WRS Q3-1

INTAS PHARMACEUTICALS LTD.

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INTAS

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Name of working standard	: QUETIAPINE FUMARATE		
Compared with EP Batch No.	: 1	Date of preparation	: 04/10/2016
Working standard No.	: S QUFU 161	Valid Up to	: 04/10/2017
Raw material Batch No.	: QF0830716	Page	: 1 of 1
Raw material A. R. No.	: 101630246		
Storage condition	: Keep container tightly closed and store below 25°C in amber colour vial.		

Reference: Ph.Eur. & Inhouse specification.

SR. NO.	TEST	RESULT	LIMITS
01.	Description	An almost white powder.	A white or almost white powder.
02.	Identification	By IR: The infrared absorption spectrum of the substance being examined is concordant with the similar preparation of Quetiapine Fumarate EP reference standard.	By IR: The infrared absorption spectrum of the substance being examined should be concordant with the similar preparation of Quetiapine Fumarate EP reference standard.
03.	Loss on drying	0.2% w/w.	Not more than 0.5 % w/w.
04.	Related substances		
	A) Impurity G	A) Below quantification limit.	A) Not more than 0.12%.
	B) Impurity N	B) Below quantification limit.	B) Not more than 0.12%.
	C) Maximum single unspecified impurity	C) 0.06%.	C) Not more than 0.10%.
	D) Total impurities	D) 0.2%.	D) Not more than 0.3%.
05.	Assay (By Potentiometry)	99.9% w/w.	Between 99.0% and 101.0% w/w, on dried basis.
		99.7% w/w as such.	Record.

Remarks :The above material is compared with **EP** standard for above tests and is suitable to use as a working standard

PREPARED BY : P
DATE : 04/10/16

CHECKED BY : [illegible]
DATE : 04/10/16

APPROVED BY : [illegible]
DATE : 04/10/16

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