

ANALISA PERMINTAAN BARANG

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IBS00462	Ketorolac Compound A	mg	0	160	-160	0	160	0	0
2	IBS00463	Ketorolac Compound B	mg	0	160	-160	0	160	0	0
3	IBS00464	Ketorolac Compound C	mg	0	160	-160	0	160	0	0
4	IBS00465	Ketorolac Compound D	mg	0	160	-160	0	160	0	0

Catatan :

1. Ketorolac Related Compound A, Ex. Pharmaffiliates, Prod. Code : PA 11 05050, CAS. No : 167105-80-8
2. Ketorolac Impurity A / Related Compound B, Ex. Pharmaffiliates, Prod. Code : PA 11 05010, CAS. No : 154476-25-2
3. Ketorolac Impurity B / Related Compound C, Ex. Pharmaffiliates, Prod. Code : PA 11 05020, CAS. No : 113502-52-6
4. Ketorolac Related Compound D, Ex. Pharmaffiliates, Prod. Code : PA 11 05090, CAS. No : 113502-55-9

- Digunakan untuk pembuatan larutan induk pada penetapan cemaran produk Ketorolac Injeksi.
- Packing original : 1 Vial @20 mg.
- Pemesanan pertama kali Dept. QC

Latar Belakang Permintaan :

- Sehubung dengan adanya transfer metode analisa penetapan cemaran produk Ketorolac Injeksi 30 mg/mL maka diperlukan pengadaan reference standard sesuai dengan metode yang telah dikembangkan oleh Dept. R&D, sehingga dapat dilakukan pengujian rutin untuk produk tersebut.

Terlampir metode analisa, rencana kebutuhan dan CoA reference standard.

Dibuat

Mengetahui


ADA 16/26/26


Hn 16/26/26

 Good Quality Improves Life's Quality PT. MERSIFARMA TM. SUKABUMI-INDONESIA	PROTOKOL TRANSFER METODE ANALISA IDENTIFIKASI, KADAR DAN CEMARAN DALAM KETOROLAK INJEKSI SECARA HPLC TRANSFER PROTOCOL METHOD ANALYSIS OF IDENTIFICATION, ASSAY AND IMPURITY IN KETOROLAC INJECTION BY HPLC	Halaman : Page 7 of 14 Pages No. Dokumen : RD.02-PTP/084.00 Dokumen Number Tanggal Dokumen : Disetujui Document Approved Date Menggantikan No. : Replaces No.
	V spl = Volume larutan sampel yang digunakan (mL) Volume of sample solution in use (mL) 30 = Kandungan Ketorolac Trometamin I (mg/mL) Amount of Ketorolac trometamin (mg/mL) FP spl = Faktor pengenceran larutan sampel Dilution factor of sample solution FP std = Faktor pengenceran larutan standar Dilution factor of standard solution F = Kadar Working Standard (% As IS) Working Standard (% As Is) 4.6. Penetapan Cemar Organic Impurity 4.6.1. Persyaratan : - Senyawa Sejenis A Ketorolac : $\leq 0,20 \%$ Requirement : Ketorolac Related Compound A $\leq 0,20 \%$ - Senyawa Sejenis B Ketorolac : $\leq 0,5 \%$ Ketorolac Related Compound B $\leq 0,5 \%$ - Senyawa Sejenis C Ketorolac : $\leq 0,5 \%$ Ketorolac Related Compound C $\leq 0,5 \%$ - Senyawa Sejenis D Ketorolac : $\leq 0,20 \%$ Ketorolac Related Compound D $\leq 0,20 \%$ - Cemaaran lain : $\leq 0,20 \%$ Other Impurity $\leq 0,20 \%$ - Total cemaran : $\leq 1,50 \%$ Impurity total $\leq 1,50 \%$ Note : Abaikan cemaran yang kurang dari 0,05 % Note: Ignore impurities of less than 0.05%. 4.6.2. Metode : Kromatografi Cair Kinerja Tinggi Method : High Performance Liquid Chromatography 4.5.3.7. Waktu Retensi : 12 Menit $\pm$ 3 Menit Retention Time 12 Minutes $\pm$ 3 Minutes 4.5.3.8. Waktu Berakhir : 40 Menit $\pm$ 8 Menit End Time 40 Minutes $\pm$ 8 Minutes 4.6.3. Catatan : Lakukan kondisi pengerjaan HPLC, dan Pelarut sesuai dengan penetapan kadar. Note : Perform HPLC, Solvent, and Mobile phase conditions according to the determination of assay. 4.6.4. Larutan Induk Ketorolac Trometamin (Konsentrasi 0.1 mg/mL) Standard Ketorolac Trometamine Main Solution (Concentration 0.1 mg/mL) 4.6.4.1. Timbang seksama 2 mg Ketorolac Trometamol BPFI. Weigh accurately 2 mg Ketorolac Trometamol BPFI. 4.6.4.2. Masukkan ke dalam labu ukur 20 mL. Put into 20 mL Volumetric Flask. 4.6.4.3. Tambahkan 0,8 mL methanol, sonikasikan 10 menit. Add 0,8 mL methanol, sonicate for 10 minutes.	

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	4.6.4.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to volume, shake until homogenous. 4.6.5. Larutan Induk Ketorolac Senyawa Sejenis A (Konsentrasi 0.1 mg/mL) Standard Ketorolac Related Compound A Main Solution (Concentration 0.1 mg/mL) 4.6.5.1. Timbang seksama 2 mg Senyawa Sejenis A Ketorolac. Weigh accurately 2 mg Ketorolac Related Compound A. 4.6.5.2. Masukkan ke dalam labu ukur 20 mL. Put into 20 mL Volumetric Flask. 4.6.5.3. Tambahkan 0,8 mL methanol, sonikasikan 10 menit. Add 8 mL methanol, sonicate for 10 minutes. 4.6.5.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to volume, shake until homogenous. 4.6.6. Larutan Induk Ketorolac Senyawa Sejenis B (Konsentrasi 0.1 mg/mL) Standard Ketorolac Related Compound B Main Solution (Concentration 0.1 mg/mL) 4.6.6.1. Timbang seksama 2 mg Senyawa Sejenis B Ketorolac. Weigh accurately 2 mg Ketorolac Related Compound B. 4.6.6.2. Masukkan ke dalam labu ukur 20 mL. Put into 20 mL Volumetric Flask. 4.6.6.3. Tambahkan 0,8 mL methanol, sonikasikan 10 menit. Add 8 mL methanol, sonicate for 10 minutes. 4.6.6.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to volume, shake until homogenous. 4.6.7. Larutan Induk Ketorolac Senyawa Sejenis C (Konsentrasi 0.1 mg/mL) Standard Ketorolac Related Compound C Main Solution (Concentration 0.1 mg/mL) 4.6.7.1. Timbang seksama 2 mg Senyawa Sejenis C Ketorolac. Weigh accurately 2 mg Ketorolac Related Compound C. 4.6.7.2. Masukkan ke dalam labu ukur 20 mL. Put into 20 mL Volumetric Flask. 4.6.7.3. Tambahkan 0,8 mL methanol, sonikasikan 10 menit. Add 8 mL methanol, sonicate for 10 minutes. 4.6.7.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to volume, shake until homogenous. 4.6.8. Larutan Induk Ketorolac Senyawa Sejenis D (Konsentrasi 0.1 mg/mL) Standard Ketorolac Related Compound D Main Solution (Concentration 0.1 mg/mL) 4.6.8.1. Timbang seksama 2 mg Senyawa Sejenis D Ketorolac. Weigh accurately 2 mg Ketorolac Related Compound D. 4.6.8.2. Masukkan ke dalam labu ukur 20 mL. Put into 20 mL Volumetric Flask. 4.6.8.3. Tambahkan 0,8 mL methanol, sonikasikan 10 menit. Add 8 mL methanol, sonicate for 10 minutes. 4.6.8.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. Add solvent up to volume, shake until homogenous. 4.6.9. Larutan standar (Konsentrasi 0.0002 mg/mL) Standard Solution (Concentration 0.0002 mg/mL)	

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	4.6.9.1. Pipet 200 µL masing -masing induk Ketorolak Tromeamine, Senyawa Sejenis A Ketorolak, Senyawa Sejenis B Ketorolak, Senyawa Sejenis C Ketorolak, Senyawa Sejenis D Ketorolak. <i>Pipette 200 µL of each main solution of Ketorolac Tromeamine, Ketorolac Compound A, Ketorolac Compound B, Ketorolac Compound C, Ketorolac Compound D.</i> 4.6.9.2. Masukkan ke dalam labu ukur 100 mL. <i>Put into 100 mL Volumetric Flask.</i> 4.6.9.3. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, shake until homogenous.</i> 4.6.9.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to volume, shake until homogenous.</i> 4.6.10. Larutan sampel [0,24 mg/mL] <i>Sample Solution [0,24 mg/mL]</i> 4.6.10.1. Pipet 1 mL sampel setara dengan 30 mg Ketorolak Trometamin <i>Pipette 1 mL sample equivalent to 30 mg Ketorolac Tromethamine.</i> 4.6.10.2. Masukkan ke dalam labu ukur 25 mL. <i>Put into 25 mL Volumetric Flask.</i> 4.6.10.3. Tambahkan pelarut hingga 15 mL, sonikasi selama 10 menit. <i>Add solvent 15 mL solvent, sonicate for 10 minute</i> 4.6.10.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 4.6.10.5. Pipet 5 mL masukkan ke labu ukur 25 mL <i>Pipette 5 mL add into 25 mL volumetric Flask</i> 4.6.10.6. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 4.6.10.7. Saring larutan menggunakan syringe filter 0,45 µm. <i>Filter the solution using 0.45 µm syringe filter.</i> 4.6.10.8. Masukkan ke dalam vial HPLC. <i>Put into HPLC vial.</i> 4.6.11. Larutan Placebo <i>Placebo Solution</i> 4.6.11.1. Pipet 1 mL placebo <i>Pipette 1 mL Placebo</i> 4.6.11.2. Masukkan ke dalam labu ukur 25 mL. <i>Put into 25 mL Volumetric Flask.</i> 4.6.11.3. Tambahkan pelarut hingga 15 mL, sonikasi selama 10 menit. <i>Add solvent 15 mL solvent, sonicate for 10 minute</i> 4.6.11.4. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i> 4.6.11.5. Pipet 5 mL masukkan ke labu ukur 25 mL <i>Pipette 5 mL add into 25 mL volumetric Flask</i> 4.6.11.6. Tambahkan pelarut sampai tanda batas, kocok sampai homogen. <i>Add solvent up to the volume, shake until homogeneous.</i>	



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SUKABUMI-INDONESIA

**PROTOKOL TRANSFER METODE ANALISA
IDENTIFIKASI, KADAR DAN CEMARAN DALAM
KETOROLAK INJEKSI SECARA HPLC
TRANSFER PROTOCOL METHOD ANALYSIS
OF IDENTIFICATION, ASSAY AND IMPURITY IN
KETOROLAC INJECTION BY HPLC**

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Document Approved		
Date		
Menggantikan No.	:	-
Replaces No.		

4.6.11.7. Saring larutan menggunakan syringe filter 0,45 µm.

Filter the solution using 0.45 µm syringe filter.

4.6.11.8. Masukkan ke dalam vial HPLC.

Put into HPLC vial.

4.7. Uji Kesesuaian Sistem :

System suitability test

4.7.1. Suntikkan larutan standar ke sistem HPLC sebanyak 6 kali.

Inject standard solution into HPLC for 6 times replication.

4.7.2. Amati respons dan hitung RSD dari hasil perhitungan alat.

Determine peak areas and calculate RSD out of each instrument responds.

Kriteria keberterimaan : RSD luas area ≤ 2,8%

Acceptance criteria : RSD area ≤ 2,8%.

RSD waktu retensi : ≤ 2,8 %

RSD retention time ≤ 2,8%

R antara Senyawa Sejenis C dan Ketorolak ≥ 2,0

R Between Compound C and Ketorolac ≥ 2,0

4.6.7. Prosedur

Procedure

Suntikkan secara terpisah pelarut, larutan standar, dan larutan sampel ke dalam sistem HPLC, ukur respons puncak utama.

Separately inject solvent, standard solution, sample solution, System suitability solution into HPLC system, measure the major peak response.

No	Larutan Solution	Jumlah injek Number of Injections
1.	Pelarut Solvent	1x
2.	Placebo Solvent	1x
3.	Standar Standard	6x
4.	Sampel Sample	6x

Tentukan jenis cemaran berdasarkan tabel berikut ini :

Determine related compound according the table below :

Cemaran Impurity	Waktu Retensi Relatif Relative Retention Time
Senyawa Sejenis A Ketorolak Ketorolac Related Compound A	0,4
Senyawa Sejenis B Ketorolak Ketorolac Related Compound B	0,6
Senyawa Sejenis C Ketorolak Ketorolac Related Compound C	0,80
Ketorolak Ketorolac	1,0
Senyawa Sejenis D Ketorolak Ketorolac Related Compound D	2,1

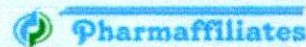


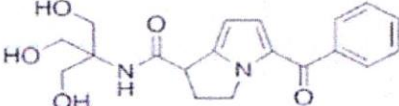
Rencana Kebutuhan Ketorolac Related Compound A

No	Nama Produk	Parameter	Sisa Forecast 2026 (Batch)	Pengujian Stabilitas (Interval)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Ketorolac Injeksi 20 mg / vial	Kadar dan Cemaran	60	12	2	144
Total (mg)						144

Kesimpulan : Dibutuhkan sebanyak 144 mg RS Ketorolac Related Compound A, Quantity 1 Vial @ 20 mg sehingga dibutuhkan 8 vial

Certificate of Analysis



Product Name	Ketorolac Related Compound A	
Lot No.	PA-KEO-02205S2V2F1	
Product Code	PA 11 05050	
CAS No.	167105-80-8	
Release Date	24 Nov 2022	
Retest Date	23 Nov 2025	
Molecular Weight	358.39	
Molecular Formula	C ₁₉ H ₂₂ N ₂ O ₅	
Storage	2 - 8°C in dark place	
Shipping	Ambient temperature in dark condition	
Synonyms	<i>rac Ketorolac Tris Amide Impurity; (±)-5-Benzoyl-2,3-dihydro-N-[2-hydroxy-1,1-bis(hydroxymethyl)ethyl]-1H-pyrrolizine-1-carboxamide; 5-Benzoyl-N-[1,3-dihydroxy-2-(hydroxymethyl)propan-2-yl]-2,3-dihydro-1H-pyrrolizine-1-carboxamide;</i>	

ANALYTICAL INFORMATION			
S. No.	Tests	Result	Specifications
1.	Description	White solid	White to off white solid
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	Loss (% w/w)	0.19	-
4.	Residue on Ignition (% w/w)	0.05	-
5.	Chromatographic Purity (% by HPLC)	99.3	NLT 95.0
6.	Assay (% m), on as is basis	99.1	-

Summary Product is characterized by using IR, NMR, MS, TGA, HPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

Quality concern, if any: Inform within 3 months of Invoice Date.

Date of Issue 12 Mar 2024

Vial No. : 15342
Version : 05

(Checked by)

Authorized Signatory

(Lakhinder Singh)
Lot Certifier
PS

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Signature
16/03/24

Rencana Kebutuhan Ketorolac Related Compound B / Ketorolac Impurity A

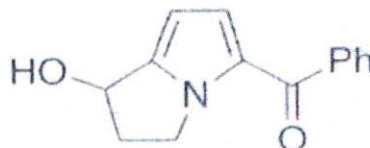
No	Nama Produk	Parameter	Sisa Forecast 2026 (Batch)	Pengujian Stabilitas (Interval)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Ketorolac Injeksi Injeksi 30 mg / mL	Kadar dan Cemaran	60	12	2	144
Total (mg)						144

Kesimpulan : Dibutuhkan sebanyak 144 mg RS Ketorolac Related Compound B / Ketorolac Impurity A, Quantity 1 Vial @ 20 mg sehingga dibutuhkan 8 vial

Certificate of Analysis



Product Name	Ketorolac - Impurity A
Lot No.	PA-KEO-12201S2V47F1
Product Code	PA 11 05010
CAS No.	154476-25-2
Release Date	22 May 2023
Retest Date	21 May 2026
Molecular Weight	227.26
Molecular Formula	C ₁₄ H ₁₃ NO ₂
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	Descarboxy 1-Hydroxy Ketorolac; (2,3-Dihydro-1-hydroxy-1H-pyrrolizin-5-yl)phenylmethanone; Ketorolac Hydroxy Impurity; Ketorolac 1-hydroxy analog; Ketorolac Tromethamine IP Impurity; 5-Benzoyl-2,3-dihydro-1H-pyrrolizin-1-ol, Ketorolac Related Compound B (USP);



ANALYTICAL INFORMATION			
S. No.	Tests	Result	Specifications
1.	Description	Brown powder	Brown to light brown powder
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	LOD (% w/w)	0.56	-
4.	Residue on Ignition (% w/w)	3.40	-
5.	Chromatographic Purity (% by HPLC)	99.6	NLT 95.0
6.	Assay (% m/m) on as is basis	95.6	-

Summary Product is characterized by using IR, NMR, MS, TGA, HPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

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Date of Issue 07 Mar 2025

Vial No. : 15867
Version : 05



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(Lakhvinder Singh)
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Handwritten signature and date: 16/07/26

Rencana Kebutuhan Ketorolac Related Compound C / Ketorolac Impurity B

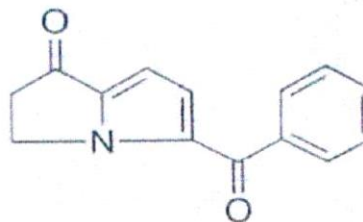
No	Nama Produk	Parameter	Sisa Forecast 2026 (Batch)	Pengujian Stabilitas (Interval)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Ketorolac Injeksi Injeksi 30 mg / mL	Kadar dan Cemaran	60	12	2	144
Total (mg)						144

Kesimpulan : Dibutuhkan sebanyak 144 mg RS Ketorolac Related Compound C / Ketorolac Impurity B, Quantity 1 Vial @ 20 mg sehingga dibutuhkan 8 vial

Certificate of Analysis



Product Name	Ketorolac - Impurity B
Lot No.	PH-KEO-02202S1V4F1
Product Code	PA 11 05020
CAS No.	113502-52-6
Release Date	22 May 2023
Retest Date	21 May 2026
Molecular Weight	225.25
Molecular Formula	C ₁₄ H ₁₁ NO ₂
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	Ketorolac 1-Keto Analogue; 1-Keto Ketorolac; 5-Benzoyl-2,3-dihydro-1H-pyrrolizin-1-one, Ketorolac - Impurity B



ANALYTICAL INFORMATION

S. No.	Tests	Result	Specifications
1.	Description	Yellow solid	Yellow to pale yellow solid
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	LOD (% w/w)	0.06	-
4.	Residue on Ignition (% w/w)	0.01	-
5.	Chromatographic Purity (% by HPLC)	99.8	NLT 95
6.	Assay (% m/m) on as is basis	99.7	-

Summary Product is characterized by using IR, NMR, MS, TGA, HPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

Quality concern, if any: Inform within three months of Invoice Date.

Date of Issue 18 Jan 2025

Vial No. : 14593
Version : 05



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16/09/24

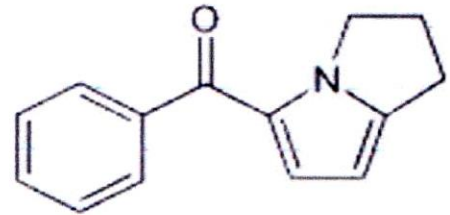
Rencana Kebutuhan Ketorolac Related Compound D

No	Nama Produk	Parameter	Sisa Forecast 2026 (Batch)	Pengujian Stabilitas (Interval)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Ketorolac Injeksi 20 mg/ml	Kadar dan Cemaran	60	12	2	144
Total (mg)						144

Kesimpulan : Dibutuhkan sebanyak 144 mg RS Ketorolac Related Compound D, Quantity 1 Vial @ 20 mg sehingga dibutuhkan 8 vial



Product Name	Ketorolac Related Compound D
Lot No.	PA-KEO-02209S2V4F1
Product Code	PA 11 05090
CAS No.	113502-55-9
Release Date	08 Jul 2022
Retest Date	07 Jul 2025
Molecular Weight	211.26
Molecular Formula	C ₁₄ H ₁₃ NO
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	Phenyl(2,3-dihydro-1H-pyrrolizin-5-yl)methanone; Ketorolac 1-Decarboxy Impurity; 1-Decarboxy Ketorolac; (2,3-dihydro-1H-pyrrolizin-5-yl)(phenyl)methanone; (2,3-Dihydro-1H-pyrrolizin-5-yl)phenylmethanone; 5-Benzoyl-2,3-dihydro-1H-pyrrolizine.;



ANALYTICAL INFORMATION

S. No.	Tests	Result	Specifications
1.	Description	Off white powder	White to off white powder
2.	Identification by:		
	IR	Conforms	To conform to structure
	NMR	Conforms	To conform to structure
	MS	Conforms	To conform to structure
3.	LOD (% w/w)	0.59	-
4.	Residue on Ignition (% w/w)	0.01	-
5.	Chromatographic Purity (% by HPLC)	98.6	NLT 95.0
6.	Assay (% m/m) on as is basis	98.01	-

Summary Product is characterized by using IR, NMR, MS, TGA, HPLC

Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.

Quality concern, if any: Inform within three months of Invoice Date.

Date of Issue -

Authorized Signatory

Vial No. : 14572
Version : 05

(Checked by)

(Lakhvinder Singh)
Lot Certifier
SR

[Signature]
26/07/21