# DIVI'S LABORATORIES LIMITED
## QUALITY CONTROL DEPARTMENT

REVIEWED
lucky.wijaya , 14:02:53, 07/02/2017

## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Product: DEXTROMETHORPHAN HBr | | Mfg. Date | Oct-2016 |
| Grade | BP/USP | Retest Date | Sep-2021 |
| Batch Number | S-2121016 | Expiry Date | NA |
| Batch Quantity | 1115 Kg | Rev. No. | SG/01/06 |
| Dispatch Quantity | 1000 Kg | Sl. No. | DU1FP17000103/1 |
| Q.A.R. No. | DU1/FP/1701/000038 | | |

| S. No. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1 | STANDARD (PHARMACOPOEIAL) | | |
| 1.1 | Description | Almost white crystalline powder | White crystalline powder |
| 1.2 | Solubility | | |
| 1.2.1 | In Alcohol | Freely soluble in Alcohol. | Freely soluble |
| 1.2.2 | In Chloroform | Freely soluble in Chloroform. | Freely soluble |
| 1.2.3 | In Water | Sparingly soluble in Water. | Sparingly soluble |
| 1.2.4 | In Ether | Insoluble in Ether. | Insoluble |
| 1.3 | Appearance of solution | A 5.0% w/v solution in alcohol will be clear and colourless. | Solution is clear and colorless |
| 1.4 | Melting Point | About 125°C (with decomposition) | 125.2°C to 125.7°C |
| 1.5 | Identification by IR spectrum (USP) | Concordant with WS. | Concordant with working standard spectrum |
| 1.6 | Identification by IR spectrum (BP) | Concordant with WS. | Concordant with working standard spectrum |
| 1.7 | Identification by Specific optical rotation | Should comply with the test | Complies |
| 1.8 | Identification Test for Levomethorphan content by HPLC | Not more than 0.10% | Not detected |
| 1.9 | Specific optical rotation | 2.0%w/v solution in 0.1N HCl shows +28.0° to +30.0° at 589nm. Calculated on anhydrous basis. | 28.8 ° |
| 1.10 | pH | A 1 in 100 solution in water has a pH between 5.2 and 6.5 | 5.6 |
| 1.11 | Water (USP) | Between 3.5% and 5.5%w/w | 5.0 %w/w |
| 1.12 | Water (BP/EP) | Between 4.0% and 5.5%w/w | 5.0 %w/w |
| 1.13 | Residue on ignition | Not more than 0.1%w/w | 0.0 %w/w |
| 1.14 | N,N Dimethyl aniline | Colour is not more than that of standard (0.001%w/v) | Less than 0.001%w/v |
| 1.15 | Acidity or Alkalinity | NMT 0.4ml of 0.01N HCl is consumed | 0.3 mL |
| 1.16 | Phenolic compounds | No blue-green colour develops. | No Blue-green color |

Remarks: APPROVED (Sample Conforms to above Specification)
Special Comments: –

| | | | |
|---|---|---|---|
| Analyst | M.Srilatha | Person In-charge of testing | P.Venkataiah |
| Date | Jan 16 2017 12:21PM | Date | Jan 16 2017 1:33PM |
| Printed by: D.Sireesha | Printed on: Jan 19 2017 11:00AM | Copy No.: 1 | Page No.: 1 of 2 |

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DU1FP17000103/1

"An ISO-9001, ISO-14001 and OHSAS-18001 Triple certified company"
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| S. No. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| | | | observed |
| 1.17 | Related substances by HPLC | | |
| 1.17.1 | Any individual impurity | Not more than 0.5% | Not detected |
| 1.17.2 | Any other individual impurity | Not more than 0.25% | Not detected |
| 1.17.3 | Any other unknown impurity | Not more than 0.10% | Not detected |
| 1.17.4 | Total impurities | Not more than 1.0% | 0.0 % |
| 1.18 | Assay by Titration | NLT 99.0%w/w and NMT 101.0%w/w calculated on anhydrous basis | 100.1 %w/w |
| 1.19 | Assay by HPLC | NLT 98.0%w/w and not more than 102.0%w/w calculated on anhydrous basis. | 100.0 %w/w |
| 2 | ADDITIONAL TESTS (IN-HOUSE) | | |
| 2.1 | Residual solvents | | |
| 2.1.1 | Methanol | Not more than 200 ppm | Not detected |
| 2.1.2 | Acetone | Not more than 200 ppm | Not detected |
| 2.1.3 | Toluene | Not more than 250 ppm | Not detected |

Remarks: APPROVED (Sample Conforms to above Specification)
Special Comments: –

| Analyst | M.Srilatha | Person In-charge of testing | P.Venkataiah |
|---|---|---|---|
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