



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/25/550
Generic Name	Hydralazine Hydrochloride Injection USP		
Mother Batch No.	A25NQ002	Reference	USP
Child Batch No.	A25NQ002	Batch size	54545 Ampoules
Mfg. Date	12/2025	Exp. Date	11/2027
Specification No. (STS No.)	QC/LA/FG/STS/140	Standard Test Procedure No.	QC/LA/FG/STP/140
Sampled Quantity	127 Ampoules	Sampling Date	09/12/2025
Released Date	24/12/2025		

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	1.07 ml
4.	Extractable Volume	NLT 1.0 ml	1.07 ml
5.	pH	3.4 to 4.4	4.00
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*	71.0 particles/container 3.0 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	Sandeep Yadav	Meenakshi Panday	Aditya Singh
Designation	Chemist QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	24/12/25	24/12/25	24/12/25

Format No.: F/QC/013/03-04

Approved By
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: Bsc
Enrollment No. II-009545
Avadh University Avadh



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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 %)	20.52 mg (102.60%)
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	Sandeep Yadav	Meenakshi Panday	Aditya Singh
Designation	Chemist QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	24/12/25	24/12/25	24/12/25

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Name: Aditya Singh
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