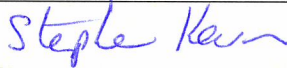


CERTIFICATE OF ANALYSIS	
Product Name	ACEPROMAZINE MALEATE
Product Code	ARK2015
Compendial References	USP 41
Lot No/Batch Number	B-APMZM133-129
2-Acetyl-10-(3-dimethylaminopropyl) Phenothiazine Hydrogen Maleate	

No	SPECIFICATION	RESULT
1	<b>CHARACTERISTICS:</b> A yellow crystalline powder.	A yellow crystalline powder.
2	<b>IDENTIFICATION:</b> Infra-Red Spectrum. HPLC	Conforms Conforms
3	<b>MELTING RANGE:</b> Limit: Between 136 – 139 °C.	138.1 – 138.2 °C.
4	<b>pH:</b> Limit: 4.0 – 5.5.	4.1
5	<b>WATER:</b> Limit: Not more than 1.0%.	0.03%
6	<b>RESIDUE ON IGNITION:</b> Limit: Not more than 0.2%.	0.01%
7	<b>RELATED COMPOUNDS:</b> Limit: Not more than 0.5% of any secondary spot.	NMT 0.5% of any secondary spot.
8	<b>ASSAY (HPLC):</b> Limit: 98.0% - 101.0%.	100.0%
9	<b>RESIDUAL SOLVENTS:</b> Limit: NMT 500 ppm Methanol NMT 890 ppm Toluene NMT 2000 ppm n-Propanol	LT LOQ      Methanol LT LOQ      Toluene 917.8 ppm    n-Propanol
10	<b>MICROBIOLOGICAL QUALITY:</b> Limit: TAMC NMT 10 <sup>3</sup> cfu/g TYMC NMT 10 <sup>2</sup> cfu/g It meets the requirements of the test for absence of <i>Salmonella</i> species, <i>Staphylococcus aureus</i> , <i>Candida albicans</i> and <i>Pseudomonas aeruginosa</i> .	LT 10 cfu/g LT 10 cfu/g Conforms

<b>Date of Manufacture:</b>	14 November 2018
<b>Date of Approval</b>	25 February 2019
<b>Expiry Date:</b>	14 November 2022
<b>Approved by:</b>	Stephen Kearns, QC Specialist
<b>Signature:</b>	
<b>Date:</b>	27 Feb 19

