

CERTIFICATE OF ANALYSIS

Product : Ketoconazole USP			Page 1 of 2	
Batch No.	SBML/KTN/17086	Empirical Formula C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄	Report No. & Date	RN/002 & 23/12/2017
Batch Size	250.00 Kg		A.R. No.	FPT/70510
No. of Containers	10 Nos.	Mol. Wt. 531.4	Analysis Date	23/12/2017
Mfg. Date	DECEMBER – 2017		Reference Spec. No	FPS.072/00
Expiry Date	NOVEMBER – 2022	CAS No. 65277-42-1		

SR. NO.	TEST PARAMETER	SPECIFICATION	OBSERVATIONS / RESULTS
1.	Description	A white or almost white powder.	White powder.
2.	Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, Sparingly soluble in alcohol.	Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, Sparingly soluble in alcohol.
3.	Identification		
	A. Infrared absorption	Infrared absorption spectrum of sample should be concordant with that of working standard spectrum.	Infrared absorption spectrum of sample is concordant with that of working standard spectrum.
4.	Melting Range	Between 148.0°C and 152.0°C	149.8°C to 151.9°C
5.	Specific Rotation	Between -1.0° and +1.0° (t = 20°)	+0.03°
6.	Loss on drying	Not more than 0.5% (w/w)	0.16%
7.	Residue on Ignition	Not more than 0.1% (w/w)	0.06%
8.	Heavy metals	Not more than 0.002%.	Less than 0.002%
9.	Chromatographic Purity By TLC	The principal spot obtained from the Test solution has about the same size and R _F value as that obtained from the Standard solution and the sum of the intensities of any secondary spots obtained from the test solution does not exceed the intensity of the principal spot obtained from the Diluted standard solution.	Complies

QC.062.02/02

Contd....

Regd. Off. & Works I : W-34 & 34/1, MIDC, Taloja, Dist-Raigad, Maharashtra (India),
Works II: Plot No. L-6, MIDC, Taloja, Dist-Raigad, Maharashtra (India)
Admin Office : 312, C Wing, BSEL Tech Park, Sector - 30(A), Vashi, Navi Mumbai - 400 705
 Tel.: 91 22 - 67944000, Fax : 91 22 - 67944001
Head Office : Plot No. 163, Smt Janakidevi Public School Rd., SVP Nagar, Andheri (West), Mumbai - 400 053.
 Tel. : 91 22 26323192 / 93 / 94 Fax : 26323140 E-mail : info@sharonbio.com

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Caring for relationships

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Product : Ketoconazole USP			Page 2 of 2	
Batch No.	SBML/KTN/17086	Empirical Formula $C_{26}H_{28}Cl_2N_4O_4$	Report No. & Date	RN/002 & 23/12/2017
Batch Size	250.00 Kg		A.R. No.	FPT/70510
No. of Containers	10 Nos.	Mol. Wt. 531.4	Analysis Date	23/12/2017
Mfg. Date	DECEMBER – 2017		Reference Spec. No	FPS.072/00
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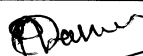
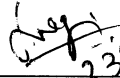
SR. NO.	TEST PARAMETER	SPECIFICATION	OBSERVATIONS / RESULTS
10.	Assay by Titrimetry (On dried basis)	Not less than 98.0% (w/w) and Not more than 102.0% (w/w).	99.9%
	Additional Test		
11.	Residual solvents <In-house>		
	Method –I		
	Methanol	Not more than 2000 ppm	991 ppm
	Acetone	Not more than 1200 ppm	Not detected
	Dimethyl Sulphoxide	Not more than 5000 ppm	Not detected
	Ethyl Acetate	Not more than 2000 ppm	19 ppm
	Method-II		
	Benzene #	Not more than 2 ppm	Not detected
12.	Particle Size	90% less than 20 μ	8.82 μ

: Are byproduct / raw material of the solvent.

Remarks : The above **Ketoconazole** Batch No. **SBML/KTN/17086** conforms in all respects to the **USP 37** and as per customer's requirement.

Packing : LDPE inner-bag each, in 1 LDPE outer black bag, in HDPE drum.

Storage : Store in well-closed containers protect from light, at a temperature not exceeding 30°C.

Prepared By : 	Checked By : 	Approved By : 
Date : 23/12/17	Date : 23/12/17	Date : 23/12/17
QC.062.02/02mprakash Yadav (Officer QC)	Prashant Phansekar (Manager QC)	Sashi Negi (Asst. Manager QA)

Regd. Off. & Works I : W-34 & 34/1, MIDC, Taloja, Dist-Raigad, Maharashtra (India),

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