



ALIVIRA

ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS

XYLAZINE HYDROCHLORIDE USP



alchem International, Inc
Compounding Chemicals You Can Trust

Batch No.	ASA001907A	Quantity	25.00 Kg
Manufacturing Date	June-2020	Retest / Expiry Date	May-2021
A.R.No.	ALIV-FP1-200080	Lot No.	40000037902
Storage Condition	Preserve in an air tight container, store at 25°C, excursions permitted between 15°C to 30°C. Protected from light.		
Customer Name	SUAN FARMA INC		
S.No.	TEST PARAMETERS	SPECIFICATIONS	RESULTS
1	Description	Colorless to white or off-white crystals/crystalline powder.	Off white crystals
2	Solubility	Sparingly soluble in dilute acid, in Acetone and in Methanol.	Complies
3	Identification tests A) By IR	The Infrared absorption spectrum of sample is concordant with spectrum obtained from standard.	Complies
	B) By TLC	RF value of the principal spot obtained from the test solution correspond to those of the principal spot obtained from the standard solution.	Complies
4	Melting Range	Between 164°C to 168°C	165.3°C to 165.9°C
5	pH	4.0 to 6.0 (1% Solution)	5.5
6	Loss on drying (105°C for 4 hours)	Not more than 1.00%	0.31 % w/w
7	Residue on ignition	Not more than 0.10%	0.06 % w/w
8	Chromatographic Purity by HPLC Total impurities	Not more than 2.0%	0.2 %
9	Assay by HPLC	Not less than 98.0% and Not more than 102.0%	98.1%
10	Residual solvents by GC		
	Methanol	Not more than 3000 ppm	124 ppm
	Isopropyl alcohol	Not more than 5000 ppm	170 ppm
	Methyl iso butyl ketone	Not more than 2260 ppm	490 ppm
	Monochlorobenzene	Not more than 360 ppm	BDL(LOD :3.7 ppm)

Remarks: The above batch complies as per USP/IH Specifications.(XYLF/01A/FP1/R3)

Note: This is for compounding application.

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Executive-QC	Dy. Manager-QC	Head-QA
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	30/09/2020	30/09/2020	30/09/2020

Format No.: QA/039/FMT-002/R1

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