DRUGS CONTROL ADMINISTRATION
Government of Telangana

L. Dis. No.: 665/A3/2019

Dated:27-08-2019

To
Virchow Biotech Pvt. Ltd,
Sy. no 172 part, Gagillapur (V),
Dundigal- Gandimaisamma (M),
Medchal-Malkajgiri (D),
Telangana-500043

Sir's,

Sub: Drugs and Cosmetics Act, 1940 and rules made there under-Issue of **World Health organization G.M.P Certificate** –Regarding.

Ref: 1) You application dated 04/02/2019.
2) Joint Inspection dated 11/07/2019 & 12/07/2019.

-X-X-X

With reference to your application cited, I forward here with **WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE** certificate for the products mentioned in the Joint inspection report of the officers of CDSCO, Hyderabad & Drug Control Administration, Telangana state vide reference 2nd cited.

This certificate is valid for a period of Three Years (3) from the date of issue. This certificate is meant for the export of Drugs only.

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

Yours Faithfully,

27.08.19

Dr. B. VENKATESWARULU
JOINT DIRECTOR & LICENSING AUTHORITY (FAC)

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LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1. SILVER NITRATE GEL **(Pack Size: 15g, 100g, 240g & 250g)**
IONSIL
Each gram contains:

Silver Nitrate	USP	2.0 mg
Polyacrylamide	USP	18.0 mg
Guar Gum	USP	12.0 mg
Glycerol	USP	124.9 mg
Ethyl Alcohol	USP	40.5 mg
Sodium Chloride	USP	3.0 mg
Methyl Paraben	USP	1.6 mg
Propyl Paraben	USP	0.2 mg
Purified Water	USP	q.s

2. NANO CRYSTALLINE SILVER GEL 0.002% w/w
SILANO (Pack Size: 10 g, 20g, 110g & 240g)
Each gram contains:

Nano Crystalline Silver	IHS	20.0 µg
Polyacrylamide	USP	15.2 mg
Methyl Paraben	USP	1.6 mg
Propyl Paraben	USP	0.2 mg
Glycerol	USP	124.9 mg
Guar gum`	USP	10.4 mg
Isopropyl alcohol	USP	20 mg
Purified Water	USP	q.s

3. SODIUM HYALURONATE CREAM 0.2% w/w **(Pack Size:15g & 30g)**
BIOZEL 15gm/30gm
Each gram of Sodium Hyaluronate Cream 0.2% w/w contains:
Ingredients:

Sodium Hyaluronate	BP	2.0mg
Potassium Phosphate monobasic	USP	2.0mg
Methyl Paraben	USP	2.0mg
Glycerol	USP	25mg
Emulsified Wax	USP	220mg
Isopropyl Palmitate	USP	4.25mg
Purified Water	USP	q.s.

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4. DEBRIDACE (PAPAIN –UREA) OINTMENT **15g/30g**

DEBRIDACE

Each gm of Ointment contains:

Papain	USP	≥521700 Units
Urea	USP	100mg
Potassium Phosphate monobasic	USP	2mg
Methyl Paraben	USP	2mg
Propyl Paraben	USP	0.2mg
Glycerol	USP	31.23mg
Emulsified Wax	USP	150mg
Isopropyl Palmitate	USP	4.25mg
Purified Water	USP	q.s.

Made up to 1gm of ointment

5. Sodium Hyaluronate Ophthalmic Solution (For Intra Ocular Use Only)

HYOPT 0.85ml (Prefilled Syringe)

Each 0.85ml contains:

Sodium Hyaluronate	BP	8.5 mg
Sodium Chloride	USP	7.20 mg
Di-sodium Hydrogen Phosphate dihydrate	USP	0.238 mg
Monosodium Phosphate Monohydrate	USP	0.034 mg
Water for Injection	USP	q.s

6. Sodium Hyaluronate Ophthalmic Solution. (For Intra Ocular Use Only)

HYOPT PLUS 0.85ml (Prefilled Syringe)

Each 0.85ml contains:

Sodium Hyaluronate	BP	11.9 mg
Sodium Chloride	USP	7.20 mg
Di-sodium Hydrogen Phosphate Dihydrate	USP	0.238 mg
Monosodium Phosphate Monohydrate	USP	0.034 mg
Water for Injection	USP	q.s

7. Sodium Hyaluronate Ophthalmic Solution. (For Intra Ocular Use Only)

HYOPT PLUS-RUS 0.85ml (Prefilled Syringe)

Each 0.85ml contains:

Sodium Hyaluronate	BP	11.9 mg
Sodium Chloride	USP	7.20 mg
Di-sodium Hydrogen Phosphate Dihydrate	USP	0.238 mg
Monosodium Phosphate Monohydrate	USP	0.034 mg
Water for Injection	USP	q.s

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8. Sodium Hyaluronate Ophthalmic Solution. (For Intra Ocular Use Only)
HYOPT SUPER **0.85ml** **(Prefilled Syringe)**
Each 0.85ml contains:

Sodium Hyaluronate	BP	25.5 mg
Sodium Chloride	USP	7.20 mg
Di-sodium Hydrogen Phosphate dihydrate	USP	0.238 mg
Monosodium Phosphate Monohydrate	USP	0.034 mg
Water for Injection	USP	q.s

9. Sodium Hyaluronate Sterile Injection **1 ml** **(For Dermal Use)**
HYFIL (Prefilled Syringe)
Each ml of Sodium Hyaluronate Sterile Injection contains:

Sodium Hyaluronate	BP	20 mg
Sodium Chloride	USP	9 mg
Potassium Phosphate	USP	0.03 mg
Sodium Phosphate	USP	0.14 mg
Water for Injection	USP	q.s

10. Sodium Hyaluronate Sterile Injection **0.5 ml** **(For Dermal Use)**
HYFIL (Prefilled Syringe)
Each 0.5 ml of Sodium Hyaluronate Sterile Injection contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	4.5 mg
Potassium Phosphate	USP	0.015 mg
Sodium Phosphate	USP	0.07 mg
Water for Injection	USP	q.s

11. Sodium Hyaluronate Sterile Injection **1 ml** **(For Dermal Use)**
HYFIL-RUS (Prefilled Syringe)
Each 1ml of Sodium Hyaluronate Sterile Injection contains:

Sodium Hyaluronate	BP	20 mg
Sodium Chloride	USP	9 mg
Potassium Phosphate	USP	0.03 mg
Sodium Phosphate	USP	0.14 mg
Water for Injection	USP	q.s

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12. Sodium Hyaluronate Sterile Injection **0.5 ml** **(For Dermal Use)**
HYFIL-RUS (Prefilled Syringe)
Each 0.5 ml of Sodium Hyaluronate Sterile Injection contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	4.5 mg
Potassium Phosphate	USP	0.015 mg
Sodium Phosphate	USP	0.07 mg
Water for Injection	USP	q.s

13. HYORTH INJECTION 20mg/ 2ml
Each ml 1% Sodium Hyaluronate Sterile Solution (Hyorth 20 mg injection in 2ml Prefilled syringe unit) for **Intra-articular use** contains

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

14. SYNOVAR-20 Injection 20mg/ 2ml
Each ml 1% Sodium Hyaluronate Solution (Synovar-20, 20 mg injections in 2ml pre filled syringe unit) for **Intra-articular use** for export purpose contains
Each ml of 1% Sodium Hyaluronate Sterile solution contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

15. Sodium Hyaluronate Sterile Solution for Intra-articular Injection 1% w/v
SYNOVAR-25 **Pack size: 2.5 ml** (Prefilled Syringe)
Each ml 1% Sodium Hyaluronate Sterile solution for Intra-articular Injection contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

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16. **Sodium Hyaluronate sterile Injection**
XUVAN Injection **20mg/2ml** (For Exclusive supply to VHPL)
Each ml 1% Sodium Hyaluronate Solution (Xuvan 20mg Injection in 2ml pre filled syringe unit) for **Intra articular use** contains

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

17. Sodium Hyaluronate Sterile Solution 20 mg /2 ml
HYAMAX (For Exclusive supply to Virchow Health care Pvt.Ltd, Mumbai)
Each ml 1% Sodium Hyaluronate solution (20 mg Injection in Prefilled Syringe unit for **Intra-articular use** contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

18. SODIUM HYALURONATE STERILE INJECTION (6 ml prefilled syringe for intraarticular use only)
HYORTH XL **6 ml**
Each ml contains:

Sodium Hyaluronate	BP	8 mg
Sodium Chloride	USP	8.5 mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16 mg
Monosodium phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

19. **Sodium Hyaluronate Sterile Injection** (6 ml prefilled syringe **for intraarticular use** only)
XUVAN XL 6ml **(For Exclusive supply to VHPL)**
Each ml contains

Sodium Hyaluronate	BP	8mg
Sodium Chloride	USP	8.5mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16mg
Monosodium phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

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20. Sodium Hyaluronate Sterile Injection (6 ml prefilled syringe for intraarticular use only)
HYAMAX FORTE (For Exclusive supply to Virchow Health care Pvt.Ltd, Mumbai)
Each ml contains

Sodium Hyaluronate	BP	8mg
Sodium Chloride	USP	8.5mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16mg
Monosodium phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

21. ***Bacillus clausii*** **Spores Suspension** Pack Size: 5ml
CLASIPRO
Each 5 ml oral suspension contains:

Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.

22. ***Bacillus clausii*** **Spores Suspension** Pack Size: 5ml
Vbac Spores **(For Exclusive supply to VHPL)**
Each 5 ml oral suspension contains:

Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.

23. Enoxaparin Sodium Injection USP 40 mg/0.4 ml (4000 anti-Xa IU/0.4ml)
(Prefilled Syringe)

Enoxaparin Sodium	USP	40 mg
Water for Injections	USP	0.4 ml

24. Enoxaparin Sodium Injection USP 60 mg/0.6 ml (6000 anti-Xa IU/0.6ml)
(Prefilled Syringe)

Enoxaparin Sodium	USP	60 mg
Water for Injections	USP	0.6 ml

25. Enoxaparin Sodium Injection USP 100 mg/ 1.0 ml (10,000 anti-Xa IU/1.0 ml)
(Prefilled Syringe)

Enoxaparin Sodium	USP	100 mg
Water for Injections	USP	1.0 ml

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26. Fondaparinux sodium injection USP
(Prefilled Syringe)
VIRINUX 2.5 mg/0.5 ml
(Sub cutaneous use/Intra Venous use)
Each single dose prefilled syringe contains
2.5 mg of Fondaparinux Sodium USP in 0.5 ml of an isotonic solution of Sodium Chloride USP and Water for Injection USP.

27. Cerebroprotein Hydrolysate for Injection 30 mg
NEUCOGNI
Each Lyophilized vial contains:

Cerebroprotein Hydrolysate	1050 mg (approx.)
Equivalent to nitrogen	30 mg

28. Cerebroprotein Hydrolysate for Injection 60 mg
NEUCOGNI
Each Lyophilized vial contains:

Cerebroprotein Hydrolysate	2100 mg (approx.)
Equivalent to nitrogen	60 mg

29. HEPARIN SODIUM INJECTION USP 25000 IU/ 5 mL (vial)
Each ml contains

Heparin Sodium (Derived from Intestinal Mucosa)	USP	5000 IU
Benzyl Alcohol (as preservative)	USP	0.95% w/v
Water for Injections	USP	q.s

30. Lyophilized Peg Interferon alfa 2b Injection 50 mcg
Vipeg
Each 0.5ml lyophilized vial contains:

		50mcg
Peg Interferon alfa 2b		
Dibasic Sodium Phosphate Anhydrous	USP	0.75mg
Monosodium Phosphate Dihydrate	USP	0.75mg
Sucrose	USP	40mg
Polysorbate-80	USP	0.05mg
Water for Injection for Lyophilization	USP	q.s

(To be stored at 2-8°C)

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31. Lyophilized Peg Interferon alfa 2b Injection 80 mcg

Vipeg

Each 0.5ml lyophilized vial contains:

Peg Interferon alfa 2b		**80mcg**
Dibasic Sodium Phosphate Anhydrous	USP	0.75mg
Monosodium Phosphate Dihydrate	USP	0.75mg
Sucrose	USP	40mg
Polysorbate-80	USP	0.05mg
Water for Injection for Lyophilization	USP	q.s

(To be stored at 2-8°C)

32. Lyophilized Peg Interferon alfa 2b Injection 100 mcg

Vipeg

Each 0.5ml lyophilized vial contains:

Peg Interferon alfa 2b		**100mcg**
Dibasic Sodium Phosphate Anhydrous	USP	0.75mg
Monosodium Phosphate Dihydrate	USP	0.75mg
Sucrose	USP	40mg
Polysorbate-80	USP	0.05mg
Water for Injection for Lyophilization	USP	q.s

(To be stored at 2-8°C)

33. Lyophilized Peg Interferon alfa 2b Injection 120 mcg

Vipeg

Each 0.5ml lyophilized vial contains:

Peg Interferon alfa 2b		**120mcg**
Dibasic Sodium Phosphate Anhydrous	USP	0.75mg
Monosodium Phosphate Dihydrate	USP	0.75mg
Sucrose	USP	40mg
Polysorbate-80	USP	0.05mg
Water for Injection for Lyophilization	USP	q.s

(To be stored at 2-8°C)

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34. Lyophilized Peg Interferon alfa 2b Injection 150 mcg

Vipeg

Each 0.5ml lyophilized vial contains:

Peg Interferon alfa 2b		**150mcg**
Dibasic Sodium Phosphate Anhydrous	USP	0.75mg
Monosodium Phosphate Dihydrate	USP	0.75mg
Sucrose	USP	40mg
Polysorbate-80	USP	0.05mg
Water for Injection for Lyophilization	USP	q.s

(To be stored at 2-8°C)

35. Recombinant Human Interferon alpha-2b Lyophilized Powder for Injection 3 MIU

INFERON 3 MIU

Each vial contains:

Recombinant human Interferon alpha-2b	IHS	**3 MIU**
Glycine	USP	20.0mg
Dibasic Sodium Phosphate Anhydrous	USP	2.3mg
Monosodium Phosphate dihydrate	USP	0.55mg
Human Serum Albumin	USP	1.0mg
Water for Injection for Lyophilization	USP	q.s

36. Recombinant Human Interferon alpha-2b Lyophilized Powder for Injection 5 MIU

INFERON 5 MIU

Each vial contains:

Recombinant human Interferon alpha-2b	IHS	**5 MIU**
Glycine	USP	20.0mg
Dibasic Sodium Phosphate Anhydrous	USP	2.3mg
Monosodium Phosphate dihydrate	USP	0.55mg
Human Serum Albumin	USP	1.0mg
Water for Injection for Lyophilization	USP	q.s

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37. TERIPARATIDE (r-Human Parathyroid Hormone) Injection 750mcg/3ml
Pack size 3ml
OSTEOTIDE
Composition:
Each ml of TERIPARATIDE (r-Human Parathyroid Hormone) Injection contains:

Recombinant human Parathyroid Hormone (1-34)	IHS	250 mcg
Succinic acid	USP	0.29 mg
Sodium Hydroxide	USP	0.05 mg
Glycerol	USP	50 mg
M-Cresol	USP	3 mg
Water for Injection	USP	q.s

38. TERIPARATIDE (r-Human Parathyroid Hormone) Injection 750mcg/3ml
Pack size 3ml **(Prefilled Cartridge with Pen Device)**
OSTEOTIDE
Composition:
Each ml of TERIPARATIDE (r-Human Parathyroid Hormone) Injection contains:

Recombinant human Parathyroid Hormone	IHS	250 mcg
Succinic acid	USP	0.29 mg
Sodium Hydroxide	USP	0.05 mg
Glycerol	USP	50 mg
M-Cresol	USP	3 mg
Water for Injection	USP	q.s

39. TERIPARATIDE (r-Human Parathyroid Hormone) (1-34) Injection 750mcg/3ml
Pack size: 3ml **(Prefilled Cartridge with Pen Device)**
ADDBON **(Exclusive supply to Virchow Health care Pvt.Ltd)**
Composition:
Each ml of TERIPARATIDE(r-Human Parathyroid Hormone) (1-34) Injection contains:

Recombinant human Parathyroid Hormone (1-34)	IHS	250 mcg
Succinic acid	USP	0.29 mg
Sodium Hydroxide	USP	0.05 mg
Glycerol	USP	50 mg
M-Cresol	USP	3 mg
Water for Injection	USP	q.s

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40. TERIPARATIDE (r-Human Parathyroid Hormone) (1-34) Injection 750mcg/3ml
Pack size: 3ml **(Prefilled Cartridge with Pen Device)**
MEGAPTH

Composition:

Each ml of TERIPARATIDE(r-Human Parathyroid Hormone) (1-34) Injection contains:

Recombinant human Parathyroid Hormone (1-34)	IHS	250 mcg
Succinic acid	USP	0.29 mg
Sodium Hydroxide	USP	0.05 mg
Glycerol	USP	50 mg
M-Cresol	USP	3 mg
Water for Injection	USP	q.s

41. RASBURICASE (r-DNA Origin), 1.5 mg/vial
(Lyophilized powder for Injection)
TULY

Each vial contains:

a. Rasburicase (r DNA Origin)	IHS	1.5 mg
b. Disodium hydrogen Phosphate dihydrate	USP	5.67mg
c. D-Mannitol	USP	10.9 mg
d. L-Alanine	USP	15.6 mg

Reconstituting agent (1 ml/vial)

Each vial contains:

a. 0.1% Propylene glycol (v/v)	USP	750 µl
b. 0.1 % Poloxamer (w/v)	USP	250 µl

42. RASBURICASE (r-DNA Origin), 7.5 mg/vial
(Lyophilized powder for Injection)
TULY

Each vial contains:

a. Rasburicase (r DNA Origin)	IHS	7.5 mg
b. Disodium hydrogen Phosphate dihydrate	USP	28.35 mg
c. D-Mannitol	USP	54.5 mg
d. L-Alanine	USP	78.0 mg

Reconstituting agent (5 ml/vial)

Each vial contains:

a. 0.1% Propylene glycol (v/v)	USP	3.75 ml
b. 0.1 % Poloxamer (w/v)	USP	1.25 ml

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B. Vay 27/08/19

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List of Products approved under Grant of WHO GMP Certificate:

43. SILVER NITRATE GEL **(Pack Size: 15g, 100g, 240g & 250g)**

IONSIL

Each gram contains:

Silver Nitrate	USP	2.0 mg
Polyacrylamide	IHS	18.0 mg
Guar Gum	USP	12.0 mg
Glycerol	USP	124.9 mg
Ethyl Alcohol	USP	40.5 mg
Sodium Chloride	USP	3.0 mg
Methyl Paraben	USP	1.6 mg
Propyl Paraben	USP	0.2 mg
Purified Water	USP	q.s

44. SILVER NITRATE GEL 0.2% **(Pack Size: 15g, 100g, 240g & 250g)**

IONSIL

Each gram contains:

Silver Nitrate	IP	2.0 mg
Polyacrylamide	-	18.0 mg
Guar Gum	-	12.0 mg
Glycerol	IP	124.9 mg
Ethyl Alcohol	IP	40.5 mg
Sodium Chloride	IP	3.0 mg
Methyl Paraben	IP	1.6 mg
Propyl Paraben	IP	0.2 mg
Purified Water	IP	q.s

45. PAPAIN –UREA OINTMENT **(Pack Size: 15g)**

DEBRIDENZYME (Exclusive supply to M/s. Virchow Healthcare Pvt Ltd., Mumbai)

Each gm of Ointment contains:

Papain	USP	≥521700 Units
Urea	USP	100mg
Potassium Phosphate monobasic	USP	2mg
Methyl Paraben	USP	2mg
Propyl Paraben	USP	0.2mg
Glycerol	USP	31.23mg
Emulsified Wax	USP	150mg
Isopropyl Palmitate	USP	4.25mg
Purified Water	USP	q.s.

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46. PAPAIN –UREA OINTMENT 15g

DEBRIDACE

Each gm of Ointment contains:

Papain	IP	≥521700 Units
Urea	IP	100mg
Potassium Phosphate monobasic	USP	2mg
Methyl Paraben	IP	2mg
Propyl Paraben	IP	0.2mg
Glycerol	IP	31.23mg
Emulsified Wax	IP	150mg
Isopropyl Palmitate	USP	4.25mg
Purified Water	IP	q.s.

Made up to 1 gm of ointment

47. Cadexomer Iodine Ointment **(Pack Size: 5g, 10g, 20g & 40g)**

DEXADINE

Each gram contains

Cadexomer Iodine	I.H.S	500mg
(Equivalent to 0.9% w/w Iodine)		

Excipients: Polyethylene glycol 400, Polyethylene glycol 4000, Poloxamer 407.

48. Cadexomer Iodine Powder **(Pack Size: 3g, 5g, & 10g)**

DEXADINE

Each gram contains

Cadexomer Iodine	I.H.S	1000mg
(Equivalent to 0.9% w/w Iodine)		

49. Sofosbuvir Tablets 400 mg

VIRSOF

Each film coated tablet contains

Sofosbuvir	400 mg
Excipients	q.s.

Colours:

Titanium dioxide, Iron oxide red

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50. Sodium Hyaluronate Ophthalmic Solution.

HYOPT PLUS 0.85ml (Prefilled Syringe)

Each 0.85ml contains:

Sodium Hyaluronate	BP	11.9mg
Sodium Chloride	IP	7.20mg
Di-sodium Hydrogen Phosphate dihydrate	USP	0.238mg
Monosodium Phosphate monohydrate	IP	0.034mg
Water for Injection	IP	q.s

51. Sodium Hyaluronate Sterile Injection 1 ml (For Dermal Use)

HYFIL (Prefilled Syringe)

Each ml of Sodium Hyaluronate Sterile Injection contains:

Sodium Hyaluronate	BP	20 mg
Sodium Chloride	IP	9 mg
Potassium Phosphate	IP	0.03 mg
Sodium Phosphate	IP	0.14 mg
Water for Injection	IP	q.s

52. Sodium Hyaluronate Sterile Solution for intra-articular injection 1% w/v

HYORTH 2.5 ml **Pack 2.5 ml (Prefilled syringe)**

Each ml 1% Sodium Hyaluronate Sterile solution for intra-articular injection contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

53. Sodium Hyaluronate Sterile Solution 20 mg /2 ml

SYNARTHROL-2 ml **pack size 2ml**

Each ml of 1% of Sodium Hyaluronate Solution for Intra-articular use contains:

Sodium Hyaluronate	BP	10mg
Sodium Chloride	USP	8.5mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28mg
Monosodium Phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

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54. Sodium Hyaluronate Sterile Solution

SYNARTHROL 2.5 ml **pack size 2.5ml**

Each ml of 1% of Sodium Hyaluronate Solution for Intra-articular use contains:

Sodium Hyaluronate	BP	10mg
Sodium Chloride	USP	8.5mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28mg
Monosodium Phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

55. Sodium Hyaluronate Sterile Injection 10 mg / ml

(2 ml pre filled syringe unit for Intra-articular use only)

SYNORTH

Each ml contain:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

56. Sodium Hyaluronate Sterile Injection 8 mg/ ml

(6 ml prefilled syringe for intra-articular use only)

SYNORTH ONE

Each ml contains:

Sodium Hyaluronate	BP	8mg
Sodium Chloride	USP	8.5mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16mg
Monosodium phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

57. Sodium Hyaluronate Sterile Solution 20 mg /2 ml

HYADROM

Each ml of 1% Sodium Hyaluronate Sterile solution contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

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58. Sodium Hyaluronate Sterile Injection
HYORTH-RUS INJECTION 20 mg/ 2 ml
2 ml prefilled Syringe for Intra-articular use
Each ml contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s

59. **SYNARTHROL-LONG**
Sodium Hyaluronate Sterile Injection (6ml prefilled syringe for Intraarticular use only)
Each ml contains:

Sodium Hyaluronate	BP	8 mg
Sodium Chloride	USP	8.5 mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16mg
Monosodium phosphate monohydrate	USP	0.04mg
Water for Injection	USP	q.s

60. Sodium Hyaluronate Sterile Injection (6 ml prefilled syringe for intraarticular use only)
HYORTH XL 6 ml
Each ml contains:

Sodium Hyaluronate	BP	8mg
Sodium Chloride	IP	8.5mg
Di-sodium Hydrogen Phosphate di-hydrate	USP	0.16mg
Monosodium phosphate monohydrate	IP	0.04mg
Water for Injection	IP	q.s

***61. Bacillus clausii* Spores Suspension** Pack Size: 5ml
TRULAC
Each 5 ml oral suspension contains:

Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.

***62. Bacillus clausii* Spores Suspension** Pack Size: 5ml
PROBACIL
Each 5 ml oral suspension contains:

Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.

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63. ***Bacillus clausii* Spores Suspension**	Pack Size: 5ml	
SULLICAB		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
64. ***Bacillus clausii* Spores Suspension**	Pack Size: 5ml	
Phara Enterobiotics		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
65. *Bacillus clausii* Spores Suspension	Pack Size: 5ml	
BACIFLORA		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
66. ***Bacillus Clausii* Spores Suspension**	Pack Size: 5ml	
FLOROBENE		
Each 5 ml oral suspension contains:		
Bacillus Clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
67. ***Bacillus clausii* Spores Suspension**	Pack Size: 5ml	
CLAUSIDIA		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
68. ***Bacillus clausii* Spores Suspension**	Pack Size: 5ml	
BIOFLORA		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	USP	q.s.
69. BACILLUS CLAUSII SPORES SUSPENSION	Pack Size: 5ml	
CLASIPRO		
Each 5 ml oral suspension contains:		
Bacillus clausii Spores	IHS	2×10^9 Spores
Purified water	IP	q.s.

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70. **Enoxaparin Sodium Injection USP 20 mg/0.2 ml** (2000 anti-Xa IU/0.2ml)
VOXAPARIN **(Prefilled Syringe)**

Each Prefilled Syringe contains		
Enoxaparin Sodium	USP	20 mg
Water for Injection	USP	q.s. to 0.2 ml

71. **Enoxaparin Sodium Injection USP 40 mg/0.4 ml** (4000 anti-Xa IU/0.4ml)
VOXAPARIN (Prefilled Syringe)

Each Prefilled Syringe contains		
Enoxaparin Sodium	USP	40 mg
Water for Injection	USP	q.s. to 0.4 ml

72. **Enoxaparin Sodium Injection USP 60 mg/0.6 ml** (6000 anti-Xa IU/0.6ml)
VOXAPARIN (Prefilled Syringe)

Each Prefilled Syringe contains		
Enoxaparin Sodium	USP	60 mg
Water for Injection	USP	q.s. to 0.6 ml

73. **Enoxaparin Sodium Injection USP 80 mg/0.8 ml** (8000 anti-Xa IU/0.8ml)
VOXAPARIN (Prefilled Syringe)

Each Prefilled Syringe contains		
Enoxaparin Sodium	USP	80 mg
Water for Injection	USP	q.s. to 0.8 ml

74. **Enoxaparin Sodium Injection USP 100 mg/ 1.0 ml** (10,000 anti-Xa IU/1.0 ml)
VOXAPARIN (Prefilled Syringe)

Each Prefilled Syringe contains		
Enoxaparin Sodium	USP	100 mg
Water for Injection	USP	q.s. to 1.0 ml

75. **Enoxaparin Sodium Injection USP 20 mg/0.2 ml** (2000 anti-Xa IU/0.2ml)
(Prefilled Syringe)

Enoxaparin Sodium	USP	20 mg
Water for Injection	USP	0.2 ml

76. **Enoxaparin Sodium Injection USP 80 mg/0.8 ml** (8000 anti-Xa IU/0.8ml)
(Prefilled Syringe)

Enoxaparin Sodium	USP	80 mg
Water for Injection	USP	0.8 ml

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77. HEPARIN INJECTION **BP** **25000 IU/ 5 mL (vial)**

Each ml contains		
Heparin Sodium (Derived from Intestinal Mucosa)	BP	5000 IU
Benzyl Alcohol (as preservative)	BP	0.95% w/v
Water for Injections	BP	q.s

78. Human Placental Extract Gel **Pack size: 20 g**

Each gram of gel contains
Extract of 0.1 gram of Fresh Human placenta
Total Nitrogen: Not more than 0.25%w/w
Brilliant Blue FCF

79. PEG L-Asparaginase Injection 3750 I.U/5mL (I.V/ I.M use) (Export Purpose)
PEGAPAR

Each mL contains		
PEG L-Asparaginase	I.H.S	750 I.U
Monobasic sodium phosphate Monohydrate	U.S.P	1.20 mg
Disodium hydrogen phosphate dihydrate	U.S.P	5.58 mg
Sodium chloride	U.S.P	8.50 mg
Water for injection	U.S.P	q.s to 1.0 mL

80. PEG L-Asparaginase Injection 3750 I.U/5mL (I.V/ I.M use)
ASPARANDO

Each mL contains		
PEG L-Asparaginase	I.H.S	750 I.U
Monobasic sodium phosphate Monohydrate	U.S.P	1.20 mg
Disodium hydrogen phosphate dihydrate	U.S.P	5.58 mg
Sodium chloride	U.S.P	8.50 mg
Water for injection	U.S.P	q.s to 1.0 mL

81. Plerixafor Injection 20mg/mL **(For S.C use)** **(Fill volume: 24 mg/1.2 mL)**

Each mL contains		
Plerixafor	I.H.S	20 mg
Excipients		q.s.

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82. Ulinastatin for Injection (I.V Use) (5ml liquid vial)

Each vial contains

Ulinastatin	J.P	1, 00,000 IU

Excipients:

Meta Cresol BP (Preservative agent), Sucrose BP (Isotonic agent), Di sodium Hydrogen Phosphate Dihydrate BP (Buffering agent), Polysorbate 80 BP (Solubilizing agent), Phosphoric Acid BP (pH Adjustment).

83. RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR-BB GEL 0.01%

HEALACE 0.01% GEL

Each Gram of Gel Contains:

r-Human Platelet Derived Growth Factor-BB	IHS	0.100 mg
Methyl Paraben	USP	0.1620 mg
Propyl Paraben	USP	0.0180 mg
Sodium Acetate	USP	0.1570 mg
Lysine Hydrochloride	USP	0.4800 mg
Sodium Chloride	USP	0.4043 mg
Meta Cresol	USP	0.0870 mg
Glacial acetic acid	USP	0.0068 µL
Carboxy Methyl cellulose sodium	USP	2.4000 mg
Purified Water	USP	q.s.

84.RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR-BB GEL 0.01%

REGREL 0.01% Gel

Each Gram of Gel Contains:

r-Human Platelet Derived Growth Factor-BB	IHS	0.100 mg
Methyl Paraben	USP	0.1620 mg
Propyl Paraben	USP	0.0180 mg
Sodium Acetate	USP	0.1570 mg
Lysine Hydrochloride	USP	0.4800 mg
Sodium Chloride	USP	0.4043 mg
Meta Cresol	USP	0.0870 mg
Glacial acetic acid	USP	0.0068 µL
Carboxy Methyl cellulose sodium	USP	2.4000 mg
Purified Water	USP	q.s.

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85.RECOMBINANT HUMAN PLATELET DERIVED GROWTH FACTOR-BB GEL 0.01%

ADVAHEAL 0.01% Gel

Each Gram of Gel Contains:

r-Human Platelet Derived Growth Factor-BB	IHS	0.100 mg
Methyl Paraben	USP	0.1620 mg
Propyl Paraben	USP	0.0180 mg
Sodium Acetate	USP	0.1570 mg
Lysine Hydrochloride	USP	0.4800 mg
Sodium Chloride	USP	0.4043 mg
Meta Cresol	USP	0.0870 mg
Glacial acetic acid	USP	0.0068 µL
Carboxy Methyl cellulose sodium	USP	2.4000 mg
Purified Water	USP	q.s.

86. TERIPARATIDE (r-Human Parathyroid Hormone) Injection 750mcg/3ml

Pack size: 3ml

OSTEOTIDE **(Prefilled Cartridge with Pen Device)**

Composition:

Each ml of TERIPARATIDE(r-Human Parathyroid Hormone) Injection contains:

Recombinant human Parathyroid Hormone	IHS	250 mcg
Succinic acid	USP	0.29 mg
Sodium Hydroxide	IP	0.05 mg
Glycerol	IP	50 mg
M-Cresol	USP	3 mg
Water for Injection	IP	q.s

87. **RASBURICASE (r-DNA Origin), 1.5 mg/vial**

(Lyophilized powder for Injection)

TULY

Each vial contains:

a. Rasburicase (r DNA Origin)	IHS	1.5 mg
b. Disodium hydrogen Phosphate dihydrate	USP	5.67mg
c. D-Mannitol	IP	10.9 mg
d. L-Alanine	USP	15.6 mg

Reconstituting agent (1 ml/vial)

Each vial contains:

a. 0.1% Propylene glycol (v/v)	IP	750 µl
b. 0.1 % Poloxamer (w/v)	IP	250 µl

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88.Rasburicase (r-DNA Origin), 1.5 mg/vial (Lyophilized powder for Injection)

VASICASE

Composition:

Each vial contains:

a. Rasburicase (r DNA Origin)	IHS	1.5 mg
b. Disodium hydrogen Phosphate dihydrate	USP	5.67mg
c. D-Mannitol	USP	10.9 mg
d. L-Alanine	USP	15.6 mg

Reconstituting agent (1 ml/vial)

Each vial contains:

a. 0.1% Propylene glycol (v/v)	USP	750 µl
b. 0.1 % Poloxamer (w/v)	USP	250 µl

89. Rasburicase (r-DNA Origin), 7.5 mg/vial (Lyophilized powder for Injection)

VASICASE

Composition:

Each vial contains:

a. Rasburicase (r DNA Origin)	IHS	7.5 mg
b. Disodium hydrogen- Phosphate dihydrate	USP	28.35 mg
c. D-Mannitol	USP	54.5 mg
d. L-Alanine	USP	78.0 mg

Reconstituting agent (5 ml/vial)

Each vial contains:

a. 0.1% Propylene glycol (v/v)	USP	3.75 ml
b. 0.1 % Poloxamer (w/v)	USP	1.25 ml

90. COMBIPACK OF SNAKE VENOM ANTISERUM WITH STERILE WATER FOR INJECTION

Vi-ASV

a. Snake Venom Antiserum I.P (20 ml vial with 10 ml of SWFI)

(Lyophilized, polyvalent enzyme refined equine Immunoglobulins),

After reconstitution each ml of polyvalent Snake venom antiserum neutralizes not less than

Indian cobra venom *(Naja naja)*	0.60 mg
Common Krait venom (*Bungarus caeruleus*)	0.45 mg
Russell's viper venom (*Vipera russelli*)	0.60 mg
Saw scaled viper venom *(Echis carinatus)*	0.45 mg
Cresol (Preservative)	NMT 0.25% v/v
Glycine I.P.	Stabilizer
Sodium Chloride I.P.	Excipient

b. Sterile Water for Injections I.P. **10 ml Ampoule**

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S. No	Facility Inspected	Category of Products	Activities
1	Formulation-I Facility	Topicals manufacturing (Creams, ointments, gels, dressings)	Manufacturing, Packing & Quality control
2	Formulation-II Facility	Biologics & Pharmaceutical Drug product manufacturing - Liquid vials - Lyophilized vials	Manufacturing, Packing & Quality control
3	Formulation-III Facility	Biologics Drug product manufacturing - Prefilled syringes -	Manufacturing, Packing & Quality control
4	Suite-I Facility	Biologics Drug substance manufacturing	Manufacturing & Quality control
5	Suite-II Facility	Biologics Drug product manufacturing - Prefilled syringes - Liquid cartridges - Liquid vials - Lyophilized vials	Manufacturing, Packing & Quality control
6	Bacipro Facility	Bacillus Clausii Spores suspension manufacturing (Blow fill seal technology)	Manufacturing, Packing & Quality control
7	Suite-V Facility	Oral solid Dosages Drug product manufacturing	Manufacturing, Packing & Quality control

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DRUGS CONTROL ADMINISTRATION
Government of Telangana

L. Dis. No.: 665/A3/2019

Dated:27-08-2019

Manufacturer : M/s Virchow Biotech Private Limited,
Survey no 172 part, Gagillapur(V),
Dundigal- Gandimaisamma (M),
Medchal-Malkajgiri (D),
Telangana-500043

When Applicable : Placing the Product on the Market as detailed below

It is certified that the above products had been authorized to be placed on the market for use in the country.

Drug License No. : **Form-25** bearing No.30/RR/AP/2005/F/R dt. 27/07/2005
valid upto 25/07/2020
Form 28 bearing No.51/RR/AP/2004/F/R dt. 20/11/2004
valid upto 19/11/2019
Form 28-D bearing No.02/RR/AP/2004/V/R dt. 27/12/2004
valid upto 26/12/2019

It is also certified that (a) the manufacturing plant in which the product is produced is subjected to inspection at suitable intervals.

The unit M/s Virchow Biotech Private Limited, Survey no 172 part, Gagillapur, Dundigal-Gandimaisamma (M), Medchal-Malkajgiri (D), Telangana-500043, India was inspected jointly by Sri. K. Prabhakar, Drugs Inspector, Quthbullapur (Mfg), DCA, Hyderabad and Sri. Mr. Bikramaditya Chowdhury, Drugs Inspector, CDSCO, Hyderabad, Sri. Mrs.L.Suganthi, Drugs Inspector, CDSCO, Hyderabad dated 11/07/2019 & 12/07/2019.

(b) The Manufacturer conforms to the requirements of Good Manufacturing Practices in the Manufacturer and Quality Control (As recommended by the World Health Organization) in respect of 90 (Ninety) Products to be sold or distributed with in the country of origin (or to be exported).

This certificate is valid for Three years (3) from the date of Issue.

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Yours Faithfully,

27/08/19

Dr. B. VENKATESWARULU
JOINT DIRECTOR & LICENSING AUTHORITY (FAC)