Letter No: MH/TZ6/CON/6105466

APPROVAL Dt: 28/03/2022

APPROVAL No: 6105466

Food & Drugs Administration, KONKAN Division OFFICE OF JOINT COMMISSIONER [K.D] 4TH FL.ESIC BLD, WAGLE ESTATE Thane - 400604

## **Change in CONSTITUTION**

To: **AKSIPRO DIAGNOSTICS PLIMITED (705058)** 

PLOT NO: K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI

VILLAGE, ADDITIONAL MIDC,, AMBERNATH (E) - 421506

Taluka: Ambernath City, District: Thane-Zone6

Ref: Your Inward Application vide Inward ID: 188148, Inw Dt: 20/12/2021, App. Type: CON

With reference to your Inward application vide Inward ID: 188148, Inw Dt: 20/12/2021, esend Dt: 03/03/2022 we have to inform you that your said application for Change in Constitution has been APPROVED and CONSTITUTION has been Changed

**OLD CONSTITUTION:** Public Limited-PUB, BHARAT SERUMS & VACCINES LTD

NEW CONSTITUTION: Limited Company-LTD, AKSIPRO DIAGNOSTICS P LIMITED

**Remarks:** Change in constitution

List of Valid Licenses for Approved Change in CONSTITUTION	#PRD	LIC No / Validity	First Issue / Rnw
Own : At my OWN Manufacturing Premises	395	28-KD/360	07/09/2002
		21/09/2026	22/09/2021
L - A V PROCESSORS PRIVATE LIMITED (05096)	12	28A-KD/2535A	06/02/2009
Plant E-52,,Anand Nagar MIDC,AMBERNATH,ADDITIONAL AMBERNATH-421506 (TZ6)		21/09/2026	22/09/2021
Own : At my OWN Manufacturing Premises	122	28D-KD/4 21/09/2026	27/06/2003 22/09/2021
Own : At my OWN Manufacturing Premises	48	28E-KD/5	01/07/2004
		21/09/2026	22/09/2021

Notings: L.A: pls discss[92-13/03/2022]~proposal approved as recommended for change in constitution wef 22-09-21 [92-28/03/2022]

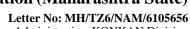


D. M. BHAMRAY **Licensing Authority** Food & Drugs Administration KONKAN Division, Maharashtra State

Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 41895 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-ld: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional) Balance: 12550

This License/Certificate is eSIGNED. Physical Signature is NOT Required.

Division	MFG ID No	Type:Change in Constitution	APPROVAL No	Issue Date
KONKAN (TZ6)	705058	CON-188148-20/12/2021	6105466	28/03/2022



APPROVAL Dt:08/04/2022

APPROVAL No: 6105656

Food & Drugs Administration, KONKAN Division OFFICE OF JOINT COMMISSIONER [K.D] 4TH FL.ESIC BLD,WAGLE ESTATE Thane - 400604

# **Change in NAME**

FDA MA

AKSIPRO DIAGNOSTICS P LIMITED (705058)

PLOT NO: K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI

VILLAGE, ADDITIONAL MIDC,, AMBERNATH (E) - 421506

Taluka: Ambernath City, District: Thane-Zone6

Ref: Your Inward Applicationvide Inward ID: 197386, Inw Dt: 30/03/2022, App. Type: NAM

With reference to your Inward application vide Inward ID: 197386, Inw Dt: 30/03/2022, esend Dt: 30/03/2022 we have to inform you that your said application for **Change in Name** has been APPROVED and NAME has been Changed

**OLD NAME:** AKSIPRO DIAGNOSTICS P LIMITED

NEW NAME: BHARAT SERUMS AND VACCINES LIMITED

**Remarks:** Change in name from Aksipro Diagnostics P Limited to Bharat Serums and Vaccines Limited.

Туре	Form	LIC No / Validity	First Issue / Rnw
Own : At my OWN Manufacturing Premises	28	KD/360 <b>21/09/2026</b>	07/09/2002 <b>22/09/2021</b>
L - A V PROCESSORS PRIVATE LIMITED (105096) Plant E-52,,Anand Nagar MIDC,AMBERNATH,ADDITIONAL AMBERNATH421506	28A	KD/2535A 21/09/2026	06/02/2009 <b>22/09/2021</b>
Own : At my OWN Manufacturing Premises	28D	KD/4 <b>21/09/2026</b>	27/06/2003 <b>22/09/2021</b>
Own : At my OWN Manufacturing Premises	28E	KD/5 <b>21/09/2026</b>	01/07/2004 22/09/2021

Notings: L.A: proposal approved as recommended wef 10-11-21[92-08/04/2022]



TPAV # D7PEB918X9





D. M. BHAMRAY

D. M. BHAMRAY
Licensing Authority
Food & Drugs Administration
KONKAN Division, Maharashtra State



Fee Payment(s): DB-Id: 423778 - 30/03/2022 (Amt: 1000) (Fees Paid for Change in Name) Balance: 11550

This License/Certificate is eSIGNED. Physical Signature is NOT Required.

Division	MFG ID No	Type:Change in Name	APPROVAL No	Issue Date
KONKAN (TZ6)	705058	NAM-197386-30/03/2022	6105656	08/04/2022

FDA MAHARASHTRA

Food & Drugs Administration, KONKAN Division OFFICE OF JOINT COMMISSIONER [K.D] 4TH FL.ESIC BLD,WAGLE ESTATE Thane - 400604

### FORM 28 [See Rule 76]

Licence to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) excluding those specified in Sch. X

 $New\ Constitution: Limited\ Company,\ (Old\ -\ Public\ Limited),\ Previous\ Validity\ was\ from\ 07/09/2017\ to\ 06/09/2022$ 

Number of licence and date of issue KD/360 & Dt: 28/03/2022, Valid upto 21/09/2026

#### 1. AKSIPRO DIAGNOSTICS P LIMITED (705058 - Limited Company)

is hereby licensed to manufacture at the premises situated at

PLOT NO: K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC,, AMBERNATH (E) - 421506, Taluka: AMBERNATH CITY,

**District: THANE-ZONE6** the following categories of drugs being drugs specified in Schedules

C, C(1), {excluding those Specified in Sch. X} to the Drugs and Cosmetics Rules, 1945.

### Names of drugs is as per the list attached, beneath

#### 2. Name of Approved Competent Technical Staff

PAN No.	Staff Name	Section	Designation	Qual
*****482G	GIRISH SHANKAR SHARMA VADLAMANI	Pyrogen, Toxicity	Vice President QA	PHD
*****504H	MAHESH GAVASANE	Bulk Drugs / API, r DNA Products	Research Executive	BPH
*****732L	MANNAN KHAMBATI	Bulk Drugs / API	GM Biotesh	MSC
******045P	MR. AMOL S. LONKAR	Parenteral preparations	OFFICER	MPH
*****900A	MR. AVINASH SHINDE	Chemical & Instrumentation	Asst. Manager	BSC
*****372H	MR. GORAKHNATH VILAS SURYAWANSHI	Chemical & Instrumentation	Executive QC	MSC
*****667P	MR. LOUKIK PRABHAKAR FEGADE	Parenteral preparations	Sr. Executive	BSC
*****556B	MR. MANDAR GAIKWAD	Bulk Drugs / API	Asst Manager Production Biotech Dept	BSC
*****883E	MR. MANOJ NERURKAR	Parenteral preparations	DGM Production	BSC
*****810A	MR. MAYUR RANE	Parenteral preparations	Sr. Executive	BSC
*****355K	MR. NARENDRA B. PAWAR	Parenteral preparations	Sr. Executive	MSC
*****728F	MR. NITIN LOKHANDE	Parenteral preparations	Executive	ВРН
*****737M	MR. PRABHAKAR UTTAM JOGDNAD	Chemical & Instrumentation	Sr. Executive	MSC
*****937C	MR. RAMESH GHANVAT	Parenteral preparations	Officer	MPH
*****905B	MR. SACHIN LIMHAN	Parenteral preparations	SR. Executive (Injection Production)	ВРН
*****547F	MR. SATISH V. GUDLE	Parenteral preparations	OFFICER	ВРН
*****276Q	MR. UMESH POLEKAR	Chemical & Instrumentation	Sr. Manager	BSC
*****933B	MR. USMAN ALI ANSARI	Bulk Drugs / API	Sr. Executive	MSC
*****399F	MR. VIDHYADHAR S. KHABALE	Parenteral preparations	Executive	MSC
*****909P	MR. VIJAY BAPU PAWAR	Chemical & Instrumentation	Sr. Executive	MSC
*****114L	MR. YOGESH VYAS	Parenteral preparations, Injection	Executive Production Biotech Dept	MPH
*****291L	MS. USHA PARMESHWAR	Chemical & Instrumentation	Sr. Executive QC	MSC

Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 418995 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-Id: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional), Balance: 7050

This License/Certificate is eSIGNED. Physical Signature is NOT Required

Circle (Loan / Own)	MFG ID No	Type:Change in Constitution	License No	Issue Date
KONKAN (T76)	705058	CON-188148-20/12/2021	KD/360	28/03/2022

*****849K	OMKAR NANDKUMAR MULUKH	Bioassay	Sr. Officer	MSC
*****573E	PANKAJ PATIL	Parenteral preparations	Officer -Production	BPH
*****351L	SACHIN MALI	Microbiology Testing, Sterility	Sr. Executive QC	MSC
*****162G	SANDIP D. PATIL	Microbiology Testing, Sterility	Manager QC	MSC
*****929F	SHAHAJI T. PATIL	Quality Assurance	Sr. Manager	BSC
*****571Q	SHRIKANT A. PANGAONKAR	Parenteral preparations	Executive	BPH
*****465C	SRINATH REDDY	Bioassay	Sr. Executive	MPH
*****294M	VINAY L. MHATRE	Chemical & Instrumentation	Chemist -QC	MSC
******097J	VINOD SINGH	Parenteral preparations	Asst. Manager	BPH
*****661C	VISHWANATH MALKAR	Chemical & Instrumentation	Sr. Manager	BSC

- **3.** The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale..
- 4. The licence shall be in force from 22/09/2021 to 21/09/2026
- **5.** The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.

**Date of Issue:** 27/04/2022



DUSHYANT BHAMRAY e-Signed on 28-03-2022 16:08

TPAV # H5H78M93F2



200

D. M. BHAMRAY
Licensing Authority
Food & Drugs Administration
KONKAN Division, Maharashtra State

#### **Conditions of Licence**

- 1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- 2. If the licencee wishes to undertake during the currency of the license, to manufacture of any drug specified in schedules  $\,C$  and  $\,C(1)$ , excluding those specified in Sch X not included above, he should apply to the licensing authority for the necessary endorsement as provided in Rule 75(3). This license will be deemed to extend to the items so endorsed.
- 3. Any change in the 102[competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
- 4. The Licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
- 5. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.



Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 418995 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-Id: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional), Balance: 7050

This License/Certificate is eSIGNED. Physical Signature is NOT Required

Circle (Loan / Own)	MFG ID No	Type:Change in Constitution	License No	Issue Date
KONKAN (T76)	705058	CON-188148-20/12/2021	KD/360	28/03/2022



Letter No: MH/TZ6/CON/6105466

Food & Drugs Administration, KONKAN Division OFFICE OF JOINT COMMISSIONER [K.D] 4TH FL.ESIC BLD,WAGLE ESTATE

Thane - 400604

### **Change in Constitution**

To: LICENSE No: KD/360 705058- AKSIPRO DIAGNOSTICS P LIMITED (Limited & Dt: 28/03/2022

Company)

PLOT NO : K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC,, AMBERNATH (E) -

421506

Taluka: AMBERNATH CITY, District: THANE-ZONE6

Sir,

### Ref: Your Inward Application vide Inward ID: 188148 (CON) Dated: 20/12/2021

With reference to your Inward application, we inform you that your said application is considered & following *LICENSE* has been granted, with the following PRODUCTS.

Туре	Form	LIC No / Validity	First Issue / Rnw
Own : At my OWN Manufacturing Premises	28	KD/360 <b>21/09/2026</b>	07/09/2002 22/09/2021
Prod Name of Drugs			

Prod	Name of Drugs		
1.	FUNGIPLUS 50 mg / (Amphotericin B for Injection U.S.P.)	(Lyophilized)	Export (USP)
165139	Each Vial contains::	- Amphotericin B USP (50 mg)	
		- Sodium Deoxycholate (. QS)	
		- Excipients: Sodium Hydroxide U.S.N.F., Phosphoric a	acid U.S.N.F. (.
		)	
2.	AMPHOTRET / (Amphotericin B for Injection U.S.P.)	Lyophilized	Export (USP)
163510	Each Vial contains::	- Amphotericin B USP (50 mg)	
		- Sodium Deoxycholate (. QS)	
3.	Amphotericin B - COX 50 mg / (Amphotericin B for Injection	U.S.P.) (Lyophilized)	Export (USP)
208621	Each Vial contains::	- Amphotericin B U.S.P. USP (50 mg)	
		- Sodium Deoxycholate (. QS)	
ı.	ANFOCIN / (Amphotericin B for Injection U.S.P.) ≥ (I	Lyophilized)	Export (USP)
190507	Each Vial contains::	- Amphotericin B USP (50 mg)	
		- Sodium Deoxycholate (. QS)	
5.	AMPHO / (Amphotericin B for Injection U.S.P.) (Lyophi	, , ,	Export (USP)
91763	Each Vial contains:	- Amphotericin B U.S.P. USP (50 mg)	• `
		- Sodium Deoxycholate (. QS)	
		- Sodium Hydroxide U.S.N.F., Phosphoric Acid U.S.N.	F. (, )
5.	Amphotericin B Lipid complex - COX Injection 100 mg / (Amphot I.V.)		Export
208633	Each ml contains::	- Amphotericin B U.S.P. USP (5 mg)	
	The second second	- Sodium Chloride B.P. BP (9 mg)	
	ACC TOTAL	- Lipids:Dimyristoylphosphatidylcholine (DMPC) 3.4 mg	7.
	11 - 1 - 1 - 1	Dimyristoylphosphatidylglycerol (DMPG as Sodium salt	
13	1 1 1 10	- Pack Size : 20 ml (- )	
1	St. T. S. S. Santalana	- This product will be manufactured by M/s. Bharat Ser	rums and
25,000	- 11 1 1/	Vaccines Ltd., & will be combipacked along with a Pre-	Sterilized filter
	month 1 1 2 - 1, -24/3	needle. (- )	
	AMPHOLIP (Combipack) / (Amphotericin B Lipid C	Complex Injection I.V.)	Export
190819	Each ml contains::	- Amphotericin B USP (5 mg)	
		- Sodium Chloride BP (9 mg)	
		- Water for Injection USP (. QS)	
		- Lipids:Dimyristoylphosphatidylcholine (DMPC) 3.4 mg	7,
		Dimyristoylphosphatidylglycerol (DMPG as Sodium salt	
		- Pack Size: 2 ml, 10 ml and 20 ml. (. )	
		- This product will be manufactured by M/s. Bharat Ser	rums and
		Vaccines Ltd., & will be combipacked along with a Pre-	Sterilized filter
		needle. (. )	

Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 418995 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-Id: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional), Balance: 7050

 $This\ License/Certificate\ is\ eSIGNED.\ Physical\ Signature\ is\ NOT\ Required$ 

Circle (Loan / Own)	MFG ID No	Type:Change in Constitution	License No	Issue Date
KONKAN (T76)	705058	CON-188148-20/12/2021	KD/360	28/03/2022

167213	Each ml contains::	- Chorionic Gonadotrophin highly purified I.H. (In House) (10000 IU) - Water for Injection U.S.P. USP (. QS) - Excipients & Stabilizers: Disodium Hydrogen Phosphate Dihydrate B.P., Benzyl Alcohol B.P., Sucrose B.P., Poloxamer 188 U.S.P. /NF, Methionine B.P., Phosphoric acid B.P. (.)
25.	HuCoG - 5000 HP / (Highly Purified Chorionic Gonadotropl	•
166547	Vial / Pre Filled Syringe Each ml contains::	- Chorionic Gonadotrophin highly purified I.H. (In House) (5000 IU) - Water for Injection U.S.P USP (. QS) - Excipients & Stabilizers: Disodium Hydrogen Phosphate Dihydrate B.P. Benzyl Alcohol B.P., Sucrose B.P., Poloxamer 188 U.S.P. /NF,
26.	va a a secovar (III alla Dariera I alla aria da a la seco	Methionine B.P., Phosphoric acid B.P. (. )
166387	HuCoG – 2000 HP / (Highly Purified Chorionic Gonadotropi / Pre Filled Syringe Each ml contains::	- Chorionic Gonadotropin highly purified I.H. (In House) (2000 IU)
		<ul> <li>Water for Injection U.S.P. USP (. QS)</li> <li>Excipients &amp; Stabilizers: Disodium Hydrogen Phosphate Dihydrate</li> <li>B.P. Benzyl Alcohol B.P., Sucrose B.P., Poloxamer 188 U.S.P. /NF,</li> <li>Methionine B.P., Phosphoric acid B.P. (.)</li> </ul>
27.	DRALGEEN / (Hydralazine Hydrochloride for Injection BI (Lyophilized)	
159973	Each vial contains::	<ul> <li>Hydralazine Hydrochloride BP (20 mg)</li> <li>Hydrochloric acid q.s. to adjust pH BP (. )</li> <li>To be reconstituted with 1.0 ml of Sterile Water for Injection U.S.P (</li> </ul>
28. 224894	DRALGEEN / (Hydralazine Hydrochloride Injection U.S.P. Each ml contains::	Export (USI  - Hydralazine Hydrochloride U.S.P. USP (20 mg)  - Water for Injection U.S.P. USP (. QS)  - Propylene Glycol U.S.P., Methyl Paraben U.S.P., Propyl Paraben U.S.P., Sodium Hydroxide U.S.P./Hydrochloric Acid U.S.P. (.)
29.	LUPRODEX DEPOT 11.25 MG (DEPOT) / (Leuprolide Acetate fo	
200575	(DEPOT) - Lyophilized 3 Month Depot Each Vial contains(As Lyophilized powder):	- Leuprorelin B.P. (as acetate) BP (11.25 mg) - Poly (D, L-lactide-co-glycolide) Biodegradable Polymer, D-Mannitol B.P. (.) - To be reconstituted with diluent (Diluent for Luprodex Depot 11.25MG) provided with the pack. (-) - For Intramuscular / Subcutaneous use. (-)
30.	LUPRODEX 3.75 MG (DEPOT) / (Leuprolide Acetate for Injec	- For Single Use only. (-) tion 3.75 MG) (DEPOT) Expor
165711	Each Vial contains (As lyophilized powder):	- Leuprorelin B.P. (As Acetate) BP (3.75 mg)  - Excipients: Poly (D, L-lactide-co-glycolide) Biodegradable Polymer, D-Mannitol B.P. (.)  - To be reconstituted with 1mL of Diluents [(Diluent for Leuprolide) Acetate for Injection) (DEPOT)] provided with the pack. (.)
31.	GYNACT - 4 / (Leuprolide Acetate Injection)	Expor
191379	Each ml contains::	<ul> <li>- Leuprorelin B.P. (as acetate) BP (1 mg)</li> <li>- Benzyl Alcohol BP (9.0 mg)</li> <li>- Sodium Chloride B.P BP (6.30 mg)</li> <li>- Water for Injection U.S.P. USP (. QS)</li> <li>- For Subcutaneous Use (.)</li> <li>- Pack Size: 2 ml and 4 ml (.)</li> </ul>
32.	GYNACT / (Leuprolide Acetate Injection)	Expor
191359	Each 0.5 ml contains::	- Leuprorelin B.P. (as acetate) BP (1 mg) - Benzyl Alcohol B.P. BP (4.5 mg) - Sodium Chloride B.P. BP (3.15 mg) - Water for Injection U.S.P. USP (. QS) - For Subcutaneous Use (.)
33. 159976	AMPHONEX / (Liposomal Amphotericin B Injection)  Each vial contains::	(Lyophilized)  - Amphotericin B Ph. Eur (50 mg)  - Excipients : q.s (.)  - Intercalated into liposomal membrane (.)
34.	KARMA HMG 150 HP / (Menotrophin for Injection B.P.) (Purified)	Freeze Dried) (Highly Export (BI

Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 418995 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-Id: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional) ,Balance: 7050

This License/Certificate is eSIGNED. Physical Signature is NOT Required  $\,$ 

Circle (Loan / Own)	MFG ID No	Type:Change in Constitution	License No	Issue Date
KONKAN (T76)	705058	CON-188148-20/12/2021	KD/360	28/03/2022

388.	UROKINASE FOR INJECTION 2,50,000 IU LYOPH	ILIZED	Domestic	
150149	Each Vial contains::	- Urokinase IP (2,50,000 IU)		
		- Excipients: Human Albumin I.P 20 mg , Sodium Citrate		
		I.P 24 mg , Disodium Hydrogen Phosphate Dih		
		7.8 mg, Sodium Dihydrogen Phosphate Dihydrate I.P		
		- For I.V. Use (. )		
389.	Urokinase for Injection 5,00,000 IU (Lyophilized)		Domestic (IP)	
150178	Each Vial contains::	- Urokinase IP (5,00,000 IU)		
		- For I.V. Use (. )		
		- Human Albumin I.P 20 mg, Sodium Citrate I.P	24 mg ,	
		Disodium Hydrogen Phosphate Dihydrate B.P 7.8 mg	g, Sodium	
		Dihydrogen Phosphate Dihydrate I.P 20 mg (.)		
390.	*	HILIZED	Domestic	
150197	Each Vial contains::	- Urokinase IP (7,50,000 IU)		
		- Excipients: Human Albumin I.P 20 mg, Sodium C		
		24 mg , Disodium Hydrogen Phosphate Dihydrate B.P	7.8 mg,	
		Sodium Dihydrogen Phosphate Dihydrate I.P 20mg (.)		
		- For I.V. Use (. )		
391.	UROKINASE FOR INJECTION - LYOPHILIZED	5,00,000 I.U.	Domestic	
224884	Each Vial contains::	- Urokinase I.P IP (5,00,000 IU)		
		- Human Albumin I.P IP (20 mg)		
		- Sodium Citrate I.P. IP (24 mg)		
		- Disodium Hydrogen Phosphate Dihydrate B.P. BP (7.8	' mg)	
		- Sodium Dihydrogen Phosphate Dihydrate I.P. IP (20 mg	g)	
		- For I.V. Use. (- )		
392.	UROKINASE FOR INJECTION 10000 I.U. (Lyophiliz	ed)	Domestic	
156595	Each Vial contains::	- Urokinase IP (10000 IU)		
		- Excipients & Stabilizers added: Human Albumin I.P., So	odium Citrate	
		I.P., Disodium Hydrogen Phosphate Dihydrate B.P., (.)		
		- For I.V. use (. )		
393.	UROKINASE FOR INJECTION 20000 I.U. (Lyophiliz	ed)	Domestic	
156598	Each Vial contains::	- Urokinase IP (20000 IU)		
		- Excipients & Stabilizers added: Human Albumin I.P., So		
		I.P., Disodium Hydrogen Phosphate Dihydrate B.P., Sodie	um	
		Dihydrogen Phosphate Dihydrate I.P. (. )		
		- For I.V. use (. )		
394.	UROKINASE FOR INJECTION 5000 I.U. (Lyophilized	d)	Domestic	
156594	Each Vial contains::	- Urokinase IP (5000 IU)		
		- Excipients & Stabilizers added: Human Albumin I.P., So	odium Citrate	
		I.P., Disodium Hydrogen Phosphate Dihydrate B.P., Sodio	um	
		Dihydrogen Phosphate Dihydrate I.P. (. )		
		- For I.V. use (. )		
395.	Urokinase for Injection 5000 IU - Lyophilized	Export	(IHS(In House))	
811444	Each vial contains:	- Urokinase BP (5000 IU)		
		- Excipients : Disodium Hydrogen Phosphate Dihydrate E	BP, Sodium	
		Dihydrogen Phosphate Dihydrate BP, Mannitol BP, Huma	an Albumin	

### Constitution Changed From Public Limited To Limited Company.

### Previous Validity was from 07/09/2017 to 06/09/2022



DUSHYANT BHAMRAY e-Signed on 28-03-2022 16:08

TPAV # H5H78M93F2

ON THE POOL & DRICE TO THE POOL OF THE POO

22

D. M. BHAMRAY Licensing Authority Food & Drugs Administration KONKAN Division, Maharashtra State

#### Applicant:

AKSIPRO DIAGNOSTICS P LIMITED (705058) PLOT NO: K-27, K-27 PART AND K-27/1, ANAND NAGAR, JAMBIVILI VILLAGE, ADDITIONAL MIDC., AMBERNATH (E) - 421506

Taluka: AMBERNATH CITY, District: THANE-ZONE6

Fee Payment(s): DB-Id: 1709 - 19/06/2014 (Amt: 2000) (), DB-Id: 416319 - 20/12/2021 (Amt: 546600) (Fees Paid for change in constitution), DB-Id: 418995 - 24/01/2022 (Amt: 1250) (Additional Fees Paid for change in constitution), DB-Id: 421709 - 28/02/2022 (Amt: 1250) (Fees Paid for CC additional), DB-Id: 421913 - 03/03/2022 (Amt: 1250) (Fees Paid for CC additional), Balance: 7050

 $This\ License/Certificate\ is\ eSIGNED.\ Physical\ Signature\ is\ NOT\ Required$ 

Circle (Loan / Own)	MFG ID No	Type:Change in Constitution	License No	Issue Date
KONKAN (T76)	705058	CON-188148-20/12/2021	KD/360	28/03/2022