

G. AMPHRAY LABORATORIES

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CERTIFICATE OF ANALYSIS

Name of Product	:	PIPERAZINE CITRATE BP / EP			
Batch No.	:	PC-197/07	Date of Receipt	:	07.03.2007
Date of Manufacture	:	March, 2007	Date of Analysis	:	07.03.2007
Date of Expiry	:	February, 2012	Sample Size	:	100 Grams
Batch Size	:	1,300 KGS.	Q. C. No.	:	G-07/1687

RESULTS OF ANALYSIS

TESTS	RESULTS	LIMITS
Characters	A white crystalline or granular powder. It melts at 190.8 ° C	A white crystalline or granular powder. It melts at 190 ° C.
Solubility	Freely soluble in water, Practically insoluble in alcohol.	Freely soluble in water, Practically insoluble in alcohol.
Identification (Second)		
Test (B)	Complies	As per B.P.
Test (C)	Complies	Give reaction of Citrates.
Appearance of Solution	5 % w/v solution "S" is clear and not more intensely coloured than reference solution B8.	5 % w/v solution "S" is clear and not more intensely coloured than reference solution B8.
Related Substances	Complies	Not more than 0.25 %
Heavy Metals	Complies	Not more than 20 ppm
Water	11.33 %	10.0 % to 14.0 %
Sulphated Ash	0.037 %	Not more than 0.1 %
Assay (On Anhydrous Basis)	99.05 % of C ₂₄ H ₄₆ N ₆ O ₁₄ .	98 % to 101 %

Additional Tests

1) Particle Size on Tyler Machine :

MICRON	MESH	% PASSING THROUGH
	16	100 %
	30	90.00 %

2) Bulk Density after 50 Tapped = 0.69 g/ml

REPORTS : THE ABOVE BATCH COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER B.P. 2007 / E.P. 2004.

**Certified True Copy
For G. AMPHRAY LABORATORIES**

AUTHORISED SIGNATORY

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CERTIFICATE OF ANALYSIS

Name of Product	:	PIPERAZINE CITRATE USP	Date of Receipt	:	07.03.2007
Batch No.	:	PC-197/07	Date of Analysis	:	07.03.2007
Date of Manufacture	:	March, 2007	Sample Size	:	100 Grams
Date of Expiry	:	February, 2012	Q. C. No.	:	G-07/1687
Batch Size	:	1,300 KGS.			

RESULTS OF ANALYSIS

TESTS	RESULTS	LIMITS
Description	A white crystalline powder, having not more than a slight odor.	A white crystalline powder.
Solubility	Soluble in water	Soluble in water.
Identification		
Test A	Melting Point 158.4 ° C	N-N dinitrosopiperazine melts between 156 ° C and 160 ° C.
Test B	Complies	It responds to the test for Citrates.
pH of 10 % w/v solution	5.80	About 5
Water	11.33 %	Not more than 12.0 %
Primary amines & ammonia	0.30	The ration A600 / A520 is not more than 0.5 % (equivalent to about 0.7 % of primary amines and ammonia.
Assay (On Anhydrous Basis)	99.05 % of C ₂₄ H ₄₆ N ₆ O ₁₄	98 % to 100.5 %.

Additional Tests

1) Particle Size on Tyler Machine :

MICRON	MESH	% PASSING THROUGH
	16	100 %
	30	90.00 %

2) Bulk Density after 50 Tapped = 0.69 g/ml

REPORTS : THE ABOVE BATCH COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER USP 30.

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