

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	FORMULIR LATAR BELAKANG PERMINTAAN BARANG HABIS PAKAI DEPARTEMEN: R&D	Diisi oleh Pemohon No. : <u>125 /LBPBHP/VII /2026</u>
Nama Barang Habis Pakai: <u>Bahan baku dan Working Standard Pramipexole HCl</u> <i>Berlaku untuk satu jenis barang</i>	Rencana Waktu Penggunaan: <u>September 2026</u> Lead time Purchasing: <u>80 Hari Kerja</u>	
Masa Waktu Pakai <u>s/d Expired Date</u>	Masa Frekuensi Pakai <u>Setiap kali trial</u>	
☒ Permintaan Item Baru	☐ Permintaan Kebutuhan Jadwal Kerja	
☐ Bahan Penunjang ☐ Perlengkapan Listrik ☐ Suku Cadang ☐ Alat Tulis ☐ Bahan Kebersihan ☐ Hardware ☐ Inkjet/Laserjet Print ☐ _____	☐ Innovator ☐ Kalibrasi ☐ Sample Bahan Kemasan ☐ Perbaikan ☒ Sample Bahan Baku ☐ Marketing Promosi ☐ Kualifikasi ☐ _____	
SYARAT WAJIB PERMINTAAN BARU 1. Sertakan Foto Barang Baru. 2. Dibatasi hanya sekali untuk awal mendaftarkan ke sistem QAD. 3. Pemesanan selanjutnya menggunakan Analisa Permintaan Barang dengan melampirkan hasil verifikasi stok fisik (kartu stok/bin card).	SYARAT WAJIB PERMINTAAN JADWAL KERJA 1. Formulir Perbaikan (jika dibutuhkan). 2. Setiap pengajuan menyertakan jadwal/timetable. 3. Dibatasi setiap mengajukan kebutuhan untuk memenuhi rencana jadwal kerja, sekalipun barang sudah terdaftar di sistem QAD.	
Digunakan untuk	<u>Bahan baku dan working standard Pramipexole HCl akan digunakan untuk analisa, trial skala laboratorium, dan trial scale-up.</u>	
Latar belakang permintaan	<u>Sehubungan dengan adanya pengembangan Obat Baru Mersi (OBM) produk Pramipexole tablet ER maka dibutuhkan bahan baku pramipexole HCl sebanyak 150 gram (100 g ex. Nosch dan 50 g ex. Hunan) dan working standard pramipexole HCl sebanyak 200 mg (100 mg ex Nosch dan 100 mg ex. Hunan)</u>	
☐ Perlu Minimum Stock <i>Tentukan Reorder Point</i>		
Dibuat:  Tgl. 16/07/2026 <i>(Staf/Koord.)</i>	Diperiksa:  Tgl. 16/07/2026 <i>(Koord./Spv/Ast. Mgr)</i>	Menyetujui:  Tgl. 16/07/2026 <i>(Kepala Departemen)</i>
Nomor Dokumen : COM-FPT/001A.00	Tanggal Berlaku : 11 SEP 2023	Disetujui oleh : 

MEMO DINAS

Tanggal : 07 Juli 2026
Kepada Yth. : Departemen Finance
Dari : Departemen Business Development
CC : Direktur Keuangan
Perihal : Pengajuan Pembelian Sampel API Pramipexole HCl
Nomor : 043/MF/MD-BD/VII/26

Dengan hormat,

Sehubungan dengan telah disetujuinya feasibility study pengembangan produk baru (Obat Baru Mersi/OBM) Pramipexole 0,375 mg dan 0,75 mg tablet dengan nomor: 009/MF/FS-BD/II/26, kami informasikan bahwa terdapat kebutuhan atas material Pramipexole HCl (est. kebutuhan tahunan sekitar 187,5 g).

In connection with the approved feasibility study for the development of a new product (New Mersi Drug/OBM) Pramipexole 0.375 mg and 0.75 mg tablets, with reference number: 009/MF/FS-BD/II/26, we would like to inform you that there is a requirement for Pramipexole HCl material (estimated annual requirement of approximately 187.5 g)

Saat ini sudah dilakukan sourcing material dengan 5 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 adalah 40 gram untuk zat aktif dan 100 miligram untuk working standard.

Currently, material sourcing has been carried out with 5 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 40 grams of active substance and 100 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/ Manufacturer	Commer. Offer	Sample Offer	Dokumen/ Documents	Detail Lain/ Other Details
1	Hunan Jiudian H. P. Co., Ltd. (China) → offer via CBC & SSN	USD 11,200/kg (0.5 kg)	USD 1,100	- Certification: WC & CoPP - Halal: statement	- Campaign production - Sample offer for 50 g of API + 100 mg of WS - ED 3 years
2	Deccan Nutraceuticals Pvt. Ltd. (India) → Direct offer	USD 10,000/kg (0.5 kg)	USD 1,100	- Certification: GMP - Halal: statement	- Campaign production - Sample offer for 100 g of API (MoQ for R&D) + 100 mg of WS - ED 3 years

No	Produsen/ Manufacturer	Commer. Offer	Sample Offer	Dokumen/ Documents	Detail Lain/ Other Details
3	Apitoria Pharma Pvt. Ltd. (India) → Direct offer	USD 7.500/kg*	USD 500*	• Certification: GMP & WC • Halal: statement	• Campaign production • Sample offer for 40 g of API + 100 mg of WS • ED 4 years *Based on the 2025 offer, so there will be a price increase. However, we have not yet received a reply
4	Nosch Labs Pvt. Ltd. (India) → Direct offer	USD 12,000/kg	USD 1,200	• Certification: CoPP • Halal: statement	• Regular production • Sample offer for 100 g of API (MoQ for R&D) + 100 mg of WS • ED 4 years
5	MSN Laboratories Pvt. Ltd. (India) → offer via Mensa	USD 25,000/kg	Free	• Certification: GMP • Halal: statement	• Campaign production • Free sample for 40 g of API + 100 mg of WS • ED 5 years
6	Macleods Pharmaceuticals Ltd. (India) → offer via IMCD	USD 14.5/g	USD 1000	• Certification: GMP • Halal: statement	• Campaign production • Free sample for 40 g of API + 20 mg of WS • ED 5 years

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

Atas arahan yang diberikan, kami sampaikan terima kasih.

We sincerely thank you for your direction and support

Hormat Kami,
Respectfully,



Muhammad Fathan Qoriba
BD Staff

Mengetahui,
Acknowledged,



Ayu Cipta Swasana
BD Asst. Manager

Menyetujui,
Approved,

	Persetujuan/Approval	Tanda Tangan/ Signature
<u>Dr. Matthew Yap, PharmD</u> Vice President	Yes agree, two company Hunan Jivdian and ma Nosh Ind. d.	 9/7/26
<u>Kristiana Yanuar Nugraheni</u> BD Manager	OK, dipilih Ichina; Indra	 9/7/26.

Bagian : R&D

ANALISA PERMINTAAN BARANG

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah
1	N/A	Pramipexole HCl ex. Hunan Jiudian Hongyang Pharmaceutical Co., Ltd	g	0	50.00 g	50.00 g	-	50.00 g
2		Working Standard Pramipexole HCl ex. Hunan Jiudian Hongyang Pharmaceutical Co., Ltd	mg	0	100.00 mg	100.00 mg	-	100.00 mg
3		Pramipexole HCl ex. Nosch Labs Pvt. Ltd	g	0	100.00 g	100.00 g	-	100.00 g
4		Working Standard Pramipexole HCl ex. Nosch Labs Pvt. Ltd	mg	0	100.00 mg	100.00 mg	-	100.00 mg

Catatan : *Tanpa kebutuhan Pilot Scale*

1. Bahan Baku dan Working Standard Pramipexole HCl ex. Hunan Jiudian Hongyang Pharmaceutical Co., Ltd dan ex. Nosch Labs Pvt. Ltd akan digunakan untuk analisa dan trial produk Pramipexole Tablet ER 0.375 dan 0.75 mg

2. Rencana penggunaan Bahan Baku Pramipexole ex Hunan Jiudian Hongyang Pharmaceutical Co:

- Analisa bahan baku (identifikasi, kadar, cemaran, kadar air, sisa pemijaran): 25 g
- Trial lab: 8 g
- Trial scale up dan optimasi: 15 g
- Cadangan: 2 g
- Total: 50 g

3. Rencana penggunaan Working Standard Pramipexole HCl ex. Hunan Jiudian Hongyang Pharmaceutical Co:

- Identifikasi A Bahan Baku: 5 mg
- Kadar bahan baku: 45 mg
- Batas Pramipexole Related Compound D: 25 mg
- Cemaran organik bahan baku: 8 mg
- Kadar obat jadi: 17 mg
- Total: 100 mg

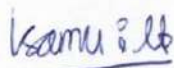
4. Rencana penggunaan Bahan Baku Pramipexole ex Nosch Labs Pvt. Ltd:

- Analisa bahan baku (identifikasi, kadar, cemaran, kadar air, sisa pemijaran): 25 g
- Trial lab: 45 g
- Trial scale up dan optimasi: 23 g
- Cadangan: 7 g
- Total: 100 g

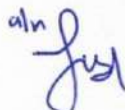
5. Rencana penggunaan Working Standard Pramipexole HCl ex. Nosch Labs Pvt. Ltd:

- Identifikasi A Bahan Baku: 5 mg
- Kadar bahan baku: 45 mg
- Batas Pramipexole Related Compound D: 25 mg
- Cemaran organik bahan baku: 8 mg
- Kadar obat jadi: 17 mg
- Total: 100 mg

Dibuat Oleh

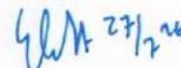


Samuel Lestyawan
Staff Formulasi

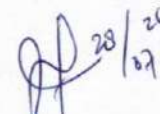


Ardian Wahyu P.
Spv. Formulasi

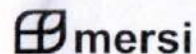
Diperiksa Oleh



Elvina Iskandar T.
Manager Formulasi



Juwita Ristiani
Manager Andev



PT. MERSIFARMA TM
SUKABUMI - INDONESIA

FORMULIR RENCANA KEBUTUHAN PENGGUNAAN BAHAN BAKU
RAW MATERIAL REQUIREMENTS PLAN FORM

DEPARTMENT
RESEARCH AND DEVELOPMENT

Nama Bahan Baku / Raw Material Name : Pramipexole HCl ex. Hunan Jiudian Hongyang

Kebutuhan Per-tablet (mg) <i>Per-Tablet Requirements</i> (mg)	Kebutuhan Analisa (g) <i>Analysis Requirements</i> (g)	Cadangan Bahan Baku (g) <i>Raw Material</i> <i>Buffer Stock</i> (g)	Kebutuhan Trial Skala Lab (g) <i>Lab Scale Trial Requirements</i> (g) 2000 pcs (3 Kali Trial Lab) (3 Time/s Trial Lab)	Kebutuhan Trial Scale Up (g) <i>Up Scale Trial Requirements</i> (g) 6250 pcs (2 kali trial scale up) (2 times trial scale up)
0.375 mg	25 g	2 g	3 g	5 g
0.75 mg			5 g	10 g
Total Kebutuhan Bahan Baku (g) <i>Raw Material Requirement in Total (g)</i>			50 g	

Catatan: Bahan Baku Pramipexole HCl ex. Hunan Jiudian Hongyang digunakan untuk analisa, trial skala lab, trial scale up, dan cadangan bahan baku. (Tanpa untuk kebutuhan Pilot) *LEF*

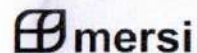
Notes: Pramipexole HCl ex. Hunan Jiudian Hongyang is used for analysis, lab scale trial, scale up trial, and backup stock

Nama Bahan Baku / Raw Material Name : Pramipexole HCl ex. Nosch Labs Pvt. Ltd

Kebutuhan Per-tablet (mg) <i>Per-Tablet Requirements</i> (mg)	Kebutuhan Analisa (g) <i>Analysis Requirements</i> (g)	Cadangan Bahan Baku (g) <i>Raw Material</i> <i>Buffer Stock</i> (g)	Kebutuhan Trial Skala Lab (g) <i>Lab Scale Trial Requirements</i> (g) 2000 pcs (20 Kali Trial Lab) <i>(20 Time/s Trial Lab)</i>	Kebutuhan Trial Scale Up (g) <i>Up Scale Trial Requirements</i> (g) 6250 pcs (3 kali trial scale up) <i>(3 times trial scale up)</i>
0.375 mg	25 g	7 g	15 g	8 g
0.75 mg			30 g	15 g
Total Kebutuhan Bahan Baku (g) <i>Raw Material Requirement in Total (g)</i>			100 g	

Catatan: Bahan Baku Pramipexole HCl ex. Nosch Labs Pvt. Ltd digunakan untuk analisa, trial skala lab, trial scale up, dan cadangan bahan baku. (Tanpa kebutuhan Pilot) *LEF*

Notes: Pramipexole HCl ex. Nosch Labs Pvt. Ltd is used for analysis, lab scale trial, scale up trial, and backup stock



PT. MERSIFARMA TM
SUKABUMI - INDONESIA

FORMULIR RENCANA KEBUTUHAN PENGGUNAAN BAHAN BAKU
RAW MATERIAL REQUIREMENTS PLAN FORM

DEPARTMENT
RESEARCH AND DEVELOPMENT

Nama Bahan Baku / Raw Material Name : Working Standard Pramipexole HCl working standard ex. Hunan Jiudian Hongyang dan ex. Nosch Labs Pvt. Ltd

Identifikasi <i>Identification</i>	Kadar Bahan Baku <i>Raw Material Assay</i>	Cemaran Organik <i>Organic Impurity</i>	Uji Batas Pramipexole Related Compound D <i>Pramipexole Related Compound D Limit Test</i>	Kadar Obat Jadi <i>Finished Good Assay</i>
5 mg	45 mg	8 mg	25 mg	17 mg
Total Kebutuhan Working Standard (g) <i>Working Standard Requirement Total (g)</i>			100 mg	

Catatan: Working Standard Pramipexole HCl ex. Hunan Jiudian Hongyang dan ex. Nosch Labs Pvt. Ltd digunakan untuk analisa

Notes: Working Standard Pramipexole HCl ex. Hunan Jiudian Hongyang and ex. Nosch Labs Pvt. Ltd is used for analysis

Dibuat Oleh

Created by

Samuel Lestyawan
(Staff Formulasi)

Diperiksa Oleh

Checked by

Ardian Wahyu Pradana
(Spv. Formulasi)

Elvina Iskandar T
(Manager Formulasi)

Juwita Ristiani
(Manager Andev)

Nomor Dokumen : RD.3-LIK/01.018F.00

Tanggal Berlaku : 23 JUN 2025

Disetujui Oleh :



HUNAN JUDIAN HONGYANG PHARMACEUTICAL CO.,LTD

Address: Tongguan Circular Economy Industrial Base, Wangcheng Economic and Technological Development Zone, Hunan, China
Tel: +86-731-88220222 Fax: +86-731-88220268 E-mail: yly@jiudianph.com

Certificate of Analysis

Product Name:	Pramipexole dihydrochloride	Batch No.:	WT202506YU01
Batch size	5.0kg	Date of Manufacture:	May 29, 2025
Date of Analysis:	Jun 02, 2025	Report No:	WC2025-06-YU01
Reference:	EP 10	Expired Date:	May 28, 2029
S.C NO.:	JDHY2025060401	Customer Code:	C-011721
Items	Acceptance criteria		Results
Characters	Appearance: White or almost white, crystalline powder		White crystalline powder
	Solubility: Freely soluble in water, soluble in methanol, sparingly soluble or slightly soluble in ethanol(96%), practically insoluble in methylene chloride.		Conforms
Identification	A. Specific optical rotation: -69.5 to -67.0 (anhydrous substances)		-67.8
	B: IR: Comparison reference standard.		Conforms
	C. Enantiomeric purity		Conforms
	D. Chemical reaction-chlorides		Conforms
Tests	Appearance of solution	The solution is clear and not more intensely colored than reference solution Y _n .	Conforms
	pH	2.8-3.4	3.1
	Related substances	Impurity A: not more than 0.15%	0.006%
		Impurity B: not more than 0.15%	0.06%
		Impurity C: not more than 0.15%	Not detected
		Unspecified individual impurity: not more than 0.10%	0.01%
		Total impurities: not more than 0.5%	0.09%
	Enantiomeric purity	Impurity D: not more than 0.5%	Not detected
	Residual solvents	Methanol: not more than 0.3%	0.004%
		Isopropanol: not more than 0.5%	0.04%
		Butanone: not more than 0.5%	Not detected
		Tetrahydrofuran: not more than 0.072%	Not detected
	Water		5.7%
	Sulfated ash	Not more than 0.1 %	0.03%
Assay	99.0-101.0% (anhydrous substance)		100.0%

Conclusion: This batch of Pramipexole dihydrochloride meets the specification of EP 10.

(Analyzed/Date):

21/6/2025.06.12

(Checked by/Date):

21/6/2025.06.12

(Approved by/Date):

21/6/2025.06.12

OT, free sample

23/12/25
JH
EIT