



Nixi Laboratories Pvt. Ltd.
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

| | | | |
|------------------------------------|---|------------------------------------|------------------|
| Product Name | HYDRALZIN 20 | AR. No. | NL/LA/FG/26/154 |
| Generic Name | Hydralazine Hydrochloride Injection USP | | |
| Mother Batch No. | A26NQ001 | Reference | USP |
| Child Batch No. | A26NQ001A | Batch size | 52727 Ampoules |
| Mfg. Date | 03/2026 | Exp. Date | 02/2028 |
| Specification No. (STS No.) | QC/LA/FG/STS/140 | Standard Test Procedure No. | QC/LA/FG/STP/140 |
| Sampled Quantity | 127 Ampoules | Sampling Date | 30/03/2026 |
| Released Date | 13/04/2026 | | |

| Sr. No. | Test | Specification | Observation |
|---------|--|---|---|
| 1. | Description | A clear, colourless solution free from particles filled in 1 ml clear/amber coloured glass ampoule. | A clear, colourless solution free from particles filled in 1 ml amber coloured glass ampoule. |
| 2. | Identification: By Infrared Absorption (IR): | The IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of USP Hydralazine Hydrochloride RS similarly treated and prepared. | Complies |
| 3. | Average Filled Volume | NLT 1.0 ml | 1.10 ml |
| 4. | Extractable Volume | NLT 1.0 ml | 1.10 ml |
| 5. | pH | 3.4 to 4.4 | 3.70 |
| 6. | Particulate matter | | |
| | Visible particles: | Should be free from visible particles | Complies |
| | For sub visible particles : (i) Equal to or greater than 10µm (ii) Equal to or greater than 25µm | NMT 600 particles /container NMT600 particles /container | 941.0 particles/container 15.0 particles/container |
| 7. | Sterility | Should comply the test of sterility | Complies |
| 8. | Bacterial Endotoxins | NMT 1.45 USP Endotoxin Units/mg | Complies |

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|--------------------|--------------------|-------------------|--------------------|
| Name | Rajan | Meenakshi Panday | Aditya Singh |
| Designation | Officer QC | Sr.Executive QC | Asst.Manager QC |
| Signature | | | |
| Date | 13/04/26 | 13/04/26 | |



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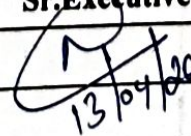
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| Sr. No. | Test | Specification | Observation |
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| 9. | Assay: Each ml contains: Hydralazine Hydrochloride IP 20 mg | 19.00 mg to 21.00 mg (95.00 % To 105.00 %) | 20.73 mg (103.65%) |
| 10. | Diethylene glycol and Ethylene glycol (By GC) | Not more than 0.1% | Not Detected |

Result: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No-
QC/LA/FG/STS/140.

Conclusion: In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|--------------------|-------------|---|---|
| Name | Rajan | Meenakshi Panday | Aditya Singh |
| Designation | Officer QC | Sr. Executive QC | Asst. Manager QC |
| Signature | @ |  | Approved By Name: Aditya Singh Designation: Asst. Manager QC Qualification: Bsc Enrollment No: 11-042323 |
| Date | 13/04/26 | 13/04/26 | Page 2 of 2 |