Food & Drugs Administration (Maharashtra State)

Letter No: MH/TZ5/RNW/25-KD/685
Food & Drugs Administration, KONKAN Division
OFFICE OF JOINT COMMISSIONER [K.D]
4TH FL.ESIC BLD,WAGLE ESTATE
Thane - 400604

License Retention With Products

Validity Period:02/03/2024 To 01/03/2029

To :

705093- RUNA CHEMICALS PVT LTD (Private Limited)
W-11,W-23 MIDC PHASE-II, DOMBIVALI, MANPADA - 421204
Taluka: Dombivali City , District: Thane-Zone5

LICENSE No : 25-KD/685
& Dt : 13/02/2024

Sir,

Ref :- Your Inward Application **vide Inward ID:- 254820 (RNW) Dated :- 07/02/2024**

With reference to your Inward application,we inform you that your said application is considered & following ***LICENSE*** has been ***Retained***

Type	Form	LIC No / Validity	First Issue / Rnw
Own: At my OWN Manufacturing Premises	25	KD/685 **01/03/2029**	02/03/2009 **02/03/2024**

Prod	Name of Drugs	
1. **470375**	**Acetone**	**Domestic (Ph. Eur.)** *- Acetone Ph Eur Ph. Eur. (100 %)*
2. **555910**	**NA / Acetone** *lits:*	**Export (NF)** *- Acetone NF (100 %)*
3. **559147**	**Acetone** *lits:*	**Domestic (NF)** *- Acetone NF (100 %)*
4. **764699**	**Acetone** *100% Product:*	**Export (BP)** *- Acetone BP (100 %)*
5. **766378**	**Acetone** *100% Product:*	**Export (Ph. Eur.)** *- Acetone Ph. Eur. (100 %)*
6. **767728**	**Acetone** *100% Product:*	**Domestic (BP)** *- Acetone BP (100 %)*
7. **479635**	**Acetonitrile** *2.5 lits to 200 lits comtainer:*	**Export (BP)** *- Acetonitrile BP (100 %)*
8. **766379**	**Acetonitrile** *100% Product:*	**Export (Ph. Eur.)** *- Acetonitrile Ph. Eur. (100 %)*
9. **767824**	**Acetonitrile** *100% Product:*	**Domestic (BP)** *- Acetonitrile BP (100 %)*
10. **767862**	**Acetonitrile** *100% Product:*	**Domestic (Ph. Eur.)** *- Acetonitrile Ph. Eur. (100 %)*
11. **479632**	**Chloroform** *2.5 lits to 200 lits comtainer:*	**Export (IP)** *- Chloroform IP (100 %)*
12. **479633**	**Chloroform** *2.5 lits to 200 lits comtainer:*	**Export (BP)** *- Chloroform BP (100 %)*
13. **767723**	**Chloroform** *100% Product:*	**Domestic (IP)** *- Chloroform IP (100 %)*
14. **767861**	**Chloroform** *100% Product:*	**Domestic (BP)** *- Chloroform BP (100 %)*
15. **767729**	**Dichloromethane** *100% Product:*	**Domestic (BP)** *- Dichloromethane BP (100 %)*
16. **476877**	**Dichloromethane(Methyl Chloride)**	**Export (BP)** *- Dichloromethane(Methyl Chloride) BP (100 %)*
17. **476342**	**Dimethyl Sulfoxide**	**Export (BP)** *- Dimethyl Sulfoxide BP (100 %)*
18. **476343**	**Dimethyl Sulfoxide** *2.5 lits to 200 lits comtainer:*	**Export (Ph. Eur.)** *- Dimethyl Sulfoxide Ph. Eur. (100 %)*
19. **476344**	**Dimethyl Sulfoxide** *2.5 lits to 200 lits comtainer:*	**Export (USP)** *- Dimethyl Sulfoxide USP (100 %)*
20. **769563**	**Dimethyl Sulfoxide** *100% Product:*	**Domestic (BP)** *- Dimethyl Sulfoxide BP (100 %)*

Fee Payment(s) : DB-Id: 495912 - 07/02/2024 (Amt: 38250) (FDA LICENSE RENEWAL) ,Balance : 1750

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

No. of Products: 47 , No. of Ingredients: 47

Division	MFG ID No	Type:License Renewal	License No	Issue Date
KONKAN (TZ5)	705093	RNW-254820-07/02/2024	25-KD/685	13/02/2024

21. 769564	**Dimethyl Sulfoxide** *100% Product:*	*- Dimethyl Sulfoxide Ph. Eur. (100 %)*	**Domestic (Ph. Eur.)**
22. 558546	**Ethyl Acetate** *lits:*	*- Ethyl Acetate Ph. Eur. (100 %)*	**Export (EP)**
23. 558547	**Ethyl Acetate** *lits:*	*- Ethyl Acetate BP (100 %)*	**Export (BP)**
24. 558548	**Ethyl Acetate** *lits:*	*- Ethyl Acetate IP (100 %)*	**Export (IP)**
25. 558549	**Ethyl Acetate** *lits:*	*- Ethyl Acetate NF (100 %)*	**Export (NF)**
26. 559144	**Ethyl Acetate** *lits:*	*- Ethyl Acetate NF (100 %)*	**Domestic (NF)**
27. 559145	**Ethyl Acetate** *lits:*	*- Ethyl Acetate Ph. Eur. (100 %)*	**Domestic (Ph. Eur.)**
28. 559146	**Ethyl Acetate** *lits:*	*- Ethyl Acetate BP (100 %)*	**Domestic (BP)**
29. 568398	**Ethyl Acetate** *lits:*	*- Ethyl Acetate IP (100 %)*	**Domestic (IP)**
30. 474000	**Iso Propyl Alcohol** *2.5 lits to 200 lits containers:*	*- Iso Propyl Alcohol Ph. Eur. (100 %)*	**Domestic (Ph. Eur.)**
31. 471779	**IsoPropyl Alcohol**	*- Iso Propyl Alcohol BP (100 %)*	**Domestic (BP)**
32. 471780	**IsoPropyl Alcohol**	*- Iso Propyl Alcohol USP (100 %)*	**Export (USP)**
33. 474003	**IsoPropyl Alcohol** *2.5 lits to 200 lits containers:*	*- Iso Propyl Alcohol IP (100 %)*	**Export (IP)**
34. 764702	**Isopropyl Alcohol** *100% Product:*	*- Isopropyl Alcohol BP (100 %)*	**Export (BP)**
35. 764703	**Isopropyl Alcohol** *100% Product:*	*- Isopropyl Alcohol Ph. Eur. (100 %)*	**Export (Ph. Eur.)**
36. 767720	**Isopropyl Alcohol** *100% Product:*	*- Isopropyl Alcohol IP (100 %)*	**Domestic (IP)**
37. 769566	**Isopropyl Alcohol** *100 % product:*	*- Isopropyl Alcohol USP (100 %)*	**Domestic (USP)**
38. 474005	**Methanol**	*- Methanol Ph. Eur. (100 %)*	**Export (Ph. Eur.)**
39. 476338	**Methanol** *2.5 lits to 200 lits comtainer:*	*- Methanol BP (100 %)*	**Export (BP)**
40. 555911	**NA / Methanol** *lits:*	*- Methanol NF (100 %)*	**Export (NF)**
41. 559148	**Methanol** *lits:*	*- Methanol NF (100 %)*	**Domestic (NF)**
42. 769567	**Methanol** *100% Product:*	*- Methanol Ph. Eur. (100 %)*	**Domestic (Ph. Eur.)**
43. 769568	**Methanol** *100% Product:*	*- Methanol BP (100 %)*	**Domestic (BP)**
44. 555909	**NA / Methylene Chloride** *lits:*	*- Methylene Chloride NF (100 %)*	**Export (NF)**
45. 559149	**Methylene Chloride** *lits:*	*- Methylene Chloride NF (100 %)*	**Domestic (NF)**
46. 724910	**Methylene Chloride / Methylene Chloride / No remark** *CORBOUYS,DRUMS, CONTAINS 100 % OF PRODUCT:*	*- Methylene Chloride Ph. Eur. (100 %)*	**Export (Ph. Eur.)**
47. 767815	**Methylene chloride** *100% Product:*	*- Methylene Chloride Ph. Eur. (100 %)*	**Domestic (Ph. Eur.)**

PAN No.	Staff Name	Section	Designation	Qual
******933L	MAHENDRA D SHEJVAL	Chemical & Instrumentation	QC CHEMIST	BSC
******249D	MILIND MANOHAR MULAY	Bulk Drugs / API, Quality Assurance	PRODUCTION MANAGER	BSC
******997P	PRAJACTA S CHAPHEKAR	Chemical & Instrumentation	QC MANAGER	BSC

This License has been Retained wef 02/03/2024 and valid up to 01/03/2029

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KONKAN (TZ5)	705093	RNW-254820-07/02/2024	25-KD/685	13/02/2024

Terms and Conditions

1) Licensee should comply with all the provisions of Drugs & Cosmetics Act, 1940 & Rules 1945 as amended up to dt.
2) Licensee should comply with all the provisions of Drugs (Price Control) Order 2013 as amended up to dt (wherever applicable).
3) Licensee should abide by all the provisions of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954 & Rules 1955 as amended up to date
4) Licensee should not manufacture any drug/cosmetic by a name belonging to another manufacturer
5) Licensee should not manufacture or sell drugs/cosmetics even if it is included in the approved list of product, if it is or as and when banned by Licensing Authority or Drugs Controller General of India or Government of India.
6) The permission is granted subject to the condition that, the product is safe, for use in context of pharmaceutical Aids, Additions and excipient used in the formulation
7) Any addition thereto or any deletion therefore will not be carried out without permission of Licensing Authority

NARENDRA PURUSHOTTAM SUPE
e-Signed on 13-02-2024 12:44

TPAV # 4AL2IC9RMT

N. P. SUPE
Licensing Authority
Food & Drugs Administration
KONKAN Division, Maharashtra State

Applicant :
RUNA CHEMICALS PVT LTD (705093)
W-11,W-23 MIDC PHASE-II, DOMBIVALI, MANPADA - 421204
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