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"GOVERNMENT RECOGNIZED EXPORT HOUSE"

WORKING STANDARD REPORT

Preparation Date	23/10/2017	Valid upto	23/10/2018
Manufacturer	GRANULES INDIA LTD.	Page no	1/1
Item Name	PARACETAMOL BP	MFG. Date	Jul 2017
Batch No	APAP/C17070552	EXP. Date	Jun 2022
Storage condition	Store below 25°C	Quantity	500 mg
TEST	OBSERVATIONS	STANDARD	
01. Description	Almost white crystalline powder.	White or almost white, crystalline powder.	
02. Solubility	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in methylene chloride.	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in methylene chloride.	
03. Identification			
A) Melting Point	170.5°C	168°C to 172°C	
B) Light absorption	The specific absorbance at the maximum is 952	The absorption maximum at 249 nm The specific absorbance at the maximum is 860 to 980	
C) Infrared absorption	The Infrared absorption spectrum of substance is concordant with the IR spectrum obtained from Paracetamol working standard.	The Infrared absorption spectrum of substance being examined should concordant with the IR spectrum obtained from Paracetamol working standard.	
D)	A violet colour develops which does not change to red.	A violet colour develops which does not change to red.	
E)	A blue colour develops at the junction of two drop.	A blue colour develops at the junction of two drop.	
04. Related Substances			
a) Impurity J	Not detected	Not more than 10 ppm	
b) Impurity K	Not detected	Not more than 50 ppm	
c) Impurity F	Not detected	Not more than 0.05%	
d) Any other impurity	Not detected	Not more than 0.05%	
e) Total other impurity	Nil	Not more than 0.1%	
05. Heavy Metals	Less than 20 ppm	Maximum 20 ppm	
06. Loss on drying	0.24%	Maximum 0.5 %	
07. Sulfated ash	0.05%	Maximum 0.1 %	
08. Assay : C ₈ H ₉ NO ₂	99.84% on as such basis 100.08% on dried basis	* 99.0% to 101.0% on dried basis	

In the opinion of undersigned the sample referred to above IS OF STANDARD QUALITY as defined in the Act and Rules made there under in above respect, as per BP & can be used as **Working Standard**.

ANALYSED BY 23/10/2017	CHECKED BY 23/10/2017
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