WRS
L4-5

(24)

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# WORKING STANDARD CERTIFICATE

## QUALIFICATION OF WORKING STANDARD

**ITEM** : LEVONORGESTREL BP/Ph.Eur. **EVALUATED WITH** : EPCRS/MH/L02/06 EPCRS/MH/L02/07

**DATE OF QUALIFICATION** : 06.10.2015 **BATCH No.** : 2.0
**DIRECTION FOR STORAGE** : Store between 2°C to 8°C.in a tightly closed container, Protect from light. #
**DIRECTION FOR USE** : Use as such
**VALIDITY OF USE** : 27.02.2017
**WORKING STANDARD No.** : WS/C/L3/05
**A.R.No.** : MH1508315
**SOURCE B. No.** : LDX150010 **SOURCE A.R.No.** MH1503379 

**REFERENCE :** BP 2015/Ph.Eur.8.0 STANDARDS Protocol No:WP/ BP/Ph.Eur /WS/C/L3 version 02

| Sr.No | TESTS | STANDARDS | RESULTS |
|---|---|---|---|
| 1) | CHARACTERS | | Complies |
| | A) APPEARANCE | A white or almost white, crystalline powder. | Complies |
| | B) SOLUBILITY | Pratically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in Ethanol (96 per cent). | Complies |
| 2) | *IDENTIFICATION | | Complies |
| | A) By Specific optical rotation | The sample complies with the test for Specific Optical Rotation | Complies |
| | B) By Infrared Spectrophotometry | The infrared spectrum of the sample is concordant with the spectrum obtained from the similar determination of Levonorgestrel CRS. | Complies |
| 3) | SPECIFIC OPTICAL ROTATION | Not less than -30.00° and Not more than -35.00°, calculated on dried basis | -33.93° |
| 4) | RELATED SUBSTANCE (Method A) | | Complies |
| | Impurity A | Not more than 0.3 % | Below disregard |
| | Impurity K | Not more than 0.3 % | Below disregard |
| | Impurity B | Not more than 0.3 % | Below LOQ (0.05%) |
| | Impurity O | Not more than 0.3 % | Below disregard |
| | Impurity M | Not more than 0.2 % | 0.1 |
| | Impurity S | Not more than 0.2 % | Below disregard |
| | Impurity U | Not more than 0.2 % | Not Detected |
| | Impurity H | Not more than 0.15 % | 0.06 |
| | Individual Unspecified impurity | Not more than 0.10% | Below LOQ (0.05%) |
| | Total impurities (other than impurity O) | Not more than 1.0% | 0.2 % |
| 5) | RELATED SUBSTANCE (Method B) | | |
| | Impurity V | Not more than 0.15 % | 0.00 |
| | Impurity W | Not more than 0.3 % | 0.0 |

**REMARKS:** *Test/s qualified as per EPCRS. All other test complies as per BP 2015 and EP 8.0 standards and certified to be used as Working Standard.
**NOTE:** #Third party may store as per specification.

**HEAD QUALITY CONTROL** **LAB QA HEAD**
**DATE :** 06.10.2015 **DATE :** 06.10.2015

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 05 MAY 2016 P.O. Box 29726 – 00202, NAIROBI TEL: 2726963 / 3544526/30 FAX: 2718073

Cipla Ltd.Cipla House,Peninsula Business Park,Ganpatrao Kadam Marg,Lower Parel,Mumbai-400013,India
Phone : (91 22) 25756210
e-mail :savio@cipla.com Website :www.cipla.com

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# WORKING STANDARD CERTIFICATE

## QUALIFICATION OF WORKING STANDARD

**ITEM** : LEVONORGESTREL BP/Ph.Eur. **EVALUATED WITH** : EPCRS/MH/L02/05 EPCRS/MH/L02/07

**DATE OF QUALIFICATION** : 06.10.2015 **BATCH No.** : 2.0

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**DIRECTION FOR USE** : Use as such

**VALIDITY OF USE** : 27.02.2017

**WORKING STANDARD No.** : WS/C/L3/05

**A.R.No.** : MH1508315

**SOURCE B. No.** : LDX150010 **SOURCE A.R.No.** MH1503379 

**REFERENCE :** BP 2015/Ph.Eur.8.0 STANDARDS Protocol No:WP/ BP/Ph.Eur /WS/C/L3 version 02

| Sr.No | TESTS | STANDARDS | RESULTS |
|---|---|---|---|
| 6) | LOSS ON DRYING | Not more than 0.50 % w/w | 0.24 % w/w |
| 7) | SULPHATED ASH | Not more than 0.10 % w/w | 0.05 % w/w |
| 8) | ASSAY (By Potentiometry) | Levonorgestrel contains not less than 98.0%w/w & not more than 102.0% w/w of $C_{21}H_{28}O_2$.Calculated with reference to the drled basis. | 98.6 % w/w |
| 9) | RESIDUAL SOLVENTS<br>(By Gas Chromatography)<br>Methanol<br>Acetone<br>Ethyl acetate<br>Tetra hydrofuran<br>Other class 1, 2, 3 residual solvents and other organic solvents. | <br><br>Not more than 1000 ppm<br>Not more than 1000 ppm<br>Not more than 4500 ppm<br>Not more than 500 ppm<br>Meets the requirements of other class 1, 2 and 3 residual solvents as per BP supplementary chapter IV D and EP chapter 5.4 and no other organic solvents are present. | Complies<br><br>Not Detected<br>Not Detected<br>1506<br>Not Detected<br>Meets the requirement |
| 10) | PURITY<br>( By mass balance method) | Not applicable | 99.5 % w/w<br>(As such basis) |

**REMARKS:** *Test/s qualified as per EPCRS. All other test complies as per.BP 2015 and EP 8.0 standards and certified to be used as Working Standard.

**NOTE:** #Third party may store as per specification.

**HEAD QUALITY CONTROL** 06.10.2015
**DATE :**

**LAB QA HEAD**
**DATE :** 06.10.2015

REGIONAL QUALITY CONTROL LABORATORY RECEIVED 05 MAY 2016 TEL: 2726963 / 3544525/30 FAX: 2718073 P.O. Box 29726 – 00202, NAIROBI

Cipla Ltd.Cipla House,Peninsula Business Park,Ganpatrao Kadam Marg,Lower Parel,Mumbai-400013,India
Phone : (91 22) 25756210
e-mail :savio@cipla.com Website :www.cipla.com