

CERTIFICATE OF ANALYSIS Working Standard



Name of CRS used: Chloramphenicol Palmitate
Lot/Batch: no .1a
Source: Ph Eur
Name of Working Standard: Chloramphenicol Palmitate
Raw Material Bno, used: OCPP/0051114M
Manufacturer: MEHTA API PVT.LTD
Date of Analysis: 27/02/2015
Validity of use: Use within one month after opening, valid up to 07/2018, when sealed.
Quantity: 5.0g

Purity/Potency: 100.0 %
Exp Date: Website information

EWS No: 10/15

Mfg Date: 07/2013, Exp Date: 07/2018

RESULTS:

Sr. No.	Test Parameters	Limits	Observation
1	Description	White or almost white fine, unctuous powder	A white fine unctuous, crystalline powder
2	Identification: A. TLC	The chromatogram of sample solution shows spots corresponding to those in the chromatogram of reference solution	The chromatogram of sample solution shows spots corresponding to those in the chromatogram of reference solution
3	Loss on drying	NMT 0.50 %	0.20%
4	Assay (On anhydrous basis)	99.0% - 102.0%	101.3%

Additional Remarks:

Storage conditions:

- Store in refrigerator at 2°C- 8° C, when not in use
- Use within 30 days after opening, kept at a temperature of below 25 °C
- Keep tightly closed and protect from light

Justification of the selection of raw material for qualification:

The Chloramphenicol palmitate raw material was taken from the current lot.

	Analysed by	Checked by	Approved by
Signature	Sam	Shelys	Shelys
Name	Shelys Mwambi	Shelys Mwambi	Shelys Mwambi
Date	31/03/2015	31/03/2015	31/03/2015
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control