

PROCHEM PHARMACEUTICALS PVT. LTD

140-141, Makkanpur Bhagwanpur, Roorkee, Dist. Haridwar (UK)

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drug & Cosmetic Act 1940 and the rule there under)

Mfg. Lic. No.-78/UA/2016

REPORT No : PCT/26/6121

PRODUCT : Itraconazole Capsules IP 100mg
Itrotab 100

BATCH No : CAR-26121

Mfg. Date : 03/2026

Exp. Date : 02/2028

Date of Receipt : 03/04/2026

Batch Size : 2.0 Lac

Sample Qty : 50 Caps

Test	Specifications	Results
Description	Green cap and Green coloured body hard gelatin capsules filled with white coloured pellets.	Complies
Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution(a)	Complies
Average Weight of Filled capsules	625 mg \pm 5 %	628.0mg
Average fill	525mg \pm 5 %	529.8mg
Uniformity of Weight	Not more than two of the individual weights deviate from the average weight by more than \pm 10% and none deviates by more than \pm 20%	Min: 522.7mg (-1.34)% Max: 541.5mg (+2.20)%
Dissolution	QNL 70 %	(95.79 - 103.54)%
Related Substance	Impurity B RRT 0.6 : NMT 0.3%	Not Detected
	Impurity C RRT 0.7 : NMT 0.3%	0.048%
	Impurity D RRT 0.7 : NMT 0.3%	0.048%
	Impurity G RRT 1.15 : NMT 0.3%	Not Detected
	Any Other secondary impurity : NMT 0.2%	BDL
Sum of All other impurities : NMT 1.0%	BDL	

Assay : Each Hard gelatin capsule contains.

Content	Found /Capsule	Claim /Capsule	% of Claim	Limits
Itraconazole IP (In pellets form)	98.52mg	100 mg	98.52%	(95-105)mg

Conclusion : In the Opinion of the under signed, the sample referred to above is of **STANDARD QUALITY/NOT OF STD. QUALITY** as defined in the act and the rules made there under IP& I H S.

ANALYSED BY:- <i>Dulish</i>	CHECKED BY:- <i>N. Singh</i>	APPROVED BY:- <i>[Signature]</i>
DATE: 08/04/2026	DATE: 08/04/2026	DATE: 08/04/2026