

# INTAS PHARMACEUTICALS LTD.

Factory : Plot No. 457, 458, Sarkhej-Bavla Highway, Matoda-382 210. Gujarat, India.  
Phone : + 91 - 02717 - 661111, 661298 Fax : + 91 - 02717 - 661106

INTAS

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Brand Name	: PARAEFFER	Batch No.	: T09262
Generic Name	: PARACETAMOL EFFERVESCENT TABLETS 1000 mg	AR Number	: TE16/08905
Composition	: Each uncoated tablet contains: Paracetamol Ph.Eur.....1000 mg	Mfg. Dt.	: 07/2016
Analysis as per	: INHOUSE (KENYA) Specification	Exp. Dt.	: 06/2018
Plant	: INTAS PHARMA.LTD.,MATODA	Spec. No.	: PME0406-01
Batch Size	: 2800.00 Nos.	Halb Batch No.	: T08905
Receipt Dt.	: 14.07.2016	Page No.	: 1 / 2
Halb Batch Size	: 1294595.000 nos		
Report Dt.	: 20.07.2016		

SR. NO.	TESTS	RESULT	LIMITS
01	Description	White, round, flat faced, beveled edged tablets plain on both sides.	White to off-white, round, flat faced, beveled edged tablets plain on both sides.
02	Average weight of tablets	3658.9 mg	3700.0 mg $\pm$ 3% (3589.0 mg to 3811.0 mg)
03	Uniformity of dosage units (By mass variation)	The acceptance value of the first 10 tablets is 2.1	The acceptance value of the first 10 tablets should be less than or equal to 15.0. If the acceptance value is greater than 15.0, test next 20 tablets and calculate the acceptance value. The final acceptance value of the 30 tablets should be less than or equal to 15.0 and no individual content of the dosage unit should be less than (1-25.0x0.01)M or more than (1+25.0x0.01)M.
04	Identification	Paracetamol : A) By HPLC: The retention time of Paracetamol peak in the chromatogram of assay preparation corresponds to the paracetamol peak obtained with standard preparation as directed under assay.  B) By UV: The UV spectra of the test preparation in range of 200 to 400 nm exhibits maxima at same wavelength as that of standard preparation having same concentration.	Paracetamol : A) By HPLC: The retention time of Paracetamol peak in the chromatogram of assay preparation should correspond to the paracetamol peak obtained with standard preparation as directed under assay.  B) By UV: The UV spectra of the test preparation in range of 200 to 400 nm should exhibit maxima at same wavelength as that of standard preparation having same concentration.



# P<sub>1</sub>-10 INTAS PHARMACEUTICALS LTD.

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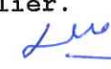


## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Brand Name : PARAEFFER		Batch No. : T09262	
		AR Number : TE16/08905	
		Halb Batch No. : T08905	
Report Dt. : 20.07.2016		Page No. : 2 / 2	
SR. NO.	TESTS	RESULTS	LIMITS
05	Resistance to crushing	210 N	Not less than 50 Newton
06	Disintegration time	2 minutes	Not more than 5 minutes.
07	Clarity of solution	Slightly opalescent, not more opalescent than reference suspension II.	Clear to slightly opalescent, not more opalescent than reference suspension II.
08	pH of solution	5.9	Between 5.4 to 6.4
09	Loss on drying at 75° C	0.8% w/w	Not more than 1.0% w/w
10	Related substances	Not Detected	A) 4-aminophenol : Not more than 0.005%
		Not Detected	B) 4-Chloroacetanilide: Not more than 0.001%
		Below Disregard Level	C) Single unknown impurity: Not more than 0.10%
		Below Disregard Level	D) Total impurities : Not more than 0.50%
11	Assay	99.2%	95.0% to 105.0% of label claim
12	Residual solvents	432 ppm	Isopropyl alcohol : Not more than 3000 ppm
13	Microbial examination *	NA	A) Microbial enumeration tests : i) Total aerobic microbial count : Not more than 10 <sup>3</sup> cfu/g
		NA	ii) Total combined Yeasts and Moulds count : Not more than 10 <sup>2</sup> cfu/g
		NA	B) Test for specified micro-organism : i) Escherichia coli : Should be absent.

Remarks : Conforms to INHOUSE (KENYA) Specification

\* To be performed for validation /exhibit batches. For commercial batches it should be performed for first five batches followed by every fifth batch or one batch per year which ever is earlier.

Q.C. HEAD :   
Rajendra D. Patel 26/07/16  
SR. GM, QC



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**QUALITY CONTROL DEPARTMENT  
CERTIFICATE OF ANALYSIS**

Name of working standard	: PARACETAMOL		
Evaluated with EP Batch No.	: 4	Date of preparation	: 10/03/2016
Working standard No.	: S PARA 161	Valid Up to	: 10/03/2017
Raw material Batch No.	: 1447/15-16	Page	: 1 of 1
Raw material A. R. No.	: 101603994		
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.	Characters	White, crystalline powder.	White or almost white, crystalline powder.
02.	Identification	By IR: The IR spectrum of the substance being examined is concordant with the reference spectrum of Paracetamol EP reference standard.	By IR: The IR spectrum of the substance being examined should be concordant with the reference spectrum of Paracetamol EP reference standard.
03.	Loss on drying	0.3%.	Not more than 0.5%.
04.	Related substances A) Impurity J B) Impurity K C) Impurity F D) Any other impurity E) Total of other impurities	A) Not detected. B) 4 ppm. C) Not detected. D) 0.01%. E) 0.01%.	A) Not more than 10 ppm. B) Not more than 50 ppm. C) Not more than 0.05%. D) Not more than 0.05%. E) Not more than 0.1%.
05.	Assay	99.6%.  99.3% as such.	99.0% to 101.0% calculated on dried basis.  Record.

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

PREPARED BY : *[Signature]*  
DATE : 10/03/16

CHECKED BY : *[Signature]*  
DATE : 10/03/16

APPROVED BY : *[Signature]*  
DATE : 10/03/16

