

NAIR BAUG, AKURLI ROAD, KANDIVLI (EAST), MUMBAI-400 101

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CERTIFICATE OF ANALYSIS

Certificate No. T/199/1116

The Drugs and Cosmetics Act 1940 and the rules there under

Name of the Manufacturer: **BDH INDUSTRIES LIMITED.**

Name of the Product : Trihexyphenidyl Tablets 2 mg

 Mfg Lic No.
 : 608
 Mfg Dt.
 : 11/2016

 Sample received as Batch No.
 : Final Product
 Exp Dt.
 : 10/2019

 Date of Receipt : 24/11/2016

Batch No. : 071116 Date of Receipt : 24/11/2016

Quantity Manufactured : 31,00,000 Tablets Date of Report : 24/11/2016

Quantity for Analysis : 16 X 10 Tablets (From Blister pack)

RESULTS OF ANALYSIS

TABLETS

| TEST | | OBSERVATION | | | | LIMIT / SPECIFICATION | |
|--------------------------|-----------------|-----------------------------|------------------|-----------|------------------------|-------------------------------------|----------------------|
| Description | | Circular, white biconvex | | | | Circular, white to almost white, | |
| | | uncoated tablets. | | | | biconvex uncoated tablets. | |
| Average weight of tablet | | 0.0825 g | | | | $0.080 \text{ g} \pm 10 \%$ | |
| Uniformity of weight | | Passes | | | | ± 10 % of Avg weight | |
| Maximum weight | | 0.088 g | | | | 0.0908 g | |
| Minimum weight | | 0.078 g | | | | 0.0743 g | |
| Diameter | | 5.46 mm | | | | $5.6 \text{ mm} \pm 0.6 \text{ mm}$ | |
| Thickness | | 2.81 mm | | | | $2.6 \pm 0.6 \text{ mm}$ | |
| Hardness | | 3.0 Kp/cm ² | | | | NLT 2 Kp/cm ² | |
| Friability | | 0.27% | | | | Max. 1% | |
| Identification | | Positive for Trihexypenidyl | | | | To comply BP | |
| (Precipitation or TLC) | | Hydrochloride | | | | | |
| Related substances | | | | | | To comply BP | |
| Individual Impurity | | Nil | | | | Max 1% | |
| Total impurity | | Nil | | | | Max 2% | |
| | | % of L. Amt. Released | | | | Limits allowed | |
| Dissolution | Passes | | | | NLT 75% within 45 mins | | |
| ě. | | | | 01.17% | 102.74% | | |
| Name of the | 100000 | lled ar | 100 | bs. Amt. | % of | Limits | |
| assayed | per tablet | | t po | er tablet | L. Amt. | Allowed | |
| Trihexyphenid | | | | | | | |
| Hydrochloride | | 2 mg | | | .966 mg | 98.30% | 90% to 110% |
| | | | | | sample com | plies with the p | prescribed standards |
| of quality as 1 | per BP and diss | olution | as per | USP. | | | * |
| | Bawant | | Bhali | | | Marie | |
| 0.444410040 | | | | | | | |
| 24/11/2016 | | | | | | | |
| | Ms. Rupali S. | | MS. M. ¥ MHATRE | | | MS R. R. TENDOLKAR | |
| DATE | ANALYST | | APPROVED CHEMIST | | | ASST.MANAGER QC | |

Doc .Ref.No. : BDH/QR/QC-FT (B) Rev : 0 DATE : 01.03.08