SYNTHEXIM

CLIOQUINOL EP

(chloro 5 iodo 7 hydroxy 8 quinoline)

specifications
660-S1177 00EP/1

04/03/2016

BATCH NUMBER **16 05 01 0017**

QUANTITY **30 kg**

Manufactured date **11/01/16**

Retesting date **10/01/19**

ANALYSIS CERTIFICATE

ANALYSIS NUMBER : **A.16.01.015** **Analysis date : 11/01/2016**

tests	*specifications*	*results*	*method*
DESCRIPTION	*almost white, light yellow, brownish yellow or yellow grey powder ; free from foreign matter*	**light yellow powder**	*European Pharmacopoeia*
IDENTIFICATION	*test B by IR conform to the reference standard*	**conform**	*European Pharmacopoeia*
ACIDITY/ALCALINITY	*≤ 0,5ml NaOH 0,01M*	**< 0,5 ml**	*European Pharmacopoeia*
Loss of DRYING	≤ 0,5%	**0,1%**	*European Pharmacopoeia*
SULFATED ASH	≤ 0,1%	**0,0%**	*European Pharmacopoeia*
HALIDES	≤ 140 ppm expressed as chlorides	**< 140 ppm**	*European Pharmacopoeia*
HPLC related substances	*Impurity A ≤ 2,0%*	**0,8%**	*European Pharmacopoeia*
HPLC related substances	*Impurity B ≤ 1,0%*	**0,2%**	*European Pharmacopoeia*
HPLC related substances	*Impurity C ≤ 1,0%*	**0,1%**	*European Pharmacopoeia*
HPLC related substances	other impurity ≤ 0,10%	**ND**	*European Pharmacopoeia*
HPLC related substances	total impurities ≤ 3,0%	**1,1%**	*European Pharmacopoeia*
ASSAY	98,0% - 102,0% on dried substance	**100,4%**	*European Pharmacopoeia*

This material complies with current Specifications of European Pharmacopoeia with supplement.
Impurity A = chloro 5 hydroxy 8 quinoline
Impurity B = dichloro 5,7 hydroxy 8 quinoline
Impurity C = diiodo 5,7 8 hydroxyquinoline

M.DESCHODT
Analyst 04/03/16

Manufactured at Synthexim plant

H.POLUDNIAK
Quality Assurance

AXYNTIS
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