

SYNOKEM PHARMACEUTICALS LIMITED, PLOT NO -35,36; SEC-6(A) IIE,SIDCUL,RANIPUR,BHEL,HARIDWAR-249403

CERTIFICATE OF ANALYSIS

Name of material	LEVONORGESTREL POWDER BP	
WRS No.	QC/WS/H/L02/17	
B. No.	A403016005	
Q.C. Reference No.	HRM -0038/17-18	
Manufacturing Date	10/2016	
Expiry Date	09/2021	
Manufactured by	IPC INDO PHYTO	
Use before Date	26/10/2018	
Effective Date	27/10/2017	

Test Carried out	Result	Specification
Description	A white, crystalline powder, odourless.	A white to almost white, crystalline powder, odourless or almost odourless.
Identification (B) By IR	Complies	The IR absorption spectrum of the sample must be concordant with the reference spectrum of standard.
Loss on drying	0.28 %w/w	NMT 0.5 %w/w
RELATED SUBSTANCES :-	No.	
Impurity A	Not detected	NMT 0.3%
Impurity B	Not detected	NMT 0.3%
Impurity K	Not detected	NMT 0.3%
Impurity O	Not detected	NMT 0.3%
Impurity M	Not detected	NMT 0.2%
Impurity S	Not detected	NMT 0.2%
Impurity U	Not detected	NMT 0.2%
Impurity H	Not detected	NMT 0.15%
Unspecified Impurity	Not detected	NMT 0.10%
Sum of Impurities other than O	Not detected	NMT 1.0%
Impurity W	Not detected	NMT 0.3%
Impurity V	Not detected	NMT 0.15%
Assay	99.05 % (as such basis) 99.33% (on dried basis)	98.0 -102.0 % (On dried basis.)
RSD.(Relative standard deviation)	0.61 %	NMT 1.00%(for multiple Assay)

Remarks: The Assay is the average value of multiple analyses.

Prepared by:

Date

27/10/17

Checked by:

Date

12/10/12