Frekuensi Pakai <u>Setiap kali trial</u>                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <input checked="" type="checkbox"/> Permintaan Item Baru                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/> Permintaan Kebutuhan Jadwal Kerja                                                                                                                                                                                                                                                                                                                                                                                              |
| <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Bahan Penunjang<br/> <input type="checkbox"/> Suku Cadang<br/> <input type="checkbox"/> Bahan Kebersihan<br/> <input type="checkbox"/> Inkjet/Laserjet Print </div> <div> <input type="checkbox"/> Perlengkapan Listrik<br/> <input type="checkbox"/> Alat Tulis<br/> <input type="checkbox"/> Hardware<br/> <input type="checkbox"/> _____ </div> </div> |                                                                                                                                                                                                                                                                                                                                                                                                                | <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Innovator<br/> <input type="checkbox"/> Sample Bahan Kemasan<br/> <input checked="" type="checkbox"/> Sample Bahan Baku<br/> <input type="checkbox"/> Kualifikasi </div> <div> <input type="checkbox"/> Kalibrasi<br/> <input type="checkbox"/> Perbaikan<br/> <input type="checkbox"/> Marketing Promosi<br/> <input type="checkbox"/> _____ </div> </div> |
| <b>SYARAT WAJIB PERMINTAAN BARU</b><br>1. Sertakan Foto Barang Baru.<br>2. Dibuat hanya sekali untuk awal mendaftarkan ke sistem QAD.<br>3. Pemesanan selanjutnya menggunakan Analisa Permintaan Barang dengan melampirkan hasil verifikasi stok fisik (kartu stok/bin card).                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                | <b>SYARAT WAJIB PERMINTAAN JADWAL KERJA</b><br>1. Formulir Perbaikan (jika dibutuhkan).<br>2. Setiap pengajuan menyertakan jadwal/timetable.<br>3. Dibuat setiap mengajukan kebutuhan untuk memenuhi rencana jadwal kerja, sekalipun barang sudah terdaftar di sistem QAD.                                                                                                                                                                              |
| Digunakan untuk                                                                                                                                                                                                                                                                                                                                                                                                                                       | Bahan aktif Norepinephrine Bitartrate USP Injectable Grade ex Harman Finocem Limited akan digunakan untuk analisa bahan baku dan trial laboratorium pada pengembangan produk Norepinephrine Injeksi.                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Latar belakang permintaan                                                                                                                                                                                                                                                                                                                                                                                                                             | 1. Bahan aktif Norepinephrine Bitartrate USP Injectable Grade ex Harman Finocem Limited digunakan untuk trial produk OBM Norepinephrine Injeksi. <i>(Skala Lab)</i><br>2. Rencana penggunaan Bahan Baku:<br>a. analisa : 22.00 G<br>b. 10 x trial laboratorium : 6.00 G<br>c. Cadangan bahan baku : 7.00 G<br>3. Lead Time : 80 Hari Kerja<br>4. Harga : USD 1,225 untuk 35 G bahan aktif + 340 mg WS (Direct) |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <input type="checkbox"/> Perlu Minimum Stock<br><i>Tentukan Reorder Point</i>                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dibuat:<br><br>Tgl. 14/09/2026<br><i>(Staff/Koord.)</i>                                                                                                                                                                                                                                                                                                            | Diperiksa:<br><br>Tgl. 14/09/2026<br><i>(Koord./Spv/Ast. Mgr)</i>                                                                                                                                                                                                                                                           | Menyetujui:<br><br>Tgl. 14/09/2026<br><i>(Kepala Departemen)</i>                                                                                                                                                                                                                                                                                                   |
| Nomor Dokumen : COM-FPT/001A.00                                                                                                                                                                                                                                                                                                                                                                                                                       | Tanggal Berlaku : <b>11 SEP 2023</b>                                                                                                                                                                                                                                                                                                                                                                           | Disetujui oleh :                                                                                                                                                                                                                                                                                                                                                   |

**DEPARTMENT**  
**RESEARCH AND DEVELOPMENT**

Nama Bahan Baku / Raw Material Name : Norepinephrine Bitartrate USP Injectable Grade ex Harman Finochem Limited

| Kebutuhan Per-4 mL<br>(mg)<br>Per-4 mL Requirements<br>(mg)             | Kebutuhan Analisa<br>(G)<br>Analysis Requirements<br>(G) | Kebutuhan Trial Lab<br>(G)<br>Laboratorium Trial Requirements<br>(G)<br>(3 bottle/s @100.00 mL)<br>(10 Time/s Trial) | Kebutuhan Trial Optimasi<br>(G)<br>Optimization Trial Requirements<br>(G)<br>(10 bottle/s @100.00 mL)<br>( 2 Kali Trial)<br>(2 Time/s Trial) | Cadangan Bahan Baku<br>(G)<br>Raw Material Reserves<br>(G) |
|-------------------------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| 8.00                                                                    | 22.00                                                    | 6.00                                                                                                                 | -                                                                                                                                            | 7.00                                                       |
| Total Kebutuhan Bahan Baku (G)<br>Raw Material Requirement in Total (G) |                                                          | 35.00                                                                                                                |                                                                                                                                              |                                                            |

**Catatan: Total Kebutuhan Bahan Baku hingga proses trial skala laboratorium adalah 35.00 G.**

*Note: Total raw material requirements up to the laboratory scale trial process are 35.00 G.*

Created by



Friska Vidya Ningrum  
(Staff Formulasi)

Checked by



Ardian Wahyu Pradana  
(Spv. Formulasi)

Verified by



Elvina Iskandar T  
(Manager Formulasi)

| ANALISA PERMINTAAN BARANG |             |                                                                                                   |        |               |                         |                        | Tanggal : 14 September 2026 |                         |                     |                      |
|---------------------------|-------------|---------------------------------------------------------------------------------------------------|--------|---------------|-------------------------|------------------------|-----------------------------|-------------------------|---------------------|----------------------|
| Bagian : R&D              |             |                                                                                                   |        |               |                         |                        |                             |                         |                     |                      |
| No                        | Kode Barang | Nama Barang                                                                                       | Satuan | Stok Saat Ini | Rencana Kebutuhan (B)   | Kekurangan (A - B + C) | Pending Penerimaan (C)      | Jumlah                  | Realisasi Pembelian | Realisasi Penggunaan |
| 1                         | IBA00307    | Bahan Aktif<br>Norepinephrine Bitartrate<br>USP Injectable Grade ex<br>Harman Finochem<br>Limited | G      | 0             | 35.00<br>6 Januari 2027 | - 35.00                |                             | 35.00<br>6 Januari 2027 | -                   | -                    |

Catatan :

1. Bahan aktif Norepinephrine Bitartrate USP Injectable Grade ex Harman Finochem Limited digunakan untuk trial produk OBM Norepinephrine Injeksi.
2. Rencana kebutuhan penggunaan bahan Baku (terlampir)
3. Lead Time : 80 Hari Kerja
4. Harga : USD 1,225 untuk 35 G bahan aktif + 340 mg WS (Direct)

Pemohon



Frisca Vidya Ningrum

Mengetahui



Elvina Iskandar T

Reply Reply All Forward

Fri 9/4/2026 12:40 PM



ashish@harmanfinochem.com (Ashish Shahare) <ashish@harmanfinochem.com>

RE: Inquiry Regarding Norepinephrine/Noradrenaline Bitartate API (Injectable Grade)

To Mega Silviana; Muhammad.Qoriba@mersifarma.com

Cc 'Kristiana Yanuar Nugraheni'; 'Ayu Cipta Swasana'; Dihya.Ardani@mersifarma.com; 'Anita Probo Hapsari'; Fadhlilatul.Karunianingsih@mersifarma.com; Edra.Astagina@mersifarma.com; Sonal Salunke; Ajit Gholap

**i** Follow up. Completed on Friday, September 4, 2026.  
You replied to this message on 9/4/2026 12:41 PM.

Dear Silviana,

I have discussed internally and have decided to provide the WS 340 mg on FOC basis to you. Also we have checked with the factory the WS is available with us.

We look forward to your valuable feedback and purchase order.

Regards  
Ashish Shahare  
AGM- API Marketing



**Harman Finochem Ltd**

Phone no :+91 2267330179

Website : <https://www.harmanfinochem.com>

Join us in Milan!  
Visit stand 2C18  
to discover what's next in Pharma



MILAN  
14-16 OCT 2026



Thu 8/27/2026 10:16 AM

ashish@harmanfinochem.com (Ashish Shahare) <ashish@harmanfinochem.com>

RE: Inquiry Regarding Norepinephrine/Noradrenaline Bitartrate API (Injectable Grade)

To Mega Silvana; Muhammad.Qoriba@mersifarma.com

Cc 'Kristiana Yanuar Nugraheni'; 'Ayu Cipta Swasana'; Dihya.Ardani@mersifarma.com; 'Anita Probo Hapsari'; Fadhiatul.Karunianingsih@mersifarma.com; Edra.Astagina@mersifarma.com; Sonal Salunke; Ajit Gholap

 You replied to this message on 8/27/2026 2:17 PM.

Dear Silvana,

Please find below our offer for your perusal.

|                |   |                                                                                                                                         |
|----------------|---|-----------------------------------------------------------------------------------------------------------------------------------------|
| Product        | : | Norepinephrine Bitartrate USP Inj                                                                                                       |
| Qty            | : | 35 Gm                                                                                                                                   |
| Rate           | : | USD 35/Gm                                                                                                                               |
| Delivery terms | : | CIP Air Jakarta                                                                                                                         |
| Packing        | : | Fibre Drum                                                                                                                              |
| Payment Terms  | : | Advance TT                                                                                                                              |
| Lead Time      | : | It's a campaign product, and the campaign is taken 2-3 times yearly.<br>The material can be supplied in 9-10 weeks once order received. |
| Validity       | : | Quotation valid up to 15 days.                                                                                                          |

## MEMO DINAS

Tanggal : 18 Agustus 2026  
Kepada Yth. : Departemen Finance  
Dari : Departemen Business Development  
CC : Direktur Keuangan  
Perihal : Pengajuan Pembelian Sampel API Norepinephrine Bitartrate Monohydrate  
Nomor : 060/MF/MF-BD/VIII/26

Dengan hormat,

Sehubungan dengan telah disetujuinya feasibility study pengembangan produk baru (Obat Baru Mersi/OBM) Norepinefrin Injeksi: 010/MF/FS-BD/II/26, kami informasikan bahwa terdapat kebutuhan atas material Norepinephrine Bitartrate Monohydrate (est. kebutuhan tahunan sekitar 1,8 kg).

*In connection with the approved feasibility study for the development of a new product (New Mersi Drug/OBM) Norepinephrine Injection, with reference number: 010/MF/FS-BD/II/26, we would like to inform you that there is a requirement for Norepinephrine Bitartrate Monohydrate material (estimated annual requirement of approximately 1,8 kg)*

Saat ini sudah dilakukan sourcing material dengan 4 source yang memenuhi syarat melalui tinjauan terhadap CoA material oleh Departemen R&D, serta kelengkapan dokumen pendukung, sesuai dengan regulasi. Adapun kebutuhan sampel untuk analisa awal dan laboratorium trial hingga trial up-scale adalah 35 gram untuk zat aktif dan 340 miligram untuk working standard.

*Currently, material sourcing has been carried out with 4 qualified sources, based on a review of the material CoA by the R&D Department and the completeness of supporting documents, in accordance with regulations. The required samples for initial analysis and laboratory trials are 35 grams of active substance and 340 milligrams of working standard*

Setelah didiskusikan dengan produsen mengenai kebutuhan sampel ini, sampel tidak dapat diberikan secara gratis untuk kuantitas yang diminta. Berikut untuk detail penawaran dari produsen:

*After discussions with the manufacturer regarding this sample requirement, it was confirmed that the requested quantity of samples cannot be provided free of charge. Below are the details of the manufacturer's offer:*

| No | Produsen/<br>Manufacturer                              | Commercial<br>Offer           | Sample<br>Offer                       | Dokumen/<br>Documents                                                                                | Detail Lain/<br>Other Details                                                                                                                                                                          |
|----|--------------------------------------------------------|-------------------------------|---------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | Shenzhen<br>Oriental<br>Pharmaceutical<br>→ Sinobright | USD 10,600/kg<br>(MOQ 0,1 kg) | USD 420,<br>together with<br>10 mg WS | <ul style="list-style-type: none"> <li>CoA: USP</li> <li>GMP: Yes</li> <li>WC:<br/>Shared</li> </ul> | <ul style="list-style-type: none"> <li>Regular production</li> <li>CIP by air</li> <li>Their internal policy only allows maximum purchase of 10 mg WS per customer. They suggest purchasing</li> </ul> |

| No | Produsen/<br>Manufacturer                         | Commercial<br>Offer                                                        | Sample<br>Offer                                                    | Dokumen/<br>Documents                                                                                                     | Detail Lain/<br>Other Details                                                                                                                                                                                                                            |
|----|---------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                   |                                                                            |                                                                    | <ul style="list-style-type: none"> <li>Halal: Statement shared</li> </ul>                                                 | <ul style="list-style-type: none"> <li>the Reference Standard directly from USP instead</li> <li>ED: 3 years</li> </ul>                                                                                                                                  |
| 2  | Surajlok Chemicals<br>→ Wolong Soko               | USD 13,000/kg<br>Quantity 1-5 kg, Packing size 1 kg<br><i>118 x 23.400</i> | USD 2,100<br>(Covers 35 grams of the sample and 340 mg of the WS.) | <ul style="list-style-type: none"> <li>CoA: USP</li> <li>GMP: Shared</li> <li>Halal: Statement shared</li> </ul>          | <ul style="list-style-type: none"> <li>Campaign production</li> <li>franco Jabodetabek, DAP</li> <li>ED: 4 years</li> </ul>                                                                                                                              |
| 3  | Zhongshan Wanhao Pharmaceutical Co., Ltd. → Yinuo | USD 14,000/kg<br>(MoQ 0,5 kg)<br><i>118 x USD 25.200</i>                   | USD 2,397.50 for 35 g and free working standard for 340 mg         | <ul style="list-style-type: none"> <li>CoA: USP</li> <li>GMP &amp; WC: Shared</li> <li>Halal: Statement shared</li> </ul> | <ul style="list-style-type: none"> <li>Regular production</li> <li>CIF by air jakarta</li> <li>ED: 1 year</li> <li>Free WS from a different batch than the sample (Already confirmed to RnD that WS from a different batch can still be used)</li> </ul> |
| 4  | Harman Finochem Ltd. → Direct offer               | USD 14/g<br>(MOQ 5 kg)<br><i>25.200</i> ✓                                  | USD 1,225 and free working standard for 340 mg                     | <ul style="list-style-type: none"> <li>CoA: USP</li> <li>GMP: Shared</li> <li>Halal: Statement shared</li> </ul>          | <ul style="list-style-type: none"> <li>Campaign production</li> <li>Production: normally 60 days</li> <li>CIP by Air Jakarta</li> <li>ED 3 years</li> </ul>                                                                                              |

Demikian hal ini kami sampaikan. Mohon arahan terkait rencana pembelian sampel untuk material tersebut.

*Thus, we kindly request your guidance regarding the plan to purchase samples of this material*

Menyetujui,  
Approved,

|                                                  | Persetujuan/Approval                | Tanda Tangan/<br>Signature   |
|--------------------------------------------------|-------------------------------------|------------------------------|
| <u>Dr. Matthew Yap, PharmD</u><br>Vice President | Harman is OK<br>Qty animal is small | <i>Matthew Yap</i><br>8/9/26 |
| <u>Kristiana Yanuar Nugraheni</u><br>BD Manager  | Harman                              | <i>Kristiana</i><br>8/9/26   |

Berikut hasil *review* CoA Norepinephrine Bitartrate ex Harman Finochem Ltd berdasarkan USP 48.

| No. | Parameter                       | USP 48<br>Monografi Norepinephrine<br>Bitartrate                                                                                     | Spesifikasi CoA                                                                                                                      | Hasil CoA                                                                              | Keterangan                                                              |
|-----|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| 1.  | Pemerian                        | Putih atau abu-abu pucat, tidak berbau, bubuk kristal. Berangsur-angsur menjadi gelap saat terpapar udara dan cahaya.                | Putih atau abu-abu pucat, bubuk kristal.                                                                                             | Serbuk putih kristal                                                                   | <del>Tidak terdapat</del> <sup>Sesuai</sup> spesifikasi dalam kompendia |
| 2.  | Kelarutan                       | Mudah larut dalam air; sedikit larut dalam alkohol; praktis tidak larut dalam kloroform dan eter                                     | Sangat larut dalam air, sedikit larut dalam alkohol, praktis tidak larut dalam kloroform dan eter                                    | Sesuai                                                                                 | <del>Tidak terdapat</del> <sup>Sesuai</sup> spesifikasi dalam kompendia |
| 3.  | pH                              | 3.5                                                                                                                                  | Sekitar 3.5                                                                                                                          | Sesuai                                                                                 | Sesuai dengan kompendial.                                               |
| 4.  | Melting point                   | 98- 104°C                                                                                                                            | 98- 104°C                                                                                                                            | 101.2-101.9°C                                                                          | Sesuai dengan kompendial.                                               |
| 5.  | Identifikasi                    | a. Spektrum serapan inframerah<br>b. Muncul warna hijau intensif<br>c. Tidak berwarna, biasanya sedikit merah muda atau sedikit ungu | a. Spektrum serapan inframerah<br>b. Muncul warna hijau intensif<br>c. Tidak berwarna, biasanya sedikit merah muda atau sedikit ungu | a. Sesuai<br>b. Sesuai<br>c. Larutan tidak berwarna                                    | Sesuai dengan kompendial.                                               |
| 6.  | Sisa Pemijaran                  | ≤ 0.1%, dari 200 mg                                                                                                                  | ≤ 0.1%                                                                                                                               | 0.05%                                                                                  | Sesuai dengan kompendial.                                               |
| 7.  | Cemaran organik (Batas Artenon) | ≤ 0.2                                                                                                                                | ≤ 0.2                                                                                                                                | 0.001                                                                                  | Sesuai dengan kompendial                                                |
| 8.  | Rotasi optik spesifik           | -10° sampai -12°                                                                                                                     | -10° sampai -12°                                                                                                                     | -12°                                                                                   | Sesuai dengan kompendial                                                |
| 9.  | Kadar air                       | 4.5 – 5.8 %                                                                                                                          | 4.5 – 5.8 %                                                                                                                          | 5.7%                                                                                   | Sesuai dengan kompendial                                                |
| 10. | Kadar                           | Titration<br>97.0% - 102.0% (anhidrat)                                                                                               | 97.0% - 102.0% (anhidrat)                                                                                                            | 100.0%                                                                                 | Sesuai dengan kompendial                                                |
| 11. | Sisa pelarut                    | NA                                                                                                                                   | Metanol ≤ 3000 ppm<br>Asetone ≤ 5000 ppm<br>Isopropil alkohol ≤ 5000 ppm<br>Diklorometane ≤ 600 ppm                                  | a. 35 ppm<br>b. Di bawah batas kuantitasi<br>c. 33 ppm<br>d. Di bawah batas kuantitasi | Tidak terdapat spesifikasi dalam kompendia                              |
| 12. | Angka mikroba aerobik           | NA                                                                                                                                   | ≤ 100cfu/g                                                                                                                           | 10 cfu/g                                                                               | Tidak terdapat spesifikasi dalam kompendia                              |
| 13. | Angka kapang khamir             | NA                                                                                                                                   | ≤ 10cfu/g                                                                                                                            | ≤ 10cfu/g                                                                              | Tidak terdapat spesifikasi dalam kompendia                              |
| 14. | Mikroorganisme spesifik         | NA                                                                                                                                   | a. Bakteri gram negative toleran empedu : tidak ada/g                                                                                | a. Tidak ada<br>b. Tidak ada<br>c. Tidak ada                                           | Tidak terdapat spesifikasi dalam                                        |

|     |                    |    |                                                                                                                                                                                                                                                                                                                          |                                                                                                                                 |                                            |
|-----|--------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
|     |                    |    | b. E.coli : tidak ada/g<br>c. Salmonella species : tidak ada/10g<br>d. P.aeruginosa : tidak ada/g<br>e. S.aureus : tidak ada/g<br>f. Clostridia : tidak ada/g<br>g. Candida albican : tidak ada/g                                                                                                                        | d. Tidak ada<br>e. Tidak ada<br>f. Tidak ada<br>g. Tidak ada<br>h. Tidak ada                                                    | kompendia                                  |
| 15. | Bakteri endotoksin | NA | $\leq 25$ (EU/mg)                                                                                                                                                                                                                                                                                                        | $\leq 20$ EU/mg                                                                                                                 | Tidak terdapat spesifikasi dalam kompendia |
| 16  | Senyawa sejenis    | NA | a. Cemarkan B pada 280 nm : $\leq 0.1\%$<br>b. Cemarkan D pada 280 nm : $\leq 0.1\%$<br>c. Cemarkan E pada 280 nm : $\leq 0.1\%$<br>d. Cemarkan F pada 254 nm : $\leq 0.1\%$<br>e. Cemarkan tidak spesifik pada 280 nm : $\leq 0.1\%$<br>f. Total cemarkan (total pada 280 nm dan cemarkan F pada 254 nm) : $\leq 0.3\%$ | a. Di bawah batas kuantitasi<br>b. 0.08%<br>c. Di bawah batas kuantitasi<br>d. Di bawah batas kuantitasi<br>e. 0.06%<br>f. 0.1% | Tidak terdapat spesifikasi dalam kompendia |

Berdasarkan hasil review CoA, CoA sudah sesuai dengan USP 48 dan terdapat tambahan pengujian di luar spesifikasi kompendia seperti batas mikroba, endotoksin, mikroba spesifik dan kadar cemarkan

A<sup>17/11/25</sup>  
M.Haqqi H.

<sup>17/11/25</sup>  
JA EIT



# Harman Finochem Limited

FACTORY : Plot No. A-100, A-100/1, A-100/2, A-120 & D-1, M.I.D.C., Industrial Area,  
Shendra, Chhatrapati Sambhajinagar - 431154, Maharashtra, INDIA.  
PH.: +91 (240) 2622001 / 6605500 / 6605580 • TELEFAX +91 (240) 2622002 • E-mail : info@harmanfinochem.com

| CERTIFICATE OF ANALYSIS                          |                               |                                                                                                                  |              |
|--------------------------------------------------|-------------------------------|------------------------------------------------------------------------------------------------------------------|--------------|
| Product                                          | NOREPINEPHRINE BITARTRATE USP |                                                                                                                  |              |
| Manufacturer                                     | M/s. HARMAN FINOCHEM LTD.     |                                                                                                                  |              |
| Batch Number                                     | SD0103025                     | A. R. Number                                                                                                     | SFPD01861    |
| Date of Manufacturing                            | November 2024                 | Date of Expiry                                                                                                   | October 2029 |
| Total Quantity Manufactured                      | 19.200 Kg.                    | Drug Lic. No.                                                                                                    | AD / 065     |
| Date of Release                                  | 24/12/2024                    |                                                                                                                  |              |
| TESTS                                            | RESULTS                       | SPECIFICATIONS / LIMITS                                                                                          |              |
| *Description                                     | White crystalline powder      | White or faintly gray, crystalline powder.                                                                       |              |
| *Solubility                                      | Complies                      | Freely soluble in purified water, Slightly soluble in Alcohol, practically insoluble in chloroform and in ether. |              |
| pH                                               | 3.50                          | It solutions are acid to litmus, having a pH of about 3.5.                                                       |              |
| Melting Range                                    | 101.2 °C – 101.9 °C           | Between 98 °C and 104 °C, without previous drying of the specimen, the melt being turbid.                        |              |
| Identification                                   | Complies                      | A. The FT-IR Spectrum of sample should concordant with spectrum of Norepinephrine Bitartrate working standard.   |              |
|                                                  | Complies                      | B. An intensely green colour develops.                                                                           |              |
|                                                  | Complies                      | C. The solution is colorless, or has at most a slight pink or slight violet colour.                              |              |
| Specific Optical Rotation (On anhydrous basis)   | - 12 °                        | -10° to -12°                                                                                                     |              |
| Water Content (By KF)                            | 5.7%                          | 4.5% to 5.8%                                                                                                     |              |
| Residue On Ignition                              | 0.05%                         | NMT 0.1%.                                                                                                        |              |
| Organic Impurities – Limit of Arterenone (By UV) | 0.001                         | NMT 0.2                                                                                                          |              |
| Assay (On anhydrous basis) By HPLC               | 100.0%                        | NLT 97.0% and NMT 102.0%<br><b>(In-house Limit: 98.5% to 101.0%)</b>                                             |              |
| Residual Solvents (By GC)                        | 35 ppm                        | Methanol : NMT 3000 ppm<br>(LOD : 4.2 ppm & LOQ : 14.1 ppm)                                                      |              |
|                                                  | BQL                           | Acetone : NMT 5000 ppm<br>(LOD : 0.6 ppm & LOQ : 2.0 ppm)                                                        |              |
|                                                  | 33 ppm                        | Isopropyl Alcohol : NMT 5000 ppm<br>(LOD : 2.7 ppm & LOQ : 8.9 ppm)                                              |              |
|                                                  | BQL                           | Dichloromethane : NMT 600 ppm<br>(LOD : 2.2 ppm & LOQ : 7.3 ppm)                                                 |              |
| <b>Additional In-house Tests:</b>                |                               |                                                                                                                  |              |
| Related substances (By HPLC) as per Ph. Eur.     | BQL                           | Impurity B at 280 nm : NMT 0.1 %<br>(LOD: 0.0003 % & LOQ: 0.0011 %)                                              |              |
|                                                  | 0.08%                         | Impurity D at 280 nm : NMT 0.1 %<br>(LOD: 0.0017 % & LOQ: 0.0055 %)                                              |              |

1 of 2

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OK, Free Sample 17% ✓

JRI

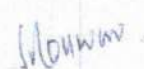
Wk 15



# Harman Finochem Limited

FACTORY : Plot No. A-100, A-100/1, A-100/2, A-120 & D-1, M.I.D.C., Industrial Area,  
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| CERTIFICATE OF ANALYSIS                                                                                             |                                                                                     |                                                                                         |              |
|---------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|--------------|
| Product                                                                                                             | NOREPINEPHRINE BITARTRATE USP                                                       |                                                                                         |              |
| Manufacturer                                                                                                        | M/s. HARMAN FINOCHEM LTD.                                                           |                                                                                         |              |
| Batch Number                                                                                                        | SD0103025                                                                           | A. R. Number                                                                            | SFPD01861    |
| Date of Manufacturing                                                                                               | November 2024                                                                       | Date of Expiry                                                                          | October 2029 |
| Total Quantity Manufactured                                                                                         | 19.200 Kg.                                                                          | Drug Lic. No.                                                                           | AD / 065     |
| Date of Release                                                                                                     | 24/12/2024                                                                          |                                                                                         |              |
| TESTS                                                                                                               | RESULTS                                                                             | SPECIFICATIONS / LIMITS                                                                 |              |
|                                                                                                                     | BQL                                                                                 | Impurity E at 280 nm : NMT 0.1 %<br>(LOD: 0.0005 % & LOQ: 0.0016 %)                     |              |
|                                                                                                                     | BQL                                                                                 | Impurity F at 254 nm : NMT 0.1 %<br>(LOD: 0.0044 % & LOQ: 0.0146 %)                     |              |
|                                                                                                                     | 0.06%                                                                               | Unspecified Impurity at 280 nm : NMT 0.10 %<br>(LOD: 0.0011 % & LOQ: 0.0038 %)          |              |
|                                                                                                                     | 0.1%                                                                                | Total impurities (Sum of the impurities at 280 nm and impurity F at 254 nm) : NMT 0.3 % |              |
| Bacterial Endotoxin Test (BET Test)                                                                                 | Less than 20 EU/mg                                                                  | NMT 25 EU/mg                                                                            |              |
| <b>Microbial Limit Test:</b>                                                                                        |                                                                                     |                                                                                         |              |
| <b>1) Microbial Enumeration Test:</b>                                                                               |                                                                                     |                                                                                         |              |
| a) Total Aerobic Microbial Count (TAMC)                                                                             | 10 cfu / g                                                                          | NMT 100 cfu / g.                                                                        |              |
| b) Total Combined Yeast & Mold Count (TYMC)                                                                         | < 10 cfu / g                                                                        | NMT 10 cfu / g.                                                                         |              |
| <b>c) Test for Specified Organisms:</b>                                                                             |                                                                                     |                                                                                         |              |
| i) Bile tolerant gram negative bacterial (Enterobacteria)                                                           | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| ii) Escherichia coli                                                                                                | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| iii) Salmonella species                                                                                             | Absent / 10 g                                                                       | Should be absent per 10g.                                                               |              |
| iv) Pseudomonas aeruginosa                                                                                          | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| v) Staphylococcus aureus                                                                                            | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| vi) Clostridia                                                                                                      | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| vii) Candida albicans                                                                                               | Absent / g                                                                          | Should be absent per g.                                                                 |              |
| <b>Remarks:</b> The Batch Complies as per USP and In-house specification.<br>*These tests are for information only. |                                                                                     |                                                                                         |              |
| Prepared by                                                                                                         | Checked by                                                                          | Approved by                                                                             |              |
|                                  |  | For Harman Finochem Ltd.                                                                |              |
| (Sr. Officer QA)                                                                                                    | (Dy. Manager QC)                                                                    | (D.G.M. QA)                                                                             |              |
| Date : 24/12/24                                                                                                     | Date : 24/12/24                                                                     | Date : 24/12/24<br>OF, Free Sample                                                      |              |