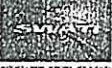
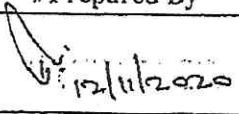
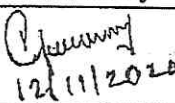
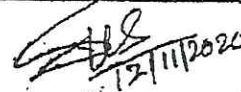



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|  | SWATI SPENTOSE PVT. LTD. UNIT-I |
| Mfg. Site Address: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India. Ph.: 0260-2433133, 2401533 | |
| CERTIFICATE OF ANALYSIS | |

| | | | |
|--------------------|---|-------------|------------------|
| Product Name | LIDOCAINE HYDROCHLORIDE MONOHYDRATE (BP/EP) | | Page No.: 1 of 2 |
| Batch No. | LDH/720018 | A. R. No. | FP/20/222 |
| Batch size | 1003.00 Kg | Released on | 27/08/2020 |
| Manufacturing Date | Jul-2020 | Expiry Date | Jun-2025 |

| Sr. No. | TEST | SPECIFICATION | RESULTS |
|---------|--|---|--------------------------|
| 1. | Appearance | White or almost white, crystalline powder. | White crystalline powder |
| 2. | Solubility | Very soluble in water, freely soluble in Ethanol (96 per cent). | Complies |
| 3. | Identification First Identification: B, D. Second identification: A, C, D. Note: If First identification performed then Second identification can be omitted. | | |
| | A) Melting point | 74 °C to 79 °C, determined without previous drying. | ---- |
| | B) IR spectrum | The IR absorption should be concordant with Reference/Working Standard. | Complies |
| | C) Colour test | A Green color is produced. | ---- |
| | D) Chloride test | It gives reaction (a) of chlorides | Complies |
| 4. | Appearance of Solution | Solution S is clear and colorless. | Complies |
| 5. | pH | Between 4.0 and 5.5 | 4.85 |
| 6. | Related Substances (By HPLC) | | |
| | Impurity-A | Not more than 0.005% | 0.0008% |
| | Impurity-II | Not more than 0.005% | Not Detected |
| | Unspecified impurities | Not more than 0.10% | 0.02% |
| | Total impurities | Not more than 0.5% | 0.05% |
| 7. | Water content | 5.5 % to 7.0 %, determined on 0.25 g. | 6.36% |

| Activity | Prepared By | Verified By | Approved By |
|-------------|---|---|---|
| Sign & Date |  12/11/2020 |  12/11/2020 |  12/11/2020 |
| Name | Mr. Himanshu Rai | Mr. Ravindra Gore | Mr. S. K. Srivastava |
| Designation | Officer-QA | Manager-QC | Head-QA |

| | |
|--|--|
|  | SWATI SPENTOSE PVT. LTD. UNIT-I |
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| Product Name | LIDOCAINE HYDROCHLORIDE MONOHYDRATE (BP/EP) | | Page No.: 2 of 2 |
| Batch No. | LDH/720018 | A. R. No. | FP/20/222 |
| Batch size | 1003.00 Kg | Released on | 27/08/2020 |
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| Sr. No. | TEST | SPECIFICATION | RESULTS |
|---------|-----------------------------|---|-----------------------|
| 8. | Sulphated ash | Maximum 0.1%, determined on 1.0 g. | 0.02% |
| 9. | Assay (By HPLC) | Lidocaine Hydrochloride contains NLT 97.5% and NMT 102.5% of Lidocaine Hydrochloride (C ₁₄ H ₂₂ N ₂ O · HCl), calculated on the anhydrous basis. | 99.6 % |
| 10. | Residual Solvent (By GC-HS) | Acetone: Not more than 5000 ppm | 936 ppm |
| | | Toluene: Not more than 890 ppm | Below Detection limit |

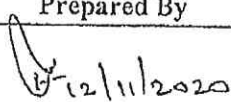
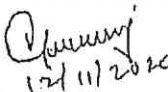
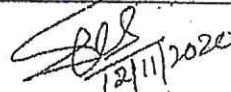
CONCLUSION:

In opinion of the undersigned, the above mentioned product **COMPLIES** as per BP-2019/EP-9.6/In-House Specification.

❖ CEP No.: R1-CEP 2013-103-Rev 00

STORAGE CONDITION:

Preserve in well closed container, protected from light & moisture. Store at a temperature not exceeding 30 °C. Excursion allowed up to 40°C.

| Activity | Prepared By | Verified By | Approved By |
|-------------|---|---|---|
| Sign & Date |  12/11/2020 |  12/11/2020 |  12/11/2020 |
| Name | Mr. Himanshu Rai | Mr. Ravindra Gore | Mr. S. K. Srivastava |
| Designation | Officer-QA | Manager-QC | Head-QA |