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/26/522
Generic Name	Hydralazine Hydrochloride Injection USP		
Mother Batch No.	A26NQ002	**Reference**	USP
Child Batch No.	A26NQ002A	**Batch size**	50909 Ampoules
Mfg. Date	07/2026	**Exp. Date**	06/2028
Specification No. (STS No.)	QC/LA/FG/STS/140	**Standard Test Procedure No.**	QC/LA/FG/STP/140
Sampled Quantity	127 Ampoules	**Sampling Date**	01/10/2026
Released Date	17/10/2026		

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	1.11 ml
4.	**Extractable Volume**	NLT 1.0 ml	1.11 ml
5.	**pH**	3.4 to 4.4	4.05
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	293.0 particles/container 0.0 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	Sunil Kumar	Aditya Singh
Designation	Chemist QC	Sr.Executive QC	Manager QC
Signature			
Date	17/10/26	17/10/26	

Name : Aditya Singh
Designation : Manager QC
Qualification : Bsc
Enrollment No. II-089545
Avadh University Ayodhya

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Sr. No.	Test	Specification	Observation
9.	**Assay:** Each ml contains: Hydralazine Hydrochloride IP 20 mg	19.00 mg to 21.00 mg (95.00 % To 105.00 %)	19.83 mg (99.15%)
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**	**Sunil Kumar**	**Aditya Singh**
Designation	**Chemist QC**	**Sr.Executive QC**	**Manager QC**
Signature			Name : Aditya Singh Designation : Manager QC Qualification : Bsc Enrollment No. U-009545 Avadh University Ayodhya
Date	17/10/26	17/10/26	